ALIMERA SCIENCES INC
Form 10-K
February 25, 2019
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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, 2018
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 001-34703

Alimera Sciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	20-0028718
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
6120 Windward Parkway, Suite 290 Alpharetta, GA	30005
(Address of principal executive offices)	(Zip Code)

(678) 990-5740
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Common Stock, $0.01 par value per share	The Nasdaq Stock Market LLC
(Title of each class)	(Name of each exchange on which registered)

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No 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 ¨ 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 ¨
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 ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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	x
Non-accelerated filer	o	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 is a shell company (as defined in Rule 12b-2 of the Act). Yes o No x

As of June 30, 2018, 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 $60,577,309 based on the closing price of the registrant’s Common Stock, on June 30, 2018, 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 February 22, 2019, there were 70,968,630 shares of the registrant’s Common Stock issued and outstanding.

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DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement with respect to the registrant's 2019 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, 2018, are incorporated by reference into Part III of this annual report on Form 10-K.

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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.

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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,” “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:

- a slowdown or reduction in our sales in due to a reduction in end user demand, unanticipated competition, regulatory issues, or other unexpected circumstances;
- 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;
- dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality;
- uncertainty regarding the pricing and reimbursement guidelines for ILUVIEN or any future products or product candidates, including ILUVIEN in new markets;
- our ability to successfully obtain the indication for non-infectious posterior uveitis in the EU, which may be delayed significantly or not occur at all;
- our ability to meet any post-market requirements for non-infectious posterior uveitis in the EU if we obtain the indication;
- our ability to successfully commercialize ILUVIEN following regulatory approval in additional markets;
- delay in or failure to obtain regulatory approval of ILUVIEN or any future products or product candidates in additional countries;
- our anticipated launches of ILUVIEN by Alimera’s distribution partners in Spain and France may be delayed or may not occur;
- the possibility that we may again fail to comply with the continuing listing standards of the Nasdaq Global Market because the closing bid price of our common stock on the Nasdaq Global Market is below $1.00 for 30 consecutive business days;
- our ability to operate our business in compliance with the covenants and restrictions in our credit facility;
- current and future laws and regulations; and
- our possible need to raise additional financing.

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 Item 1A of this report, 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.

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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. Alimera was incorporated on June 4, 2003 under the laws of the State of Delaware. 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 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). DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN has received marketing authorization in the United States (U.S.), Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Lebanon, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, the United Arab Emirates and the United Kingdom. In the U.S., Canada, Lebanon and the United Arab Emirates, 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 (IOP). In the European Economic Area (EEA) countries in which ILUVIEN has received marketing authorization, it is indicated for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies. 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. We anticipate this study to be completed in early 2020.

We commercially market ILUVIEN in the U.S., Germany, the United Kingdom, Portugal, Austria and Ireland. In addition, we have entered into various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for ILUVIEN in France, Italy, Spain, Australia, New Zealand, Canada and several countries in the Middle East. In 2016, our Middle East distributor launched ILUVIEN and initiated named patient sales in the United Arab Emirates. "Named patient sales" refers to the ability of a retinal specialist to prescribe ILUVIEN because the patient has a special need for a drug that lacks a general market authorization. Our Italian distributor launched ILUVIEN in Italy in 2017. Our Spanish distributor began selling on a named patient basis in 2017 and after receiving reimbursement in 2018, plans a full-scale launch in 2019. Our French and Canadian distributors are currently pursuing reimbursement in their respective countries. As of December 31, 2018, we have recognized revenue from sales of ILUVIEN to the Company's international distributors in the Middle East, France, Italy and Spain.

In December 2017, we filed an application for a new indication for ILUVIEN for the treatment of non-infectious posterior uveitis (NIPU) in the 17 EEA countries where ILUVIEN is currently approved for the treatment of DME. 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. In 2018, the regulatory authorities requested additional follow-up data from the clinical trials to support the application. We submitted this additional follow-up data in October 2018. We expect to obtain approval of our application for NIPU in the first half of 2019, although we can provide no assurances that we can do so.

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 NIPU 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. This provides a sustained therapeutic effect on

DME and NIPU. Other therapies that physicians currently use to treat DME, such as anti-VEGF treatments and other corticosteroids, are acute (short-acting) therapies that provide a higher initial daily dose but then rapidly decline, requiring frequent reinjection by the physician to maintain or reestablish the therapeutic effect.

Our strategy is to establish ILUVIEN as a leading therapy for DME patients and subsequently for other indications for which ILUVIEN is proven safe and effective because of its ability to treat retinal diseases consistently and continuously every day 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 our marketing expertise to commercialize ILUVIEN. We intend to use those same strengths to acquire, obtain regulatory approval for and commercialize other potential eye care products.

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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 business strategy is to:

- Maximize the Commercial Success of ILUVIEN. We commercially market ILUVIEN directly in the U.S., Germany, the United Kingdom, Portugal, Austria and Ireland. We began selling ILUVIEN in Austria in the first quarter of 2017 and in Ireland in the fourth quarter of 2017. We have approval in 12 additional countries in the EEA and we are pursuing opportunities to sell ILUVIEN in some of these countries. Our Italian distributor launched ILUVIEN in Italy in 2017. Our Spanish distributor began selling on a named patient basis in 2017, with plans for a formal launch in 2019. Our French distributor is currently pursuing reimbursement at the national level. In addition, outside the EEA, we have established distribution relationships in Canada and the Middle East. Our distributor in the Middle East began selling ILUVIEN in the United Arab Emirates in 2016, and has plans to begin selling on a named patient basis in several other Middle Eastern countries in 2019. Our distributor in Canada received regulatory approval in 2018 and is currently pursuing reimbursement with plans to sell on a named patient basis beginning in mid-2019.

- Obtain approval for ILUVIEN for NIPU. We filed an application for a new indication for ILUVIEN for the treatment of NIPU in the 17 EEA countries where ILUVIEN is currently approved for the treatment of DME. We will evaluate seeking approval for the treatment of NIPU in other countries in the Middle East and Africa where we have the license to use ILUVIEN.

- Pursue Approval for ILUVIEN for DME in Additional Countries. We plan to pursue regulatory approval for ILUVIEN for the treatment of DME, directly or with a partner, in other countries. We have entered into an agreement to distribute ILUVIEN in Australia and New Zealand. Pursuant to this agreement, our distributor has filed for approval in those countries. In addition, under a Mutual Recognition Procedure (MRP) available in the EEA, we can submit ILUVIEN for approval in any or all of the remaining 12 European Union (EU) countries where we do not have marketing approval.

- Assess the Effectiveness of ILUVIEN for Additional Retinal Diseases. We believe that ILUVIEN has the potential to address additional retinal diseases other than DME and NIPU, including Non-Proliferative Diabetic Retinopathy (NPDR), retinal vein occlusion (RVO), dry age-related macular degeneration (AMD) and wet AMD.

- Expand Our Ophthalmic Product Pipeline. We believe there are further unmet medical needs in the treatment of ophthalmic 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 2017 National Diabetes Statistics Reports published by the U.S. Centers for Disease Control and Prevention (CDC) reported that as of 2015, 30.3 million Americans, or 9.4% of the U.S. population, have diabetes and that there were 1.5 million new cases of diabetes diagnosed among people ages 18 and older. Nearly 1 in 4 four adults living with diabetes, 7.2 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 84.1 million people have prediabetes, a condition that if not treated often leads to type 2 diabetes within five years. In this population, only 11.6% of adults know they had prediabetes. The IDF estimates that there are approximately 58.0 million people in Europe with diabetes and that 22.0 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

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(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. 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 fluocinolone acetonide 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 uvea track, 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. Posterior uveitis is a persistent and recurrent disease that also commonly affects 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
- NIPU, where corticosteroids are used to reduce inflammation and prevent adhesions in the eye.

Current Treatments for DME

Anti-vascular endothelial growth factor (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 the EEA 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.

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Intravitreal corticosteroid therapies are also used to treat DME. Acute corticosteroids typically have peak effects within 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 the EEA 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 component that allows a single implant to deliver a sustained daily dose for up to 36 months as discussed in more detail below. Corticosteroids have historically been associated with significant increases in IOP, 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 NIPU

The treatment of uveitis varies according to the type of uveitis. The inflammation in non-infectious posterior uveitis or NIPU is at the back of the eye, and drops do not effectively reach the affected area. This means that treatment of NIPU uveitis focuses on (a) the localized delivery of therapies, usually a steroid, or (b) systemic therapy, administered in a tablet form or via injection. Systemic therapies very often lead to side effects that impact the whole body, unlike eye drops and injections into the eye.

Patients with NIPU 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 NIPU.

One problem for patients and clinicians is that recurrence of NIPU is very common. In chronic NIPU, 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 patients with recurrent NIPU, 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 the EEA for the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis and for the treatment of non-infectious uveitis. ILUVIEN has been shown in clinical trials to significantly reduce the recurrence of NIPU, while at the same time reducing the need for adjunctive treatments, including systemic drug treatment. In January 2018 we announced we had submitted a Type II variation to our license in the EEA to add the indication of "recurrent and persistent non-infectious uveitis affecting the posterior segment" across all registered markets in the EEA, as discussed in more detail below in "Uveitis."

In addition to corticosteroids, other therapies may be used to treat NIPU, including immunosuppressive drugs and tumor necrosis factor (TNF) antagonists.

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ILUVIEN

Overview

Our only commercial product is ILUVIEN, a sustained release corticosteroid intravitreal implant. ILUVIEN consists of a tiny non-bioerodible polyimide tube with a permeable membrane cap on one end and an impermeable silicone cap on the other end that is filled with 190 micrograms of FAc in a polyvinyl alcohol matrix. Both polyimide and the polyvinyl alcohol matrix have been demonstrated to be biocompatible with ocular tissues and have histories of safe use within the eye. ILUVIEN, which is non-bioerodible, provides consistent delivery as a result of its constant surface area which allows it to deliver a continuous microdose of FAc up to 36 months. ILUVIEN is inserted in the back of the patient's eye in a non-surgical procedure using a sterile preloaded applicator (the ILUVIEN applicator) employing a 25-gauge needle, which allows for a self-sealing wound. This procedure is similar to that commonly employed by retinal specialists in the administration of other intravitreal therapies and commonly used in clinical practice.

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, while reducing the recurrence of edema. 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, which we believe 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.

ILUVIEN has received marketing authorization in the U.S., Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Lebanon, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, the United Arab Emirates and the United Kingdom. In the U.S., Canada, Lebanon and the United Arab Emirates, 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 IOP. In the EEA countries in which ILUVIEN has received marketing authorization, ILUVIEN is indicated for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies.

The ILUVIEN technology has also demonstrated a therapeutic effect in the treatment of NIPU in two phase 3 trials. In December 2017, we filed an application for a new indication for ILUVIEN for the treatment of NIPU in the 17 EEA countries where ILUVIEN is currently approved for the treatment of DME. In mid 2018, the regulatory authorities requested additional follow-up data from the clinical trials to support the application. We submitted this additional follow-up data in October 2018. We expect that we will obtain approval of our application for NIPU in the first half of 2019, although we can provide no assurances that we can do so. In addition, if we receive approval of ILUVIEN for NIPU, it is likely that we will be required to conduct certain post-market activities to maintain the approval. These required activities could include a post-market safety or efficacy study of ILUVIEN in patients treated with ILUVIEN for NIPU. We will also be required to conduct a study assessing ILUVIEN in pediatric patients with NIPU that have been treated with ILUVIEN.

Fluocinolone Acetonide (FAc)

FAc, a non-proprietary corticosteroid, is the active compound in ILUVIEN and 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, NIPU, NPDR, RVO, dry 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 IOP, 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.

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ILUVIEN for Other Diseases of the Eye

Although we are not actively conducting clinical trials, we believe that ILUVIEN has the potential to address other ophthalmic diseases such as RVO, NPDR, dry AMD and wet AMD. Details regarding the rationale for these other indications are as follows:

- Macular edema associated with RVO. According to GlobalData, a provider of global business intelligence, 16 million adults are affected by RVO around the world. In September 2009, Allergan, Inc. introduced Ozurdex (a short duration corticosteroid) as the first approved product for macular edema following RVO. The FDA approval of Ozurdex provides evidence that corticosteroids work effectively to treat RVO.
- Moderately severe to severe non-proliferative diabetic retinopathy (NPDR) progression to proliferative diabetic retinopathy (PDR). NPDR is the most at-risk stage of diabetic retinopathy for risk of progression to PDR. Prevention of progression to PDR is clinically important, as the risks of severe vision loss, blindness and retinal detachment increase when diabetic retinopathy progresses from NPDR to PDR. A recent paper published by Charles C. Wykoff in the Journal of Ophthalmology reported that treatment of DME patients with ILUVIEN over a 36-month period, slowed both the development of PDR and the progression of diabetic retinopathy.
- Dry age-related macular degeneration (AMD). Dry AMD patients account for 90% of AMD patients, with the greatest unmet need among these patients being a treatment for geographic atrophy for which there are currently no treatments available. Pre-clinical studies in two established rat models of retinal degeneration reported at the Association for Research in Vision and Ophthalmology meetings in 2006, 2007 and 2008 described the efficacious effects of a miniaturized version of ILUVIEN in retinal degeneration. While there are no standard preclinical models of geographic atrophy, we believe these results support the exploration of ILUVIEN to treat this condition.
- Wet AMD. The size of the wet AMD market was $2 billion in 2008 according to VisionGain, an independent competitive intelligence organization. According to the American Academy of Ophthalmology, more than 11 million people in America are affected by AMD and are now benefiting from advanced treatment options such as anti-VEGF agents and photodynamic therapy (PDT). Anti-VEGF antibodies require persistent dosing to maintain a therapeutic effect, which is a burden on both the patient and the physician. Estimates as of March 2015 of the global cost of visual impairment due to AMD is $343 billion, including $255 billion in direct health care costs according to BrightFocus Foundation. We believe ILUVIEN has the potential to complement the market leading anti-VEGF antibody therapies in the treatment of wet AMD, given that corticosteroids, including FAc, have been shown to suppress the production of VEGF.

ILUVIEN Regulatory Status

Diabetic Macular Edema

ILUVIEN has received marketing authorization in the U.S., Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Lebanon, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, the United Arab Emirates and the United Kingdom. In the U.S., Canada, Lebanon and the United Arab Emirates, 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 IOP. In the EEA countries in which ILUVIEN has received marketing authorization, it is indicated for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies. 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. We anticipate this study to be completed in early 2020.

We or our distributors are currently pursuing regulatory approval in certain Middle East countries, Australia and New Zealand.

Uveitis

We do not currently have a regulatory license for ILUVIEN to treat uveitis in the EEA or the U.S., and we do not have the right to pursue approval in the U.S. In January 2018, we announced that we had applied for a Type II variation to our license for the indication of “recurrent and persistent non-infectious uveitis affecting the posterior segment” across

all registered markets in the EEA. This submission is based on the positive results of two phase 3 trials conducted by EyePoint to assess the safety and efficacy of an equivalent of the ILUVIEN insert for the treatment of posterior uveitis. These studies are

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randomized, sham injection-controlled, double-masked trials. The primary endpoint for both trials was the rate of recurrence of posterior uveitis during six months, with patients being evaluated for up to three years. The first Phase 3 trial enrolled 129 patients in 16 centers in the U.S. and 17 centers outside the U.S. and achieved its primary efficacy endpoint. Likewise, the second trial enrolled 153 patients in 15 centers in India and also met its primary endpoint. We received formal acceptance of our Type II variation submission for ILUVIEN, which was submitted through the Mutual Recognition Procedure to the United Kingdom's Medicines and Healthcare Regulatory Agency (MHRA). The United Kingdom is the Reference Member State, which is the country that prepares an assessment report on the medicinal product and then shares the report with the other countries in the EEA in which the applicant has applied for a marketing authorization. The submission to the MHRA and 16 additional European states seeks to add the indication of recurrent and persistent NIPU to the ILUVIEN label in Europe. All 17 regulatory bodies have accepted the submission, which is currently under review. We expect to obtain approval of our application for NIPU in the first half of 2019, although we can provide no assurance that we can do so.

Commercialization

ILUVIEN is the only intraocular therapy to treat DME designed to deliver a continuous microdose of FAc for up to 36 months, enabling the physician to treat DME consistently and continuously every day with a single dose. Our commercialization strategy is to establish ILUVIEN as a leading therapy for the treatment of DME and subsequently for other indications for which ILUVIEN may prove safe and effective. We commercially market ILUVIEN in the U.S., Germany, the United Kingdom, Portugal, Austria and Ireland. We began selling ILUVIEN in Austria and Ireland in 2017. Our Italian distributor launched ILUVIEN in Italy in 2017. Our Spanish distributor began selling ILUVIEN on a named patient basis in 2017, and after receiving reimbursement, plans a formal launch in early 2019. We also plan to commercialize ILUVIEN, directly or with a partner, in other EEA and non-EEA countries pending the receipt of reimbursement and future applicable regulatory approvals. Although we anticipate that ILUVIEN will be administered as a standalone therapy, it is possible that ILUVIEN will be used in conjunction with other therapies. Our commercialization strategy in any jurisdiction is subject to and depends upon the approval of ILUVIEN by the applicable regulatory authorities.

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.

We have various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for commercialization of ILUVIEN in Italy, Spain, France, 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 approval or reimbursement, or they will seek approval or reimbursement with our oversight in those countries, if such approval or reimbursement has not already been obtained.

We develop our medical marketing, promotion and communication materials with the goal of ensuring that influential retinal specialists are presenting our data from the pivotal Phase 3 clinical trials that supported our approval in the U.S. and Europe (the FAME studies), clinicians' real world data, including our most recent post-market study in the U.S. (the USER study), and messages at key meetings in the U.S. and the EEA.

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.

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

- the manufacture of the ILUVIEN implant and final assembly and packaging of ILUVIEN (Alliance Medical Products Inc., a Siegfried Company (Alliance))

- the manufacturer of the components of the ILUVIEN applicator (FlexMedical or an affiliate of Flextronics International, Ltd. (Flextronics))
- the manufacture of ILUVIEN's active pharmaceutical ingredient (FARMABIOS SpA/Byron Chemical Company Inc.) and

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- the quality release testing of ILUVIEN in the EEA including the United Kingdom, 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 activities. The manufacturing process for ILUVIEN consists of filling the polyimide tube with a paste consisting of 190 micrograms of FAc in an aqueous slurry of polyvinyl alcohol, cutting the tubes, capping the tubes with a permeable membrane cap on one end and an impermeable silicone cap on the other end, curing at high temperature, loading ILUVIEN inside the ILUVIEN applicator, packaging and sterilizing the product. This process has been validated at Alliance.

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 2021 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.

Under our agreement with Flextronics, which we entered into in 2012, Flextronics agreed to manufacture the components of the ILUVIEN applicator for us at its facility located near Tijuana, Mexico. We purchased certain equipment for Flextronics' facility that Flextronics uses solely to manufacture the components of the ILUVIEN applicator for us. Unless terminated earlier in accordance with the terms of the agreement, our agreement with Flextronics automatically renews for successive terms of one year unless either party delivers written notice of non-renewal to the other at least 18 months prior to the end of the then current term.

Business Segments

Our business has three segments: U.S., International and Other. Financial information about our business segments can be found in this annual report on Form 10-K in (a) Part I, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Segment Review" and (b) Note 18 of the accompanying consolidated financial statements.

Customers

Our revenues for the fiscal years ended December 31, 2018 and 2017 were generated from product sales primarily in the U.S., Germany and the United Kingdom. In the U.S., two large pharmaceutical distributors accounted for 69% and 73% of our consolidated revenues for the years ended December 31, 2018 and 2017, 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 provide competition to 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

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edema following RVO in the U.S. In the EEA, the indications are similar except for the indication to treat diabetic retinopathy in patients with DME.

- 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, 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 panuveitis. 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.
- YUTIQ™ (fluocinolone acetonide intravitreal implant) 180 micrograms, for intravitreal injection, marketed by Eyepoint, is a non-bioerodible intravitreal micro-insert that contains 180 micrograms of FAc that is designed to release .25 micrograms/day over the course of 36 months. YUTIQ is indicated for the treatment of chronic NIPU, in the U.S. It is not approved for any indication in Europe and EyePoint does not have the right to pursue any approval in Europe, where we are currently pursuing the approval of ILUVIEN for NIPU. YUTIQ is very similar to ILUVIEN, although the amount of FAc in the YUTIQ implant is slightly less and it utilizes a different injector. The two drugs are approved for different indications in the U.S., with ILUVIEN being approved for the treatment of DME and YUTIQ being approved for the treatment of chronic NIPU.
- 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 Alcon/ Novartis, Ampio Pharmaceuticals, Aerpio, Aerie, Allegro, and Clearside are developing drug therapies or sustained delivery platforms for the treatment of retinal diseases. Specifically, Alcon/ Novartis is developing Brolucizumab, a VEGF-targeted single-chain antibody fragment in development for retinal diseases including DME.

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.

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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 NIPU, 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 2018, we recognized approximately $998,000 of royalty expense. During 2017, we recognized approximately $621,000 of royalty and profit share expense.

Following the signing of the New Collaboration Agreement, we retained a right to offset $15.0 million of future royalty payments. This offset will be reduced by up to $5.0 million upon the earlier of the approval of ILUVIEN for posterior uveitis in any EU country or January 1, 2020, unless certain conditions under the New Collaboration Agreement are not met. As of December 31, 2018, the balance of the Future Offset was approximately $14.9 million. We valued the additional rights we acquired under the New Collaboration Agreement utilizing a present value analysis of approximately $2,851,000. Because there was no approved indication for ILUVIEN for uveitis at the time, we expensed the $2,851,000 as a non-cash charge as in-process research and development expense in 2017. We also recognized $2,851,000 for recoverable collaboration costs for the value of the right of offset as a reduction of operating expenses. As a result, there was no impact on our operating loss or net loss for 2017.

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. We were not in breach of our agreement with EyePoint as of December 31, 2018.

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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 $310,000 as of our last renewal in October 2018.

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. We anticipate this study to be completed in early 2020.

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 must maintain compliance with the FDA’s 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,

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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 NIPU, we filed a type II variation in these 17 countries in the EEA using the same procedure.

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 the current presidential administration and Congress have attempted to repeal it and replace it with a different health care law and have affected some of its key provisions through the Tax Cuts and Jobs Act enacted in December 2017. While we cannot predict what impact on federal reimbursement policies this law or any replacement law will have in general or specifically on any product we commercialize, the ACA or any replacement may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. Any rebates, discounts, taxes costs or regulatory or systematic changes on healthcare resulting from the ACA or its replacement may have a significant effect on our profitability in the future. We cannot predict whether the ACA will continue 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 the projected value of certain development projects and 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.

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.

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As of December 31, 2018, we owned or licensed seven U.S. utility patents, one U.S. design patent and one U.S. patent application as well as numerous foreign counterparts to many of these patents and patent applications relating to ILUVIEN or the ILUVIEN applicator. We licensed our seven utility patent rights 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 patent application pending 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 seven U.S. patents that expire between March 2019 and August 2027 and counterpart filings to these patents in a number of other jurisdictions. The two European patents that EyePoint licensed to us that are directed to our low-dose device expire in April 2021 and October 2024. 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 $1.1 million and $4.2 million in research and development during 2018 and 2017, respectively. The 2017 investment includes a $2.9 million non-cash charge as in-process research and development expense for the additional rights we acquired under the New Collaboration Agreement with EyePoint.

Employees

As of January 31, 2019, we had 124 employees, all 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.

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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.

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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 appearing at the end of this report, before making an investment decision. 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 OUR BUSINESS, INCLUDING OUR DEPENDENCE ON ILUVIEN

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 commercial production of the ILUVIEN implant, the commercial production of the ILUVIEN applicator and the supply of the active pharmaceutical ingredient in ILUVIEN, the suppliers may be unable to meet their contractual or quality requirements or choose not to supply us in a timely manner or in the minimum guaranteed quantities. If our manufacturers are unable to obtain these essential supplies, their ability to manufacture ILUVIEN and thus our supply of ILUVIEN for sale would be delayed, which could significantly reduce our sales of ILUVIEN and have an adverse impact on our business.

We depend on the commercial success of our only product, ILUVIEN, which in the near term will depend almost entirely on our ability to successfully commercialize ILUVIEN on our own in the countries where we sell direct, and on our distributors' ability to successfully commercialize ILUVIEN in other countries.

We are a pharmaceutical company with only one product available for commercial sale in a limited number of markets. Because we do not currently have any products or product candidates available for sale or in clinical development other than ILUVIEN, our future success depends on our and our distributors' successful commercialization of ILUVIEN. We launched ILUVIEN in Germany and the United Kingdom in 2013 and in the U.S. and Portugal in 2015. We began selling ILUVIEN in Austria and Ireland in 2017. Our distributors in Italy and Spain generated revenues for us in 2017 through sales of ILUVIEN, as did our distributor in the Middle East. We expect that our distributors in France and Spain will launch ILUVIEN in their respective countries in 2019, although the timing and success of the commercial launch of ILUVIEN in any new country depends on each specific pricing and reimbursement timeline established by the applicable regulatory authority in that country. In December 2017, we filed an application for a new indication for ILUVIEN for the treatment of non-infectious posterior uveitis (NIPU) in the 17 EEA countries where ILUVIEN is currently approved for the treatment of DME. We expect to obtain approval of our application for NIPU in the first half of 2019, although we can provide no assurances that we can do so.

We have incurred and expect to continue to incur significant expenses and to use a substantial portion of our cash resources:

- to continue to support our sales efforts in the U.S., Austria, Germany, Ireland, Portugal and the United Kingdom,
- to pursue the approval of and reimbursement for ILUVIEN in other countries and
- to grow our operational capabilities.

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 increase 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, our business may be seriously harmed. We and our distributors may not be able to commercialize ILUVIEN successfully, which would have a material adverse effect on our business and prospects. In the near term, 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.

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The United Kingdom's vote to leave the EU, or "Brexit," could have a material adverse effect on us.

On June 23, 2016, the United Kingdom held a referendum and voted in favor of leaving the EU (Brexit). After the referendum, the United Kingdom set the Brexit date as March 29, 2019. This result has created political and economic uncertainty, particularly in the United Kingdom and the EU, and this uncertainty may last for years. Our business in the United Kingdom, the EU and worldwide could be adversely affected during this period of uncertainty, and perhaps longer, by the United Kingdom's referendum decision. There are many ways in which our business could be adversely affected, only some of which we can identify.

We currently operate in Europe through a subsidiary based in the United Kingdom, which currently provides us with certain operational and other benefits. The United Kingdom'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 United Kingdom to another country in the EU.

For example, our reference member state for our marketing authorization in the EEA for ILUVIEN is the United Kingdom's MHRA. Because of Brexit, we likely need to select a new reference member state for the EU, which will require filing and receiving acceptance from such member state to make such change. A change in our reference member state may require us to modify our marketing authorization in the 17 countries in the EEA where we currently have market authorization for ILUVIEN. In addition, the quality release testing of ILUVIEN for the EEA occurs in the United Kingdom. Due to Brexit, we will need to establish a quality release-testing site for ILUVIEN in a different location in the EEA. In addition to the cost and risk of establishing a new testing site, this change will also require a modification to our marketing authorization in the 17 countries where we have a license. Any delay in the acceptance by governmental authorities of these modifications, or any other changes to our marketing authorizations or how we conduct business caused by Brexit may disrupt our operations or limit our ability to sell ILUVIEN in the EEA for a period of time, which could adversely affect our operating results and growth prospects.

In addition, 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 United Kingdom, 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 United Kingdom and other countries, including the U.S., and by the possible imposition of trade or other regulatory barriers in the United Kingdom. These possible negative impacts, and others resulting from the United Kingdom's actual or threatened withdrawal from the EU, may adversely affect our operating results and growth prospects.

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 additional markets, which may have an adverse effect on our business and results of operations.

ILUVIEN has received marketing authorization in the U.S., Canada, Lebanon, the United Arab Emirates and in the following countries of the EEA: Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom. We have launched ILUVIEN in the U.S., Germany, the United Kingdom, Portugal, Ireland and Austria. Our distributors will continue to sell ILUVIEN in Italy and Spain in 2019. 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. The withdrawal of an approval could harm our business materially.

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

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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.

Even if we do receive additional regulatory approvals for ILUVIEN, 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 a limited indication, the size of our potential market for ILUVIEN will be reduced. ILUVIEN has received marketing authorization in Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. In the U.S., Canada, 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 (IOP). 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.

We rely on a single manufacturer for ILUVIEN, a single manufacturer for the ILUVIEN applicator and a single manufacturer for ILUVIEN's active pharmaceutical ingredient. Our business would be seriously harmed if any of these third parties are unable to satisfy our demand and alternative sources are not available.

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 the ILUVIEN implant, final assembly of the injector with the implant and release testing for the U.S. (Alliance Medical Products, Inc., a Siegfried Company (Alliance)),
- the manufacture of the ILUVIEN applicator (FlexMedical or an affiliate of Flextronics International, Ltd. (Flextronics)),
- the manufacture of ILUVIEN's active pharmaceutical ingredient (FARMABIOS SpA./Byron Chemical Company Inc. (FARMABIOS)),
- the sterilization of the final product, and
- the quality release testing of ILUVIEN in the European Economic Area (EEA) including the United Kingdom, post Brexit (AndersonBrecon Limited trading as Packaging Coordinators, Inc. (PCI)).

If any of the third-party manufacturers (a) breach their agreements, (b) are unable to meet their contractual or quality requirements or (c) become unwilling to perform for any reason, we may be unable, or may be unable in a timely manner, to locate alternative acceptable manufacturers, 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 ILUVIEN implants, the ILUVIEN applicator or the active pharmaceutical ingredient in

a timely manner from these third parties could

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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.

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 product development and 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 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 to manufacture products at another facility, we would need 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.

The terms of our 2018 Loan and Security Agreement with Solar Capital Ltd. require us to meet certain operating covenants and place restrictions on our operating and financial flexibility.

Our $40.0 million Loan and Security Agreement (2018 Loan Agreement) with Solar Capital Ltd. (Solar Capital) contains certain operating covenants and restricts our operating and financial flexibility. The 2018 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 2018 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 our 2018 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 2018 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 are liquidated, Solar

Capital’s right to repayment would be senior to the rights of our stockholders.

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

As of December 31, 2018, we had approximately $13.0 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

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control, and we may need capital to fund our operations and support our growth sooner than we might anticipate. These factors include:

- the level of 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 out-license ILUVIEN, 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.

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

For the reasons described above, we may need to raise alternative or additional financing to fund our operations and support growth. General market conditions or the market price of our common stock may not support capital-raising transactions such as an additional public or private offering of our common stock or other securities. In addition, our ability to raise additional capital may depend on our stock being quoted on the Nasdaq Stock Market or upon obtaining stockholder approval. There can be no assurance that we will be able to satisfy the criteria for continued listing on Nasdaq or that we will be able to obtain stockholder approval if it is necessary. 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 collaboration 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 our 2018 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 commercialize ILUVIEN or any future products or product candidates or otherwise successfully operate our business.

ILUVIEN and any future products or product candidates may not be commercially viable in the U.S. 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.

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 current pricing of other therapies. Due to numerous factors beyond our control, including efforts to provide for containment of health care costs, the U.S. may not support our current level of governmental pricing and reimbursement for ILUVIEN, which would reduce our anticipated revenue from ILUVIEN.

In the U.S., the Medicare and Medicaid programs currently provide reimbursement for ILUVIEN, but the reimbursement amount for ILUVIEN could be modified in the future, and the types of patients for whom ILUVIEN is reimbursed could be reduced to a smaller subset of patients. In addition, in some states, Medicare reimburses physicians for less than the cost of ILUVIEN. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive

reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. The current presidential

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administration and Congress have indicated they may further reform the Medicare program and the U.S. healthcare system, but have not made any definitive proposals that allow us to gauge the impact of such potential reforms, if any, on our business and operations. Some of these changes and proposed 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 Medicare program, local Medicare carriers 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 expect to 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.

ILUVIEN and any future products or product candidates may not be commercially viable in the European Economic Area 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, 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 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. For example, in November 2016 we began a review process with The National Institute for Health and Care Excellence (NICE) in the United Kingdom. This review could result in beneficial or detrimental changes to the limitations on the use of ILUVIEN in England and Wales. Our business could be materially adversely affected if NICE imposes those limitations.

In addition, due to price referencing within the EEA 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 in the future. For example, if we were to obtain pricing in France that is lower than our current established price in Portugal, the Portuguese government may choose to revisit the current level of reimbursement. This 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 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. (An “indication” is a condition that makes a particular treatment or procedure advisable.) 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

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and state statutes, along with requirements in Europe, such as the Medicines Act of 1968 in the United Kingdom 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.

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. 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, multiple and 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.

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Maintaining our commercial infrastructure is a significant undertaking that requires substantial financial and managerial resources, and we may not be successful in our efforts or we may experience difficulties with these efforts. We may also encounter unexpected or unforeseen challenges, which may negatively affect our commercial efforts for ILUVIEN.

We anticipate that in the near term our ability to generate revenues will depend almost entirely on our ability to successfully commercialize ILUVIEN. We launched ILUVIEN in Germany and the United Kingdom in 2013, and in the U.S. and Portugal in 2015. We launched ILUVIEN in Ireland and Austria in 2017. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources. We anticipate that our distributors in Italy, the Middle East, Spain and France will continue to generate revenues for us in 2019, if they are able to continue to successfully commercialize ILUVIEN in those territories.

As of January 31, 2019, we had 124 employees, all of whom were full-time employees. As our commercialization plans and strategies evolve beyond our initial planned EEA launches, 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 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.

We may not be successful in maintaining and expanding our commercial operations for numerous reasons, including the failure to attract, retain and motivate the necessary skilled personnel and failing to develop a successful marketing strategy. Failure to maintain and expand our commercial operations will have a negative outcome on our ability to commercialize ILUVIEN and generate revenue.

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 or been recommended for 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 could result in the withdrawal of our marketing or regulatory authorization for ILUVIEN in certain jurisdictions, including certain EU member states where ILUVIEN has already received marketing authorization.

In addition, there are 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.

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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.

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, including NIPU for ILUVIEN in the EEA, 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.

We may not be able to obtain regulatory approval for ILUVIEN for the NIPU Indication in the EEA, or if we do obtain regulatory approval, we may not be able to meet any post-marketing requirements for such approval; if we fail to obtain that approval or do not meet any requirements, our opportunity for future growth could be limited.

On December 12, 2017, we filed a Type II Variation for ILUVIEN through the Mutual Recognition Procedure with the MHRA in the United Kingdom as the reference member state. The submission to the MHRA and the appropriate bodies of the 16 European states seeks to add to the ILUVIEN label in these countries the indication of recurrent and persistent non-infectious uveitis affecting the posterior segment. All 17 bodies have accepted the submission.

Although we believe that the uveitis clinical trials demonstrated the benefits of ILUVIEN for NIPU, the regulatory agencies may not agree, and they may not approve the use of ILUVIEN for NIPU. In addition, if we receive approval of ILUVIEN for NIPU, it is likely that we will be required to conduct certain post-market activities to maintain the approval. These required activities could include a post-

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market safety or efficacy study of ILUVIEN in patients treated with ILUVIEN for NIPU. We will also be required to conduct a study assessing ILUVIEN in pediatric patients with NIPU that have been treated with ILUVIEN. Implementing and maintaining these studies could be costly. If we are unable to meet any requirements, we could lose our approval. If we do not receive approval for NIPU for ILUVIEN in these countries, if the approval process is delayed significantly, or if we are unable to meet any post-market requirements, we could face adverse publicity, which could negatively affect our reputation and our operations and could have a material adverse effect on our business. If we gain approval for NIPU but it is subsequently revoked and we are required to remove ILUVIEN for NIPU from the EEA market, our opportunity for future growth could be limited.

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

The development and commercialization of new 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.

We may not be successful in our efforts to expand our portfolio of ophthalmic products.

In the future, we may choose to commercialize a portfolio of new ophthalmic drugs in addition to ILUVIEN. We may seek to do so through our internal research programs and 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

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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.

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

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, including adding new products in the ophthalmic field. 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.

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 Dave 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. Kenneth Green, Ph.D., our Chief Scientific Officer, will retire on March 31, 2019, although he will serve as a consultant to us for at least one year.

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 have incurred operating losses in each year since our inception and may continue to incur substantial and increasing losses.

We are not currently generating enough revenues to cover our current expenses or our anticipated future expenses. ILUVIEN is our only product currently approved for commercial sale. As a result of these factors, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. As of December 31, 2018, we had accumulated a deficit of $377.1 million. Our ability to generate significant revenue and achieve profitability depends on our ability to successfully market and sell ILUVIEN and expand the geographic areas where we or our distributors can sell ILUVIEN, and to complete the development of and obtain necessary regulatory approvals for future ophthalmic products or product candidates. 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.

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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 2018 financial statements included 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 continue to be subject to quarterly fluctuations. The revenues we generate and our operating results will be affected by numerous factors, including:

- the commercial success of ILUVIEN, including its timing;
- 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, such as NIPU;
- regulatory developments affecting ILUVIEN, our future product candidates or our competitors' products;
- the emergence of products or treatments that compete with ILUVIEN;
- sales and marketing expenses;
- variations in the level of expenses related to our products or future development programs;
- the status of our preclinical and 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.

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.

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

As of December 31, 2018, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $122.5 million and $153.3 million, respectively, which expire at various dates beginning in 2020 through 2038, 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 our 2018 Loan Agreement with Solar Capital and we raise such funds by selling additional equity, this could further limit the use of our NOLs in the future.

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. Moreover, these rules and regulations require substantial costs related to legal and financial compliance and to director and officer liability insurance.

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 Nasdaq, SEC 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,

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- 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.

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.

Our internal information technology systems, or those of our third-party 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. We must maintain the confidentiality and integrity of that confidential information. 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, contract research organizations (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'

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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 manufacture 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.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities may involve the controlled use of potentially hazardous substances, including chemical and biological materials. In addition, our operations may produce hazardous waste products. Federal, state and local laws and regulations in the U.S. govern the use, manufacture, storage, handling and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we comply with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur liability as a result of any such contamination or injury. If an accident occurs, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, operating results and financial condition.

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 and the United Kingdom 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.

In addition, we rely on third parties for several important aspects of our business. During challenging and uncertain economic times and in tight credit markets, there may be a disruption or delay in the performance of our third party contractors, suppliers or partners. If those third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected. We sell to two large pharmaceutical distributors in the U.S. and they accounted for 69% and 73% of our consolidated revenues for the years ended December 31, 2018 and 2017, respectively.

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The term loan under our 2018 Loan and Security Agreement matures on July 1, 2022, and our interest rate is based on LIBOR. As a result, we are exposed to the risks associated with the expected replacement for LIBOR by the anticipated January 1, 2022 deadline.

The term loan under our 2018 Loan Agreement matures on July 1, 2022, and our interest rate is based on LIBOR, which is expected to be replaced by January 1, 2022. As a result, we are exposed to the risks associated with the expected replacement for LIBOR, which could result in our paying a higher interest rate during the first six months of 2022 than we would have otherwise paid if LIBOR had not been replaced.

EyePoint has received regulatory approval in the U.S. for a drug to treat uveitis with fluocinolone acetonide (FAc), the active pharmaceutical ingredient in ILUVIEN. EyePoint's drug, YUTIQ, also uses the same insert technology as ILUVIEN, but with their own inserter. If EyePoint subsequently commercializes this drug, our opportunity for future growth could be limited.

Our license agreement with EyePoint permits EyePoint to develop a drug to treat chronic non-infectious uveitis affecting the posterior segment of the eye (NIPU) using the technology of the polyimide insert, but not the ILUVIEN inserter. EyePoint has conducted clinical trials with such a drug, named YUTIQ, for the treatment of NIPU and received approval from the FDA in the fourth quarter of 2018 for the treatment of NIPU. When EyePoint commercializes YUTIQ in the U.S., its similarities to ILUVIEN may create confusion in the market place. In addition, EyePoint is seeking pricing and reimbursement for YUTIQ that are lower than ILUVIEN, which could ultimately result in lower reimbursement levels for ILUVIEN. This potential market place confusion or any impact to our reimbursement for ILUVIEN could have a material adverse effect on our revenues, business and operations.

RISKS RELATED TO INTELLECTUAL PROPERTY AND OTHER LEGAL MATTERS

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.

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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. The patent rights relating to ILUVIEN licensed to us from EyePoint include seven U.S. patents that expire between March 2019 and August 2027, two European patents expiring 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. 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.

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. While we require all of our employees, consultants, advisors and any third parties who have access to our

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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.

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

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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.

In addition to patented technology, we rely upon unpatented proprietary technology, processes, trade secrets and know-how. 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. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff were previously employed by other pharmaceutical or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their drug development activities for us.

RISKS RELATED TO THE OWNERSHIP OF OUR COMMON STOCK

The failure to maintain a minimum closing share price of $1.00 per share of our common stock could result in the delisting of our shares on the Nasdaq Global Market, which could materially reduce the liquidity of the common stock and have an adverse effect on its market price.

To retain our listing on the Nasdaq Global Market, we must maintain a minimum bid price of $1.00 per share. Our stock price is currently above $1.00. If the minimum bid price of our common stock were to fall below $1.00 per share for 30 consecutive business days, as has occurred twice within the past nine months, we would likely receive notification from the Nasdaq Global Market that we were not in compliance with the $1.00 minimum bid price rule, in which case we could be subject to delisting from the Nasdaq Global Market unless our common stock closed at or above $1.00 per share for 10 consecutive business days during the 180 days immediately following failure to maintain the minimum bid price. If our stock price did not achieve that level, our stock could be delisted from the Nasdaq Global Market, transferred to a listing on the Nasdaq Capital Market, or delisted from the Nasdaq markets altogether. Twice within the past nine months, we have received notice from Nasdaq that we failed to comply with the Nasdaq Global Market's minimum bid requirement because our stock price was below $1.00 per common share for 30 consecutive business days. In each case we were able to regain compliance, first in July 2018 and again in February 2019, when the closing bid price of our common stock equaled or exceeded the $1.00 minimum bid price requirement for 10 consecutive business days. We cannot provide any assurances, however, that we will continue to comply with Nasdaq's $1.00 minimum bid price requirement or if we fail to do so, we will again be able to regain compliance by the applicable deadline.

The delisting of our shares from the Nasdaq Global Market could materially reduce the liquidity of our common stock and have an adverse effect on its market price. Further, trading of our common stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors would likely not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules as a "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our common stock. A delisting would also likely make it more difficult for us to obtain financing through the sale of our equity. Any such sale of equity would likely be more dilutive to our current

stockholders than would be the case if our shares were listed. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and to raise capital.

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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 is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- our ability to successfully commercialize ILUVIEN in the U.S., Austria, Germany, Ireland, Portugal and the United Kingdom;
- the ability of our distributors to commercialize ILUVIEN in the countries where they have obtained distribution rights;
- whether ILUVIEN is approved for sale in any additional jurisdiction;
- whether our filing for a Type II variation for ILUVIEN for NIPU in 17 countries in the EEA is approved;
- whether ILUVIEN or any future products or product candidates, if approved in additional jurisdictions, achieves and maintains commercial success;
- FDA or international regulatory actions, including failure to receive or maintain regulatory approval for ILUVIEN or any future products or product candidates;
- quarterly variations in our results of operations or those of our competitors;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies and levels;
- our ability to meet our repayment and other obligations under our loan agreements;
- additions or departures of key personnel;
- commencement of, or our involvement in, litigation;
- the impact of Brexit on our business;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board of directors or management;
- results from our clinical trial programs;
- our ability to develop and market new and enhanced products or product candidates on a timely basis;
- general economic conditions and slow or negative growth of our markets; and
- political instability, natural disasters, war and/or events of terrorism.

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.

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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. 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.

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.

Investors that participated in our Series A Convertible Preferred Stock financing, including some of our large shareholders and our executive officers, key employees, directors and their affiliates, beneficially own, in the aggregate, a majority of the outstanding voting power of our common stock. As a result, these stockholders, if acting together, may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions, and this concentration of voting power may have the effect of delaying or impeding actions that could be beneficial to you, including actions that our Board of Directors may support.

In addition, 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.

Significant sales of our common stock could depress or reduce the market price of our common stock, or 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 and Series C 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. Additionally, a small number of investors have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

We may sell our shares in registered public offerings. For example, in August 2016, we sold an aggregate of 18,900,000 shares of our common stock at a price of $1.40 each, resulting in gross proceeds of approximately $26.5 million, before deducting underwriting fees, commissions and offering expenses.

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 determined it was 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 December 31, 2018, we were obligated to issue: (a) a total of 12,447,355 shares of common stock upon the exercise of outstanding common stock options (b) a total of 900,252 shares of common stock upon the vesting of restricted stock units (RSUs), under which 889,752 shares of common stock were issued in early 2019; and (c) a total of 1,795,663 shares of common stock upon the exercise of outstanding common stock warrants. Upon the exercise of the stock options and vesting of the RSUs in accordance with their respective terms, the shares so acquired may be resold freely, subject to restrictions imposed on our affiliates under the SEC's Rule 144. 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.

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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 our 2010 Equity 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. The number of shares available for future grant under our 2010 Equity Incentive Plan increases each year by an amount equal to the lesser of 4% of all shares of our capital stock outstanding as of January 1st of each year, 2,000,000 shares, or such lesser number as determined by our Board of Directors. On January 1, 2019, an additional 2,000,000 shares became available for future issuance under our 2010 Equity Incentive Plan in accordance with the annual increase. In addition, as of January 1, 2019, a total of 494,422 shares of our common stock were available for issuance under our 2010 Employee Stock Purchase Plan. The number of shares eligible for purchase under our Employee Stock Purchase Plan is automatically increased as of January 1st of each year by the number of shares of common stock necessary to cause the number of shares of common stock then available for purchase to be restored to 494,422 shares.

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), provided that any increases resulting solely from the annual increases resulting from the “evergreen” provisions of equity incentive plans in effect in

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October 2012 shall not be subject to this restriction and shall not be included for purposes of determining whether such 20% increase has occurred;

- 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.

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.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

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. Our lease for this facility expires in September 2021. In our international segment, our EEA headquarters are located in Aldershot, United Kingdom, consisting of approximately 6,000 square feet of office space. Our lease for this facility expires in December 2024, but is cancelable without penalty in December 2019. In our international segment, we lease approximately 1,000 square feet of office space in each of Dublin, Ireland, Berlin, Germany, and Lisbon, Portugal. Our leases for these facilities in Ireland, Germany and Portugal expire in June 2019, June 2021 and March 2020, respectively. 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

On December 22, 2016, Cantor Fitzgerald & Co. (Cantor Fitzgerald) filed a complaint against us in the Supreme Court of the State of New York, County of New York (the Court). This complaint mirrored a complaint that Cantor Fitzgerald filed against us in November 2016 in the United States District Court for the Southern District of New York and then voluntarily dismissed.

In the operative complaint, Cantor Fitzgerald alleged breach of a letter agreement pursuant to which we had engaged Cantor Fitzgerald to assist us in obtaining bank or loan financing. Cantor Fitzgerald alleged that our agreement in October 2016 with Hercules Capital, Inc. (Hercules) to restructure and amend our then existing $35 million debt facility with Hercules and to secure an additional $10 million in debt financing required the payment to Cantor Fitzgerald of an advisory fee of 2% of $45 million, or $900,000, plus expenses of $24,890. Cantor Fitzgerald sought compensatory and punitive damages, pre- and post-judgment interest, plus attorneys' fees and costs.

On January 12, 2017, we filed a counterclaim against Cantor Fitzgerald for breach of contract. We alleged in the counterclaim, among other things, that Cantor Fitzgerald failed to meet its obligations to provide services to us as required under the letter agreement. We sought compensatory and other damages, arising from, among other things, our additional out-of-pocket costs incurred as a result of Cantor Fitzgerald's breach.

The litigation with Cantor Fitzgerald was settled by agreement of the parties on October 31, 2018.

Previous developments in the foregoing litigation were reported in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2018, June 30, 2018 and September 30, 2018.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

Our common stock has been trading on The Nasdaq Global Market (Nasdaq) under the symbol "ALIM" since our IPO on April 22, 2010. Before then, there was no established public trading market for our common stock.

Stockholder Data

As of February 22, 2019, there were 33 holders of record of our common stock, and there were 70,968,630 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.

Recent Sales of Unregistered Securities

In 2016, 2017 and 2018, 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.

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ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

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.

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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 set forth in the section entitled "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 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 represent a significant market opportunity.

Our only commercial product is ILUVIEN®, which has received marketing authorization in the U.S., Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Lebanon, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, the United Arab Emirates and the United Kingdom. In the U.S., Canada, Lebanon and the United Arab Emirates, ILUVIEN is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP). In the European Economic Area (EEA) countries in which ILUVIEN has received marketing authorization, it is indicated for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies.

We commercially market ILUVIEN in the U.S., Germany, the United Kingdom, Portugal, Austria and Ireland. We began selling ILUVIEN in Austria and Ireland in 2017.

In addition, we have entered into various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for ILUVIEN in France, Italy, Spain, Australia, New Zealand, Canada and several countries in the Middle East. In 2016, our Middle East distributor launched ILUVIEN and initiated named patient sales in the United Arab Emirates. Our Italian distributor launched ILUVIEN in Italy in 2017. Our Spanish distributor began selling on a named patient basis in 2017 and upon receiving reimbursement, plans a full-scale launch in 2019. Our French and Canadian distributors are currently pursuing reimbursement in their respective countries. As of December 31, 2018, we have recognized sales of ILUVIEN to the Company's international distributors in the Middle East, France, Italy and Spain.

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, the technology underlying ILUVIEN now includes the treatment of uveitis, including non-infectious posterior uveitis (NIPU) in Europe, the Middle East and Africa. In December 2017, we filed an application for a new indication for ILUVIEN for the treatment of non-infectious posterior uveitis (NIPU) in the 17 EEA countries where ILUVIEN is currently approved for the treatment of DME. 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. The regulatory authorities requested additional follow-up data from the clinical trials to support the application. This additional follow-up data was submitted in October 2018. We expect that we will obtain approval of our application for NIPU in the first half of 2019, although we can provide no assurances that we can do so.

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 accumulated commercialization costs incurred in previous quarters. The New Collaboration Agreement converted the 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 2018, we recognized approximately $998,000 of royalty expense. During 2017, we recognized

approximately $621,000 of royalty and profit share expense.

Following the signing of the New Collaboration Agreement, we retained a right to offset $15.0 million of future royalty payments. This offset will be reduced by up to $5.0 million upon the earlier of the approval of ILUVIEN for posterior uveitis in any EU country or January 1, 2020, unless certain conditions under the New Collaboration Agreement are not met.

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We commenced operations in June 2003. Since our inception we have incurred significant losses. As of December 31, 2018, we had accumulated a deficit of $377.1 million. We expect to incur substantial losses through the continued commercialization of ILUVIEN as we:

- continue the commercialization of ILUVIEN in the U.S. and EEA, where we sell direct, and in other countries in the EEA and the Middle East, where we sell through our distributors;
- continue to seek regulatory approval of ILUVIEN for other indications and in other jurisdictions;
- evaluate the use of ILUVIEN for the treatment of other diseases; and
- advance the clinical development of any future products or product candidates either currently in our pipeline, or that we may license or acquire in the future.

As of December 31, 2018, we had approximately $13.0 million in cash and cash equivalents.

On January 5, 2018, we entered into a $40.0 million Loan and Security Agreement (2018 Loan Agreement) with Solar Capital Ltd. (Solar Capital). Under the 2018 Loan Agreement, we borrowed the entire $40.0 million as a term loan that matures on July 1, 2022 (Solar Capital Loan). We used the proceeds of the Solar Capital Loan to refinance the then outstanding loan (Hercules Loan) under our previous loan agreement with Hercules Capital, Inc. (Hercules Loan Agreement) and to pay closing expenses associated with the 2018 Loan Agreement. We expect to use the remaining loan proceeds to provide additional working capital for general corporate purposes. (See Note 10 of our notes to consolidated financial statements below.)

Our revenues for the fiscal years ended December 31, 2018 and 2017 were generated from product sales primarily in the U.S., Germany and the United Kingdom. In the U.S., two large pharmaceutical distributors accounted for 69% and 73% of our consolidated revenues for the years ended December 31, 2018 and 2017, 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.

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Results of Operations - Year ended December 31, 2018 compared to year ended December 31, 2017

	Years Ended December 31,	
	2018	2017
	(In thousands, except share and per share data)	
NET REVENUE	$46,970	$35,912
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(4,679)	(3,438)
GROSS PROFIT	42,291	32,474
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	11,274	12,844
GENERAL AND ADMINISTRATIVE EXPENSES	14,525	13,039
SALES AND MARKETING EXPENSES	23,517	23,210
DEPRECIATION AND AMORTIZATION	2,645	2,684
RECOVERABLE COLLABORATION COSTS	—	(2,851)
OPERATING EXPENSES	51,961	48,926
NET LOSS FROM OPERATIONS	(9,670)	(16,452)
INTEREST EXPENSE AND OTHER	(4,775)	(5,579)
UNREALIZED FOREIGN CURRENCY (LOSS) GAIN, NET	(65)	5
LOSS ON EARLY EXTINGUISHMENT OF DEBT	(1,766)	—
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	—	188
NET LOSS BEFORE TAXES	(16,276)	(21,838)
PROVISION FOR TAXES	(106)	(163)
NET LOSS	(16,382)	(22,001)
GAIN ON EXTINGUISHMENT OF PREFERRED STOCK	38,330	$—
NET INCOME (LOSS) AVAILABLE TO STOCKHOLDERS	$21,948	$(22,001)
NET INCOME (LOSS) PER SHARE — Basic	$0.25	$(0.33)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic	88,002,208	66,993,649
NET INCOME (LOSS) PER SHARE — Diluted	$0.25	$(0.33)
WEIGHTED AVERAGE SHARES OUTSTANDING — Diluted	88,737,788	66,993,649

Revenue

We began generating revenue from ILUVIEN in 2013. 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 increased by approximately $11.1 million, or 31%, to approximately $47.0 million for 2018, compared to approximately $35.9 million for 2017. The increase was attributable to increased sales volume in the U.S. and international segments, including increases in both the markets where we sell direct and the markets where we sell to distributors.

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

Gross profit is affected by costs of goods sold, which includes (a) costs of manufactured goods sold and (b) payments to EyePoint in the form of (1) royalty payments under the New Collaboration Agreement (after July 1, 2017), and (2) payments based on a percentage of net profits under our previous agreement with EyePoint (before July 1, 2017). Additionally, cost of goods sold from our international distributors fluctuates depending on the timing of the shipment of ILUVIEN to the distributor.

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Cost of goods sold, excluding depreciation and amortization increased by approximately $1.3 million, or 38%, to approximately $4.7 million for 2018, compared to approximately $3.4 million for 2017. The increase was primarily attributable to our increased sales volume and an increase of approximately $380,000 in royalty expense payable to EyePoint in 2018 compared to profit share and royalty expenses payable to EyePoint in 2017.

Gross profit increased by approximately $9.8 million, or 30%, to approximately $42.3 million for 2018, compared to approximately $32.5 million for 2017. Gross margin was 90% for both years. 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 includes salaries and related expenses for research and development and medical affairs personnel, including medical sales liaisons, 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. Until we reach profitability, if at all, we do not expect to change the focus of these activities. We expense both internal and external development costs as they are incurred.

Research, development and medical affairs expenses decreased by approximately $1.5 million, or 12%, to approximately $11.3 million for 2018, compared to approximately $12.8 million for 2017. The decrease was primarily attributable to a $2.9 million non-cash charge during 2017 for in-process research and development expense for the additional rights to uveitis acquired from EyePoint; we had no such expense in 2018. This decrease was partially offset by increases of approximately $510,000 in costs associated with ongoing clinical studies, $490,000 in personnel costs and $180,000 in scientific communication costs.

General and Administrative Expenses

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

General and administrative expenses increased by approximately $1.5 million, or 12%, to approximately $14.5 million for 2018, compared to approximately $13.0 million for 2017. The increase was primarily attributable to increases of approximately $600,000 for one-time non-cash accrued severance expenses due to the transition of our previous chief executive officer to a consulting role, $310,000 in audit and legal fees, and $250,000 of state franchise taxes.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of professional 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 market reimbursement for and the execution of launch plans for ILUVIEN. 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 increased by approximately $300,000, or 1%, to approximately $23.5 million for 2018, compared to approximately $23.2 million for 2017. The increase was primarily attributable to increased personnel costs.

Recoverable Collaboration Costs

See “Other Segment” below for a discussion of this line item.

Operating Expenses

As a result of the changes in expenses described above, total operating expenses increased by approximately $3.1 million, or 6%, to approximately $52.0 million for 2018, compared to approximately $48.9 million for 2017. The increase was primarily attributable to an increase of approximately $1.5 million in general and administrative expenses and the increases in research, development and medical affairs expenses described above.

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Interest Expense and Other

For 2017, interest expense consisted primarily of interest and amortization of deferred financing costs and debt discounts associated with the Hercules Loan Agreement. As described in Overview above, we entered into a new loan facility with Solar Capital on January 5, 2018 and refinanced the Hercules Loan with the proceeds. For 2018, interest expense consisted of interest and amortization of deferred financing costs and debt discounts associated with the Solar Capital Loan. Interest income consisted primarily of interest earned on our cash, cash equivalents and investments.

Interest expense and other. Interest expense and other decreased by approximately $800,000, or 14%, to approximately $4.8 million for 2018, compared to approximately $5.6 million for 2017. The decrease was primarily attributable to the lower effective interest rate on the Solar Capital Loan compared to the effective interest rate on the Hercules Loan.

Loss on early extinguishment of debt

We recorded a loss on early extinguishment of debt of approximately $1.8 million for 2018 as a result of refinancing the Hercules Loan by entering into the 2018 Loan Agreement on January 5, 2018.

Change in Fair Value of Derivative Warrant Liability

Warrants to purchase our Series A Convertible Preferred Stock or common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC), are classified as liabilities. We record these derivative financial instruments as liabilities in our balance sheet measured at their fair value. We record the changes in fair value of such instruments as non-cash gains or losses in the consolidated statements of operations.

During 2017, we recognized a gain of approximately $188,000 related to the decrease in fair value of our derivative warrant liability. The change in fair value was primarily due to the reduction in time remaining to exercise the warrants. The right to exercise the related warrants expired on October 1, 2017.

Gain on Extinguishment of 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 the outstanding approximately 8,416 shares of Series B Preferred Stock. Under the Exchange Agreement, the holders of Series B Preferred Stock exchanged their shares of Series B Preferred Stock for an aggregate of 10,150 shares of Series C Convertible Preferred Stock, par value $0.01 per share (Series C Preferred Stock). We determined that the Exchange Agreement resulted in an extinguishment of the Series B Preferred Stock. As a result, we recognized a gain of $38,330,000 on the extinguishment of preferred stock during 2018. (See Note 12 to our notes to consolidated financial statements below.)

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

We calculated net Income (loss) per share in accordance with ASC 260, Earnings Per Share. Basic earnings per share is computed by dividing net income (loss) available to stockholders by the weighted average number of shares outstanding for the period. Diluted earnings per share 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.

We had net income available to stockholders for 2018 due to the gain on extinguishment of preferred stock. (See Note 12 to our notes to consolidated financial statements below.)

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Basic and diluted earnings per share attributable to shares of common stock and shares of preferred stock that are convertible into common stock (participating securities) are as follows:

	Years Ended December 31,	
	2018	2017
	(In thousands, except share and per share data)	
Net income (loss) available to stockholders	$21,948	$(22,001)
Allocation of undistributed earnings (loss):		
Earnings (loss) attributable to common stock	$17,459	$(22,001)
Earnings attributable to participating securities	$4,489	$—
Basic shares:		
Weighted average common shares	70,002,906	66,993,649
Weighted average participating shares	17,999,307	—
Total basic weighted average shares	88,002,206	66,993,649
Diluted shares:		
Weighted average common shares	70,002,906	66,993,649
Dilutive weighted average shares	735,580	—
Total dilutive weighted common shares	70,738,486	66,993,649
Weighted average participating shares	17,999,307	—
Total dilutive weighted average shares	88,737,786	66,993,649
Basic EPS	$0.25	$(0.33)
Diluted EPS	$0.25	$(0.33)

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 14.2 million and 31.7 million for 2018 and 2017, respectively.

Potentially dilutive common stock equivalents are excluded from the diluted earnings per share denominator for periods of net loss because of their anti-dilutive effect. Therefore, for 2017, the weighted average shares used to calculate both basic and diluted loss per share were the same.

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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 allocate certain operating expenses between 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 2018 or 2017.

U.S. Segment

	Years Ended December 31,	
	2018	2017
	(In thousands)	
NET REVENUE	$32,337	$26,146
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(3,246)	(2,482)
GROSS PROFIT	29,091	23,664
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	6,457	5,780
GENERAL AND ADMINISTRATIVE EXPENSES	8,147	7,580
SALES AND MARKETING EXPENSES	16,569	16,588
OPERATING EXPENSES	31,173	29,948
SEGMENT LOSS FROM OPERATIONS	$(2,082)	$(6,284)

U.S. Segment - Year ended December 31, 2018 compared to year ended December 31, 2017

Net Revenue. Net revenue increased by approximately $6.2 million, or 24%, to approximately $32.3 million for 2018, compared to approximately $26.1 million for 2017. The increase was primarily attributable to a 16% increase in end user demand.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $700,000, or 28%, to approximately $3.2 million for 2018 compared to approximately $2.5 million for 2017. The increase was primarily attributable to our increased sales volume.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately $700,000, or 12%, to approximately $6.5 million for 2018, compared to approximately $5.8 million for 2017. The increase was primarily attributable to increased costs associated with ongoing clinical studies.

General and administrative expenses. General and administrative expenses increased by approximately $500,000, or 7%, to approximately $8.1 million for 2018, compared to approximately $7.6 million for 2017. The increase was primarily attributable to increases of $270,000 in audit and legal fees, and $250,000 of state franchise taxes.

Sales and marketing expenses. Sales and marketing expenses were approximately $16.6 million for both 2018 and 2017.

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International Segment

	Years Ended December 31,	
	2018	2017
	(In thousands)	
NET REVENUE	$14,633	$9,766
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(1,433)	(956)
GROSS PROFIT	13,200	8,810
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	3,946	3,314
GENERAL AND ADMINISTRATIVE EXPENSES	3,259	2,605
SALES AND MARKETING EXPENSES	5,910	5,394
OPERATING EXPENSES	13,115	11,313
SEGMENT INCOME (LOSS) FROM OPERATIONS	$85	$(2,503)

International Segment - Year ended December 31, 2018 compared to year ended December 31, 2017

Net Revenue. Net revenue increased by approximately $4.8 million, or 49%, to approximately $14.6 million for 2018, compared to approximately $9.8 million for 2017. The increase was primarily attributable to increased sales volume in both the markets where we sell direct and the markets where we sell to distributors.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $440,000, or 46%, to approximately $1.4 million for 2018, compared to approximately $960,000 for 2017. The increase was primarily attributable to our increased sales volume.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately $600,000, or 18%, to approximately $3.9 million for 2018, compared to approximately $3.3 million for 2017. The increase was primarily attributable to increases of approximately $370,000 in personnel costs and $180,000 in scientific communication costs.

General and administrative expenses. General and administrative expenses increased by approximately $700,000, or 27%, to approximately $3.3 million for 2018, compared to approximately $2.6 million for 2017. The increase was primarily attributable to increased personnel costs.

Sales and marketing expenses. Sales and marketing expenses increased by approximately $500,000, or 9%, to approximately $5.9 million for 2018, compared to approximately $5.4 million for 2017. The increase was primarily attributable to increases of approximately $310,000 in marketing costs and $290,000 in personnel costs.

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Other Segment

	Years Ended December 31,	
	2018	2017
	(In thousands)	
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	$871	$3,750
GENERAL AND ADMINISTRATIVE EXPENSES	3,119	2,854
SALES AND MARKETING EXPENSES	1,038	1,228
DEPRECIATION AND AMORTIZATION	2,645	2,684
RECOVERABLE COLLABORATION COSTS	—	(2,851)
OPERATING EXPENSES	7,673	7,665
SEGMENT LOSS FROM OPERATIONS	$(7,673)	$(7,665)

Our chief operating decision maker manages and evaluates our U.S. and International segments based on net 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 the Other segment within our Consolidated Financial Statements.

Within the respective financial statement line items included in the Other segment, stock-based compensation expense, collectively, decreased by approximately $600,000, or 12%, to $4.4 million for 2018, compared to $5.0 million for 2017. Additionally, within general and administrative expenses we had an increase of approximately $600,000 of one-time non-cash accrued severance expenses due to the transition of our previous chief executive officer to a consulting role.

Depreciation and amortization decreased by approximately $100,000, or 4%, to approximately $2.6 million for 2018, compared to approximately $2.7 million for 2017.

In July 2017, we acquired the license rights to uveitis from EyePoint for Europe, the Middle East and Africa and restructured our collaboration agreement. The New Collaboration Agreement included a conversion of our obligation to share profits from the commercialization of ILUVIEN to a royalty on net revenue. As consideration for the uveitis rights and the profit share conversion, we agreed to reduce our right to utilize EyePoint’s share of previous losses associated with the commercialization of ILUVIEN that could have been used to partially offset future profit sharing payments under the prior collaboration agreement. This right of offset was previously fully reserved on our financial statements due to the uncertainty of future realizability. We valued the transaction utilizing a present value analysis at approximately $2.9 million. Because there was no approved indication for ILUVIEN for uveitis at the time, we expensed the $2.9 million as a non-cash charge as in-process Research and Development Expense during 2017. We also recognized a Recovery of Prior Collaboration Costs of $2.9 million for the value of the right of offset as a reduction of operating expenses in the same period. As a result, there was no impact on our operating loss or net loss for 2017.

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Liquidity and Capital Resources

Since inception, we have incurred recurring losses, negative cash flow from operations and have accumulated a deficit of $377.1 million through December 31, 2018. We have funded our operations through the public and private placement of common stock, convertible preferred stock, warrants, the sale of certain assets of the non-prescription business in which we were previously engaged and certain debt facilities.

In September 2014, we entered into a sales agreement with Cowen and Company, LLC (Cowen) to offer shares of our common stock from time to time through Cowen, as our sales agent for the offer and sale of the shares up to an aggregate offering price of $35.0 million. We paid a commission equal to 3% of the gross proceeds from the sales of shares of our common stock under the sales agreement. During 2017, we sold 4,203,015 shares of our common stock at a weighted average price of $1.43 per share through an at-the-market offering, for total gross proceeds of approximately $6.0 million, reduced by approximately $180,000 of related commissions, issuance costs and placement agent fees. We used the net proceeds from this offering for general corporate purposes and working capital. Our sales agreement with Cowen to sell additional shares expired on August 13, 2017.

On January 5, 2018, we entered into the $40.0 million 2018 Loan Agreement with Solar Capital. Under the 2018 Loan Agreement, we borrowed the entire $40.0 million as a term loan that matures on July 1, 2022.We used the proceeds of the 2018 Loan Agreement to refinance the then existing Hercules Loan and for related expenses. We expect to use the remaining proceeds of the Solar Capital Loan to provide additional working capital for general corporate purposes. (See Note 10 of our notes to consolidated financial statements below.)

As of December 31, 2018, we had approximately $13.0 million in cash and cash equivalents. We commercially market ILUVIEN in the U.S., Germany, the United Kingdom, Portugal, Austria and Ireland. We began selling ILUVIEN in Austria and Ireland in 2017. We may have to raise additional capital to fund the continued commercialization of ILUVIEN. If we are unable to raise additional financing, we will need to adjust our commercial plans so that we can continue to operate with our existing cash resources. The actual amount of funds that we will need will depend on many factors, some of which are beyond our control. We may need funds sooner than currently anticipated.

We cannot be sure that additional financing will be available when needed or that, if available, the additional financing would be obtained on terms favorable 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 may have a preference over our common stock. If we were to attempt to raise additional funds through strategic collaboration agreements we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. 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 commercialize ILUVIEN or any future products or product candidates or operate our business; 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 2018, net cash used in our operations of $11.6 million was primarily due to our net loss of $16.4 million, which is subject to further adjustment for non-cash items. These items included charges of approximately $4.4 million for stock compensation expense, $2.6 million of depreciation and amortization expense, a $1.8 million charge for the loss on early extinguishment of debt and $840,000 of amortization costs associated with our debt discount. Further reducing cash from operations was a $6.0 million increase in accounts receivable which was driven by increased revenue and a $930,000 increase in inventory. This reduction was offset by a $1.4 million increase in accounts payable and accrued expenses and other current liabilities.

For 2017, net cash used in our operations of $12.9 million was primarily due to our net loss of $22.0 million, which is subject to further adjustment for non-cash items. These items included charges of approximately $5.0 million for stock compensation expense, $2.7 million of depreciation and amortization expense and $1.4 million of amortization costs associated with our debt discount. Further reducing cash from operations was a $1.1 million increase in inventory. This reduction was offset by a $2.6 million decrease in accounts receivable.

For 2018, net cash used in our investing activities was approximately $175,000, which was primarily due to the purchase of equipment and software.

For 2017, net cash used in our investing activities was approximately $240,000, which was primarily due to the purchase of manufacturing equipment and software.

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For 2018, net cash provided by our financing activities was approximately $950,000, which was primarily due to entering into the $40.0 million 2018 Loan Agreement with Solar Capital, offset by paying off the $35.0 million Hercules Loan and related debt costs of $3.7 million.

For 2017, net cash provided by our financing activities was approximately $5.7 million. In the second and third quarters of 2017, we sold a total of 4,203,015 shares of our common stock through our at-the-market offering, resulting in total gross proceeds of approximately $6.0 million, prior to the payment of $180,000 of related commissions, issuance costs and placement agent fees.

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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 aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of 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, 2018 and 2017, we had received a total of $1.0 million and $500,000, respectively of payments that have not been 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 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, we may adjust these estimates, which could have an effect on earnings in the period of adjustment.

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

Our 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. We may either refund the sales price paid by the Customer by issuance of a credit, or exchange the returned product with replacement inventory. We typically do not provide cash refunds. We estimate 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.

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The estimation process for product returns involves, in each case, a number of interrelating assumptions, which vary for each Customer. We estimate the amount of our product sales that may be returned by our Customers and record 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

We enter into agreements in which we license certain rights to our products to partner companies that act as distributors. The terms of these arrangements may include payment to us of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services we provide; 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, we 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 we recognize revenue when, or as, performance obligations are satisfied. We use 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, we evaluate the recognition of milestone payments. Typically, milestone payments are associated with events that are not entirely within our control 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, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price.

Customer Payment Obligations

We receive payments from our Customers based on billing schedules established in each contract, which vary across locations, but generally range between 30 to 120 days. Occasionally, the timing of receipt of payment for our international Customers can be extended. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation is that our Customer will pay for the product or services within one year or less of receiving those products or services.

Additional Critical Accounting Policies and Estimates

Research and Development Costs

Research and development expenditures are expensed as incurred, pursuant to ASC 730, Research and Development. Costs to license technology to be used in our research and development that have not reached technological feasibility, defined as regulatory approval for ILUVIEN or any future products or product candidates, and have no alternative future use are expensed when incurred. Payments to licensors that relate to the achievement of preapproval development milestones are recorded as research and development expense when incurred.

Clinical Trial Prepaid and Accrued Expenses

We record prepaid assets and accrued liabilities related to clinical trials associated with contract research organizations (CROs), clinical trial investigators and other vendors based upon amounts paid and the estimated amount of work completed on each clinical trial. The financial terms of agreements vary from vendor to vendor and may result in uneven payment flows. As such, if we have advanced funds exceeding our estimate of the work completed, we record a prepaid asset. If our estimate of the work completed exceeds the amount paid, an accrued liability is recorded. All such costs are charged to research and development expenses based on these estimates. Our estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and discussions with our CROs and review of contractual terms. However, if we have incomplete or inaccurate information, we may underestimate or overestimate activity levels

associated with various clinical trials at a given point in time. In this event, we could record significant research and development expenses in future periods when the actual level of activities becomes known. To date, we have not experienced material changes in these estimates. Additionally, we do not expect material adjustments to research and development expenses to result from changes in the nature and level of clinical trial activity and related expenses that are currently subject to estimation. In the future, as we expand our clinical trial activities, we expect to have increased levels of research and development costs that will be subject to estimation.

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Stock-Based Compensation

We have stock-based compensation under which various types of equity-based awards may be granted, including restricted stock units (RSUs) and stock options, to employees, directors and consultants or other service providers. The exercise prices of stock options generally equal the fair values of our common stock at the dates of grant. We recognize compensation cost for all stock-based awards based on the grant date fair value in accordance with the provisions of ASC 718, Compensation — Stock Compensation. We recognize the grant date fair value as compensation cost of employee stock-based awards using the straight-line method over the actual vesting period, adjusted for our estimates of forfeiture. Typically, we grant stock options with a requisite service period of four years from the grant date. We have elected to use the Black-Scholes option pricing model to determine the fair value of stock-based awards.

We concluded that this was the most appropriate method by which to value our share-based payment arrangements, but if any share-based payment instruments should be granted for which the Black-Scholes method does not meet the measurement objective as stated within ASC 718, we will use a more appropriate method for valuing that instrument. However, we do not believe that any instruments granted to date and accounted for under ASC 718 would require a method other than the Black-Scholes method.

Our determination of the fair market value of share-based payment awards on the grant date using option valuation models requires the input of highly subjective assumptions, including the expected price volatility and option life. 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 our common stock over the expected term of the stock option grant. To estimate the expected term, we use the “simplified” method for “plain vanilla” options as discussed within the SEC’s Statement of Accounting Bulletin (SAB) 107. We believe that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method are true for us and for our share-based payment arrangements. We intend to use 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.

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, 2018, we had federal NOL carry-forwards of approximately $122.5 million and state NOL carry-forwards of approximately $153.3 million, respectively, subject to further limitation based upon the final results of our Internal Revenue Code (IRC) sections 382 and 383 analyses. These NOLs are available to reduce future income otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2029 and 2037, our federal NOL created in 2018 will carry forward indefinitely and the state NOL carry-forwards will expire at various dates between 2020 and 2038.

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 IRC Section 382 (Section 382) (or comparable provisions of state law) in the event that 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 it is determined that significant ownership changes have occurred since we generated our NOL carry-forwards, it 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.

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If we were to determine that we are able to realize any of our net deferred tax assets in the future, an adjustment to the valuation allowance would 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, 2018 and December 31, 2017 are approximately $68,000 and $52,000, 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.

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 our subsidiaries operating outside of the U.S.

Our 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.

The financial statements of the foreign subsidiaries whose functional currency is not the U.S. dollar have been translated into U.S. Dollars in accordance with ASC 830-30, Translation of Financial Statements. For the subsidiaries operating outside of the U.S. that are denominated in the Euro, assets and liabilities are translated at end-of-period rates while revenues and expenses are translated at average rates in effect during the period in which the activity took place. Equity is translated at historical rates and the resulting cumulative translation adjustments are included as a component of accumulated other comprehensive income.

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.

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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 69 and are incorporated herein.

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

None.

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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, 2018.

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, 2018, 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, 2018.

The independent registered public accounting firm of Grant Thornton LLP, as auditor of the consolidated balance sheets of Alimera Sciences Inc. and its subsidiaries as of December 31, 2018 and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for 2018, has issued an attestation report on our internal control over financial reporting, which is included on page 62.

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 2018 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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Alimera Sciences, Inc.
Opinion on internal control over financial reporting
We have audited the internal control over financial reporting of Alimera Sciences, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2018, based on criteria established in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in the 2013 Internal Control—Integrated Framework issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated financial statements of the Company as of and for the year ended December 31, 2018, and our report dated February 25, 2019 expressed an unqualified opinion on those financial statements.

Basis for opinion
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Controls over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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Definition and limitations of internal control over financial reporting
A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ GRANT THORNTON LLP
Atlanta, GA
February 25, 2019

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ITEM 9B. OTHER INFORMATION
None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item regarding our directors, including the audit committee and audit committee financial experts, our executive officers, our corporate governance, our code of conduct and compliance with Section 16(a) of the Exchange Act will be included in our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of fiscal year ended December 31, 2018 (2019 Proxy Statement) and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation will be included in our 2019 Proxy Statement and is incorporated herein by reference.

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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 included in our 2019 Proxy Statement and is incorporated herein by reference.

Equity Compensation Plan Information

The following table provides information as of December 31, 2018, with respect to shares of our common stock that may be issued, subject to certain vesting requirements, under our existing equity compensation plans, including our 2010 Equity Incentive Plan (2010 Plan), 2005 Equity Incentive Plan (2005 Plan), 2004 Equity Incentive Plan (2004 Plan) and 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	13,347,607	(1)	$ 2.63	(2)	666,271	(3)
Equity compensation plans not approved by security holders	—		—		—	
Total	13,347,607		$ 2.63		666,271	

(1) Of these shares, 12,241,009 were subject to options then outstanding under the 2010 Plan, 154,058 were subject to options then outstanding under the 2005 Plan, 52,288 were subject to options then outstanding under the 2004 Plan and 900,252 were outstanding restricted stock units then outstanding under the 2010 Plan.

(2) The weighted-average exercise price does not take into account restricted stock units, which do not have an exercise price.

(3) Represents 263,498 shares of common stock available for issuance under our 2010 Plan and 402,773 shares of common stock available for issuance under our ESPP. No shares are available for future issuance under the 2005 Plan or 2004 Plan. In addition, our 2010 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year equal to the least of: (1) 2,000,000 shares of our common stock; (2) 4% of the shares of common stock outstanding at that time; and (3) such other amount as our board of directors may determine. On January 1, 2019, an additional 2,000,000 shares became available for future issuance under our 2010 Plan in accordance with the annual increase. 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 494,422 shares of our common stock. As such, on January 1, 2019, an additional 91,649 shares became available for future issuance under our ESPP. These additional shares from the annual increase under the 2010 Plan and the ESPP are not included in the table above.

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

The information required by this item regarding certain relationships and related transactions and director independence will be included in our 2019 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item regarding principal accounting fees and services will be included in our 2019 Proxy Statement and is incorporated herein by reference.

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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

Not applicable.

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ALIMERA SCIENCES, INC.
INDEX TO FINANCIAL STATEMENTS

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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, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated February 25, 2019 expressed an unqualified opinion.

Going concern
The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 4 to the consolidated financial statements, the Company has incurred recurring losses, negative cash flows from operations, and has an accumulated deficit of $377,127,000 as of December 31, 2018. These conditions, along with the other matters as set forth in Note 4, 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 4. 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 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.

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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. 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 supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

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

Atlanta, Georgia
February 25, 2019

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ALIMERA SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS
AS OF DECEMBER 31, 2018 AND 2017

	December 31, 2018	2017
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,043	$ 24,067
Restricted cash	32	34
Accounts receivable, net	17,259	11,435
Prepaid expenses and other current assets	2,109	2,278
Inventory (Note 5)	2,405	1,508
Total current assets	34,848	39,322
NON-CURRENT ASSETS:		
Property and equipment, net	1,355	1,410
Intangible asset, net	16,723	18,664
Deferred tax asset	1,182	528
TOTAL ASSETS	$ 54,108	$ 59,924
CURRENT LIABILITIES:		
Accounts payable	$ 6,355	$ 5,905
Accrued expenses (Note 8)	3,643	3,582
Capital lease obligations	236	184
Total current liabilities	10,234	9,671
NON-CURRENT LIABILITIES:		
Note payable (Note 10)	37,873	34,365
Capital lease obligations — less current portion	305	203
Other non-current liabilities	2,974	766
COMMITMENTS AND CONTINGENCIES (Note 11)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $.01 par value — 10,000,000 shares authorized at December 31, 2018 and 2017:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 600,000 issued and outstanding at December 31, 2018 and 2017; liquidation preference of $24,000 at December 31, 2018 and 2017	19,227	19,227
Series B Convertible Preferred Stock, 0 authorized and outstanding at December 31, 2018; 8,417 authorized and 8,416.251 issued and outstanding at December 31, 2017; liquidation preference of $0 and $50,750 at December 31, 2018 and 2017, respectively	—	49,568
Series C Convertible Preferred Stock, 10,150 authorized issued and outstanding at December 31, 2018; 0 authorized and outstanding at December 31, 2017; liquidation preference of $10,150 and $0 at December 31, 2018 and 2017, respectively	11,117	—
Common stock, $.01 par value — 150,000,000 shares authorized, 70,078,878 shares issued and outstanding at December 31, 2018 and 69,146,381 shares issued and outstanding at December 31, 2017	701	691
Additional paid-in capital	346,108	341,622
Common stock warrants	3,707	3,707
Accumulated deficit	(377,127)	(399,075)
Accumulated other comprehensive loss — foreign currency translation adjustments	(1,011)	(821)

TOTAL STOCKHOLDERS' EQUITY	2,722	14,919
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 54,108	$ 59,924

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

	Years Ended December 31,	
	2018	2017
	(In thousands, except share and per share data)	
NET REVENUE	$46,970	$35,912
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(4,679)	(3,438)
GROSS PROFIT	42,291	32,474
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	11,274	12,844
GENERAL AND ADMINISTRATIVE EXPENSES	14,525	13,039
SALES AND MARKETING EXPENSES	23,517	23,210
DEPRECIATION AND AMORTIZATION	2,645	2,684
RECOVERABLE COLLABORATION COSTS	—	(2,851)
OPERATING EXPENSES	51,961	48,926
NET LOSS FROM OPERATIONS	(9,670)	(16,452)
INTEREST EXPENSE AND OTHER	(4,775)	(5,579)
UNREALIZED FOREIGN CURRENCY (LOSS) GAIN, NET	(65)	5
LOSS ON EARLY EXTINGUISHMENT OF DEBT	(1,766)	—
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	—	188
NET LOSS BEFORE TAXES	(16,276)	(21,838)
PROVISION FOR TAXES	(106)	(163)
NET LOSS	(16,382)	(22,001)
GAIN ON EXTINGUISHMENT OF PREFERRED STOCK	38,330	$—
NET INCOME (LOSS) AVAILABLE TO STOCKHOLDERS	$21,948	$(22,001)
NET INCOME (LOSS) PER SHARE — Basic	$0.25	$(0.33)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic	88,002,208	66,993,649
NET INCOME (LOSS) PER SHARE — Diluted	$0.25	$(0.33)
WEIGHTED AVERAGE SHARES OUTSTANDING — Diluted	88,737,788	66,993,649

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

	Years Ended December 31,	
	2018	2017
	(In thousands)	
NET LOSS	$(16,382)	$(22,001)
OTHER COMPREHENSIVE (LOSS) INCOME		
Foreign currency translation adjustments	(190)	451
TOTAL OTHER COMPREHENSIVE (LOSS) INCOME	(190)	451
COMPREHENSIVE LOSS	$(16,572)	$(21,550)

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

	Common Stock		Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional Paid-In Capital	Common Stock Warrants	Accumulated Deficit	Accum Other Compr Loss
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
	(In thousands, except share data)											
BALANCE — December 31, 2016	64,862,904	$649	600,000	$19,227	8,416	$49,568	—	$—	$330,781	$3,707	$(377,074)	$(1,272
Issuance of common stock, net of issuance costs	4,282,748	42	—	—	—	—	—	—	5,859	—	—	—
Exercise of stock options	729	—	—	—	—	—	—	—	1	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	4,981	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(22,001)	—
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	—	—	451
BALANCE — December 31, 2017	69,146,381	$691	600,000	$19,227	8,416	$49,568	—	$—	$341,622	$3,707	$(399,075)	$(821
Issuance of common stock, net of issuance costs	930,934	10	—	—	—	—	—	—	73	—	—	—
Exercise of stock options	1,563	—	—	—	—	—	—	—	2	—	—	—
Preferred stock exchange, net of transaction costs (Note 12)	—	—	—	—	(8,416)	(49,568)	10,150	11,117	—	—	38,330	—
Stock-based compensation	—	—	—	—	—	—	—	—	4,411	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(16,382)	—
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	—	—	(190
BALANCE — December 31, 2018	70,078,878	$701	600,000	$19,227	—	$—	10,150	$11,117	$346,108	$3,707	$(377,127)	$(1,01

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

	Years Ended December 31,	
	2018	2017
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(16,382)	$(22,001)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,645	2,684
Unrealized foreign currency transaction loss	65	(5)
Amortization of debt discount	842	1,416
Deferred taxes (benefit)	(653)	(92)
Loss on early extinguishment of debt	1,766	—
Stock compensation expense	4,411	4,981
Change in fair value of derivative warrant liability	—	(188)
Changes in assets and liabilities:		
Accounts receivable	(5,995)	2,610
Prepaid expenses and other current assets	129	(67)
Inventory	(933)	(1,018)
Accounts payable	556	644
Accrued expenses and other current liabilities	1,547	(271)
Other long-term liabilities	449	(1,567)
Net cash used in operating activities	(11,553)	(12,874)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(175)	(238)
Net cash used in investing activities	(175)	(238)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	2	1
Proceeds from sale of common stock	83	6,084
Payment of issuance cost of common stock	—	(183)
Issuance of debt	40,000	—
Payment of principal on notes payable	(35,000)	
Payment of extinguishment of debt costs	(2,544)	—
Payment of deferred financing costs	(1,142)	—
Payment of preferred stock exchange costs	(122)	—
Payments on capital lease obligations	(327)	(182)
Net cash provided by financing activities	950	5,720
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(248)	483
NET DECREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(11,026)	(6,909)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH — Beginning of year	24,101	31,010
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH — End of year	$13,075	$24,101
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$3,571	$4,117
Cash paid for income taxes	$239	$74
Supplemental schedule of noncash investing and financing activities:		

Property and equipment acquired under capital leases	$575	$282

The Company paid no dividends during the years ended December 31, 2018 and 2017.
See Notes to Consolidated Financial Statements.

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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, research and development of ophthalmic pharmaceuticals. The Company was formed on June 4, 2003 under the laws of the State of Delaware.

The Company is presently focused on diseases affecting the back of the eye, or retina, because the Company's management believes these diseases are not well treated with current therapies and represent a significant market opportunity. The Company's only commercial product is ILUVIEN®, which has received marketing authorization in the United States (U.S.), Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Lebanon, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, the United Arab Emirates and the United Kingdom. In the U.S., Canada, Lebanon and the United Arab Emirates, ILUVIEN is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP). In the European Economic Area (EEA) countries in which ILUVIEN has received marketing authorization, it is indicated for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies.

As part of the approval process in Europe, the Company committed to conduct a five-year, post-authorization, open label registry study in 800 patients treated with ILUVIEN. Due to its post market safety surveillance not showing any unexpected safety signals, the Company requested and received approval to modify its protocol to cap enrollment in the study. Enrollment was completed with 562 patients enrolled in this study. The Company anticipates this study to be completed in early 2020.

The Company commercially markets ILUVIEN in the U.S., Germany, the United Kingdom, Portugal, Austria and Ireland.

In addition, the Company has entered into various agreements under which distributors provide or will provide regulatory, reimbursement or sales and marketing support for ILUVIEN in France, Italy, Spain, Australia, New Zealand, Canada and several countries in the Middle East. In 2016, the Company's Middle East distributor launched ILUVIEN and initiated named patient sales in the United Arab Emirates. The Company's Italian distributor launched ILUVIEN in Italy in 2017. The Company's Spanish distributor began selling on a named patient basis in 2017 and is currently pursuing reimbursement at the national level. The Company's French and Canadian distributors are currently pursuing reimbursement in their respective countries. As of December 31, 2018, the Company has recognized sales of ILUVIEN to the Company's international distributors in the Middle East, France, Italy and Spain.

In July 2017, the Company amended its license with EyePoint Pharmaceuticals US, Inc. (EyePoint), formerly known as pSivida US, Inc., for the technology underlying ILUVIEN to include the treatment of uveitis, including non-infectious posterior uveitis (NIPU) in Europe, the Middle East and Africa (Note 9). 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. In December 2017, the Company filed an application for a new indication for ILUVIEN for NIPU in the 17 EEA countries where ILUVIEN is currently approved for the treatment of DME. The regulatory authorities requested additional follow-up data from the clinical trials to support the application. The Company submitted this additional follow-up data in October 2018. The Company expects to obtain approval of its application for NIPU in the first half of 2019, although the Company can provide no assurances that it can do so.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates in Financial Statements

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

Principles of Consolidation

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

Cash, Cash Equivalents and Restricted Cash

Cash equivalents include highly liquid investments that are readily convertible into cash and have a maturity of 90 days or less when purchased. Generally, cash and cash equivalents held at financial institutions are in excess of federally insured limits. Cash and cash equivalents were $13,043,000 and $24,067,000 as of December 31, 2018 and 2017, respectively, with approximately 82.0% and 93.0% 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, 2018 and 2017, 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 7).

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.

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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.

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 $1,096,000 and $4,216,000 for 2018 and 2017, respectively. During 2017, the Company expensed $2,851,000 of in-process Research and Development Expense in connection with the New Collaboration Agreement (see Note 9).

Stock-Based Compensation

The Company has stock-based compensation plans under which various types of equity-based awards are granted, including restricted stock units (RSUs) and stock options. The fair values of 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.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Derivative Financial Instruments

The Company generally does not use derivative instruments to hedge exposures to cash flow or market risks. However, certain warrants to purchase Series A Convertible Preferred Stock or common stock that did not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the ASC, were classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. These warrants were considered derivative instruments at issuance because the warrant agreements (a) provided for settlement in Series A Convertible Preferred Shares or common shares at the option of the holder; (b) provided for future adjustment to the warrant exercise price for common shares; and (c) contained anti-dilution provisions whereby the number of shares for which the warrants were exercisable and/or the exercise price of the warrants were subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. Because the rights to exercise these warrants expired on October 1, 2017, the warrant exercise price no longer can be adjusted. The primary underlying risk exposure pertaining to the warrants was the change in fair value of the underlying common stock.

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 for the warrants considered to be derivative instruments.

Foreign Currency Translation

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 earnings of these subsidiaries are translated into U.S. dollars using average exchange rates.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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. Basic EPS is computed by dividing net income (loss) 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.

The Company had net income available to stockholders for 2018 due to the gain on extinguishment of preferred stock (Note 12).

Basic and diluted earnings per share attributable to common and participating shares of common stock for 2018 and 2017 were as follows:

	Years Ended December 31,	
	2018	2017
	(In thousands, except share and per share data)	
Net income (loss) available to stockholders	$21,948	$(22,001)
Allocation of undistributed earnings (loss):		
Earnings (loss) attributable to common stock	$17,459	$(22,001)
Earnings attributable to participating securities	$4,489	$—
Basic shares:		
Weighted average common shares	70,002,906	66,993,649
Weighted average participating shares	17,999,307	—
Total basic weighted average shares	88,002,206	66,993,649
Diluted shares:		
Weighted average common shares	70,002,906	66,993,649
Dilutive weighted average shares	735,580	—
Total dilutive weighted common shares	70,738,486	66,993,649
Weighted average participating shares	17,999,307	—
Total dilutive weighted average shares	88,737,786	66,993,649
Basic EPS	$0.25	$(0.33)
Diluted EPS	$0.25	$(0.33)

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,	
	2018	2017
Series A convertible preferred stock	—	9,022,556
Series B convertible preferred stock	—	8,416,251
Common stock warrants	1,795,663	1,795,663

Stock options	12,447,355	11,595,510
Restricted stock units	—	839,285
Total	14,243,018	31,669,265

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 net loss from operations adjusted for certain non-cash items, such as stock-based compensation expense and depreciation and amortization. The Company does not report balance sheet information by segment because it is not reviewed by the Company's chief operating decision maker. The Company has three reportable segments, U.S., International and Other. See Note 18.

Adoption of New Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (Topic 606), which amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB subsequently issued an additional, clarifying ASU to address issues arising from implementation of the new revenue recognition standard, which became effective for interim and annual periods beginning on January 1, 2018. The new standard was required to be adopted using either a full-retrospective or a modified-retrospective approach. The Company adopted the new revenue guidance on January 1, 2018 using the modified-retrospective approach. The Company elected the practical expedient to apply the new revenue standard only to contracts that were not completed as of January 1, 2018.

Adoption did not have a material impact on the Company's financial statements on an ongoing basis. See Note 3 for additional information regarding the Company's revenues and how the company accounts for revenue.

In August 2016, the FASB issued ASU 2016-15, Classification of Certain Cash Receipts and Cash Payments (Topic 230). ASU 2016-15 is intended to add or clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows and to eliminate the diversity in practice related to such classifications. The standard is effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018, and the adoption of this guidance did not have a material impact on the Company's financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230) - Restricted Cash. ASU 2016-18 requires a statement of cash flows to explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The standard is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018, and the adoption of this guidance did not have a material impact on the Company's financial statements. The Company's condensed consolidated statement of cash flows for the year ended December 31, 2017 has been reclassified for this ASU.

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope Modification Accounting. The new standard clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. This standard became effective on January 1, 2018, and the Company adopted it on that date. The adoption of this guidance did not have a material impact on the Company's financial statements.

Accounting Standards Issued but Not Yet Effective

In February 2016, the FASB issued ASU 2016-02, Leases (ASC 842), to increase transparency and comparability among organizations for lease recognition and disclosure. ASU 2016-02 requires lessees to recognize lease assets and lease liabilities on the balance sheet, while recognizing expenses on the income statements in a manner similar to current guidance. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. The Company did not early adopt this standard and therefore the standard will be effective for the Company in the first quarter of 2019. ASU 2016-02 requires that leases

be recognized and measured as of the earliest period presented, using a modified retrospective approach, with all periods presented being adjusted and presented under the new standard. In July 2018, the FASB issued ASU 2018-11, Leases (ASC 842): Targeted Improvements, which provides companies an optional adoption method to ASU 2016-02 whereby a company does not have to adjust comparative period financial statements for the new standard.

The Company will adopt this ASU on January 1, 2019 and will not restate comparative periods. The Company is substantially complete with its implementation plan. The Company plans to elect the transition package of three practical expedients permitted within the standard. In accordance with the package of practical expedients, the Company will not reassess initial direct costs, lease classification, or whether its contracts contain or are leases. The Company also made an accounting policy election to not recognize right-of-use assets and liabilities for leases with a term of 12 months or less, unless the leases include options to renew or purchase the underlying asset that are reasonably certain to be exercised.

Based on the Company's lease portfolio as of December 31, 2018, the Company plans to recognize an operating lease liability and related right-of-use asset on our balance sheet of approximately $1,250,000, which represents the present value of our future minimum lease payments related to operating leases, primarily related to leases of real estate. The Company expects the deferred tax impacts of the adjustment to be nominal.

In February 2018, the FASB issued ASU 2018-02, Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, to allow reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. Upon adoption of the ASU, entities will be required to describe the accounting policy for releasing income tax effects from accumulated other comprehensive income. The standard is required to be adopted for periods beginning after December 15, 2018, with early adoption available. The Company will adopt this standard effective January 1, 2019, and the Company does not believe the adoption of this standard will have a material impact on the Company's financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This ASU replaces the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. The standard is effective for annual periods beginning after December 15, 2019, including interim periods within those annual periods, with early adoption available. The Company has implemented process controls and systems to ensure compliance with this standard. The Company is in the process of determining the effect that the adoption will have on its financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Stock-based Compensation: Improvements to Nonemployee Share-based Payment Accounting, which amends the existing accounting standards for share-based payments to nonemployees. This ASU aligns much of the guidance on measuring and classifying nonemployee awards with that of awards to employees. Under the new guidance, the measurement of nonemployee equity awards is fixed on the grant date. Entities will apply the ASU by recognizing a cumulative-effect adjustment to retained earnings as of the beginning of the annual period of adoption. The Company will adopt this standard effective January 1, 2019, and the Company does not believe the adoption of this standard will have a material impact on the Company's financial statements.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2018 and 2017, the Company had received a total of $1,000,000 and $500,000, respectively, of payments that it has not recognized as revenue based on the Company's analysis in connection with Topic 606. These deferred revenues are included as a component of other non-current liabilities on the Company's 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.

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 either refund the sales price paid by the Customer by issuance of a credit, or exchange the returned product with 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, a number of 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.

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 timing of receipt of payment for the Company’s international Customers can be extended. 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 in one year or less of receiving those products or services.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. 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 $377,127,000 from the Company's inception through December 31, 2018. As of December 31, 2018, the Company had approximately $13,043,000 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 $40,000,000 Loan and Security Agreement dated January 5, 2018 with Solar Capital Ltd. as Collateral Agent, and the parties signing the 2018 Loan Agreement from time to time as Lenders, including Solar Capital in its capacity as a Lender (see Note 10). 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.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

5. INVENTORY

Inventory consisted of the following:

	December 31,	
	2018	2017
	(In thousands)	
Component parts (1)	$ 129	$ 404
Work-in-process (2)	924	587
Finished goods	1,352	517
Total inventory	2,405	1,508

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

6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31,	
	2018	2017
	(In thousands)	
Furniture and fixtures	$392	$392
Office equipment	869	864
Automobiles	870	663
Software	1,275	1,122
Leasehold improvements	474	482
Manufacturing equipment	1,087	1,088
Total property and equipment	4,967	4,611
Less accumulated depreciation and amortization	(3,612)	(3,201)
Property and equipment — net	$1,355	$1,410

Depreciation and amortization expense associated with property and equipment totaled $705,000 and $744,000 for the years ended December 31, 2018 and 2017, respectively.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

7. INTANGIBLE ASSET

As a result of the U.S. Food and Drug Administration's (FDA) approval of ILUVIEN in September 2014, the Company was required to pay EyePoint a milestone payment of $25,000,000 (the EyePoint Milestone Payment) in October 2014 (see Note 9).

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 $16,723,000 and $18,664,000 as of December 31, 2018 and 2017, respectively, and amortization expense was $1,940,000 for both the years ended December 31, 2018 and 2017, respectively.

The estimated remaining amortization as of December 31, 2018 is as follows (in thousands):

Years Ending December 31	
2019	$1,940
2020	1,946
2021	1,940
2022	1,940
2023	1,940
Thereafter	7,017
Total	$16,723

8. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2018	2017
	(In thousands)	
Accrued clinical investigator expenses	$781	$696
Accrued compensation expenses	1,427	511
Accrued rebate, chargeback and other revenue reserves	346	305
Accrued End of Term Payment (see Note 10)	—	1,400
Other accrued expenses	1,089	670
Total accrued expenses	$3,643	$3,582

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

9. LICENSE AGREEMENTS

EyePoint Agreement

In February 2005, the Company entered into an agreement with EyePoint (formerly known as pSivida US, Inc.) 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.

2008 Amended and Restated Collaboration Agreement

Pursuant to the payment terms of the 2008 Amended and Restated Agreement (the 2008 Agreement), the Company was required to share with EyePoint 20% of the net profits of ILUVIEN, determined on a cash basis, and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN. In connection with this Agreement, the Company was entitled to recover out of EyePoint's share of the net profits of ILUVIEN, 20% of ILUVIEN's commercialization costs (as defined in the EyePoint Agreement) that were incurred prior to product profitability. (The Company's future rights to recover these amounts from EyePoint are referred to as the Future Offset.) In connection with the New Collaboration Agreement discussed below, the Future Offset was further amended.

New Collaboration Agreement - 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 amends and restates the EyePoint Agreement.

Prior to 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 expands the license to include uveitis, including NIPU, in Europe, the Middle East and Africa and also allows the Company to pursue an indication for posterior uveitis 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 2018, the Company recognized approximately $998,000 of royalty expense, which is included in cost of goods sold, excluding depreciation and amortization. As of December 31, 2018, approximately $428,000 of this royalty expense was included in the Company's accounts payable. During 2017, the Company recognized approximately $621,000 of royalty and profit share expense.

In connection with the New Collaboration Agreement, the Company and EyePoint first agreed to cap the Future Offset amount at $25,000,000 as of June 30, 2017 and the Company agreed to forgive $10,000,000 of the total $25,000,000 of the Future Offset at the July 10, 2017 amendment date. Following the signing of the New Collaboration Agreement, the Company retains 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 these financial statements. As of December 31, 2018, the balance of the Future Offset was approximately $14,937,000. The Company will be able to recover this as a reduction of future royalties as follows:

- In the first two years following the increase in royalty amount to 6%, the royalty will be reduced to 4% for net revenues and other related consideration up to $75,000,000 annually and 5% for net revenues and other related consideration in excess of $75,000,000 on an annual basis; and
- Beginning with the third year following the increase in royalty amount to 6%, the royalty will be reduced to approximately 5.2% for net revenues and other related consideration up to $75,000,000 annually and to approximately 6.8% for net revenues and other related consideration in excess of $75,000,000 on an annual basis.

The Company will forgive up to $5,000,000 of the remaining $15,000,000 of Future Offsets upon the earlier of the approval of ILUVIEN for posterior uveitis in any EU country or January 1, 2020, unless certain conditions under the

New Collaboration Agreement are not met. The Company expects that it will obtain approval of its application for NIPU in the first half of 2019. If the amounts recoverable by the Company associated with the Future Offsets are less than $5,000,000 at that time, the Company will pay EyePoint the difference in cash.

The Company valued the New Collaboration Agreement utilizing a present value analysis at approximately $2,851,000.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

10. LOAN AGREEMENTS

Hercules Loan Agreement

In April 2014, Alimera Sciences Limited (Alimera UK), a subsidiary of the Company, entered into a loan and security agreement (Hercules Loan Agreement) with Hercules Capital, Inc. (Hercules) providing for a term loan of up to $35,000,000 (Hercules Loan). The Company amended the Hercules Loan Agreement several times. On October 20, 2016 Alimera UK and Hercules entered into a fourth amendment to the Hercules Loan Agreement (the Fourth Loan Amendment), which provided the operative loan agreement terms during 2017. On January 5, 2018 the Company paid off the Hercules Loan on behalf of Alimera UK.

The Fourth Loan Amendment provided for interest only payments that were scheduled through November 30, 2018. Pursuant to the Fourth Loan Amendment, interest on the Hercules Loan accrued at a floating per annum rate equal the greater of (i) 11.0% and (ii) the sum of (A) 11.0% plus (B) the prime rate as reported in The Wall Street Journal, or if not reported, the prime rate most recently reported in The Wall Street Journal, minus 3.5%. In addition to the interest described above, the principal balance of the Hercules Loan bore “payment-in kind” interest at the rate of 1.0% (PIK Interest), which PIK Interest was to be added to the outstanding principal balance of the Hercules Loan. The interest rate on the Hercules Loan was 12.0% as of December 31, 2017.

Under the Hercules Loan Agreement as amended by the Fourth Loan Amendment, any principal prepayment of the Hercules loan triggered a prepayment penalty based on when the prepayment occurred. Because the Company prepaid the Hercules Loan Agreement on January 5, 2018, the Company paid 2.0% of the principal amount repaid, or $709,000, which is included in loss on early extinguishment of debt for 2018. Before Alimera UK entered into the Fourth Loan Agreement, Alimera UK was already obligated to pay an end of term payment of $1,400,000, which was paid when the Company paid off the Hercules loan on January 5, 2018.

2014 Warrant

In connection with Alimera UK entering into the 2014 Loan Agreement, the Company issued a warrant that granted Hercules the right to purchase up to 285,016 shares of the Company’s common stock at an exercise price of $6.14 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 1,258,993 and decrease the exercise price to $1.39 per share. The right to exercise this warrant expires on November 2, 2020.

2016 Warrant

In connection with Alimera UK entering into the Fourth Loan Amendment, the Company agreed to issue a new warrant to Hercules (the 2016 Warrant) that granted Hercules the right to purchase up to 458,716 shares of the Company’s common stock at an exercise price of $1.09 per share. The right to exercise this warrant expires on October 20, 2021.

Solar Capital Loan Agreement

On January 5, 2018, the Company entered into a $40,000,000 Loan and Security Agreement (2018 Loan Agreement) with Solar Capital Ltd. (Solar Capital), as Collateral Agent (Agent), and the parties signing the 2018 Loan Agreement from time to time as Lenders, including Solar Capital in its capacity as a Lender (collectively, the Lenders). Under the 2018 Loan Agreement, the Company borrowed the entire $40,000,000 as a term loan that matures on July 1, 2022. The Company used the proceeds of the term loan to refinance the Hercules Loan Agreement and pay related expenses. The Company expects to use the remaining loan proceeds to provide additional working capital for general corporate purposes.

Interest on the 2018 Loan Agreement is payable at one-month LIBOR plus 7.65% per annum. The 2018 Loan Agreement provides for interest only payments for the first 30 months ending on July 1, 2020, followed by 24 months of payments of principal and interest. 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 January 1, 2021, followed by 18 months of payments of principal and interest. As of December 31, 2018, the interest rate on the 2018 Loan Agreement was approximately 10.0%.

As part of the fees and expenses incurred in conjunction with the 2018 Loan Agreement discussed above, the Company paid Solar Capital a $400,000 fee at closing. The Company is obligated to pay a $1,800,000 fee upon repayment of the term loan in full ($2,000,000 if the interest only period has been extended to 36 months). The Company may elect to prepay the outstanding principal balance of the 2018 Loan Agreement in increments of $10,000,000 or more. The Company must pay a

prepayment premium upon any prepayment of the 2018 Loan Agreement before its maturity date, whether by mandatory or voluntary prepayment, acceleration or otherwise, equal to:

a. 2.00% of the principal amount prepaid for a prepayment made on or after January 5, 2018 through and including January 5, 2019;

b. 1.00% of the principal amount prepaid for a prepayment made after January 5, 2019 through and including January 5, 2020; and

c. 0.50% of the principal amount prepaid for a prepayment made after January 5, 2020 and greater than 30 days before the maturity date.

The Company is also obligated to pay additional fees under the Exit Fee Agreement (Exit Fee Agreement) dated as of January 5, 2018 by and among the Company, Solar Capital as Agent, and the Lenders. The Exit Fee Agreement survives the termination of the 2018 Loan Agreement and has a term of 10 years. The Company is obligated to pay up to, but no more than, $2,000,000 in fees under the 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 Exit Fee Agreement). To the extent that Alimera 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:

a. 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

b. 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.

The Company agreed, for itself and its subsidiaries, to customary affirmative and negative covenants and events of default in connection with the 2018 Loan Agreement. The occurrence of an event of default could result in the acceleration of the Company’s obligations under the 2018 Loan Agreement and an increase to the applicable interest rate, and would permit Solar Capital to exercise remedies with respect to the collateral under the 2018 Loan Agreement.

The Company’s obligations to Agent and the Lenders 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 AS C.V., a Dutch subsidiary 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 AS C.V. 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.

Extinguishment of Debt

In accordance with the guidance in ASC 470-50, Debt, the Company accounted for the extinguishment of the Hercules Loan Agreement as an extinguishment and recognized a loss on early extinguishment of debt of approximately $1,766,000 within the consolidated statements of operations for 2018. The loss on early extinguishment consisted primarily of the early termination fee paid to Hercules and unamortized debt discounts including the remaining portion of warrant values and debt issuance costs.

Fair Value of Debt

As of December 31, 2018 and 2017, the weighted average interest rates of the Company’s notes payable approximate the rate at which the Company could obtain alternative financing and the fair value of the warrants that were issued in connection with the Company’s notes payable are immaterial. Therefore, the carrying amount of the notes approximated their fair value at December 31, 2018 and 2017.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

11. COMMITMENTS AND CONTINGENCIES

Term Note Payable

Under the 2018 Loan Agreement with Solar Capital (see Note 10), as of December 31, 2018, the Company was obligated to make future minimum principal payments, excluding the $1,800,000 fee that will be due upon repayment of the term loan in full, as follows:

Years Ending December 31	(In thousands)
2019	$ —
2020	8,333
2021	20,000
2022	11,667
Total	40,000
Less unamortized repayment fee	(1,296)
Less unamortized deferred financing costs	(831)
Less current portion	—
Non-current portion	$ 37,873

As of December 31, 2018 and 2017, the Company had $345,000 and $363,000 accrued and unpaid interest payable under the 2018 Loan Agreement with Solar Capital and the Hercules Loan Agreement, respectively. These amounts are included in accounts payable on the Company's Consolidated Balance Sheets.

Operating Leases

The Company leases office space and equipment under non-cancelable agreements accounted for as operating leases. The leases generally require that the Company pay taxes, maintenance and insurance. Management expects that in the normal course of business, leases that expire will be renewed or replaced by other leases. In August 2014, the Company signed a lease for office space in the U.S. through September 2021. In December 2014, Alimera UK signed a lease for office space in the United Kingdom through December 24, 2024, although the lease is cancellable after December 17, 2019. The lease has a contingent escalation clause based on inflation beginning in 2020. The Company also leases office space in Ireland, Germany and Portugal under leases that expire in June 2019, June 2021 and March 2020, respectively. As of December 31, 2018, a schedule by year of future minimum payments under all of the Company's operating leases is as follows:

Years Ending December 31	(In thousands)
2019	$ 564
2020	421
2021	300
Total	$ 1,285

Rent expense under all operating leases totaled approximately $509,000 and $499,000 for the years ended December 31, 2018 and 2017, respectively.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Capital Leases

The Company leases equipment under capital leases. 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.

As of December 31, 2018, a schedule by year of future minimum payments under capital leases, together with the present value of minimum lease payments, is as follows (in thousands):

Years Ending December 31	(In thousands)
2019	$ 328
2020	297
2021	76
Total	701
Less amount representing interest	(42)
Less amount representing executory costs	(118)
Present value of minimum lease payments	541
Less current portion	(236)
Non-current portion	$ 305

Property and equipment under capital leases, which are included in property and equipment (Note 6), consisted of the following:

	December 31,	
	2018	2017
	(In thousands)	
Automobiles	$870	$663
Office equipment	60	63
Less accumulated depreciation	(315)	(311)
Total	$615	$415

Depreciation expense associated with property and equipment under capital leases was approximately $281,000 and $172,000 for the years ended December 31, 2018 and 2017, respectively.

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 May 2013, the Company entered into an agreement with the first of three contract research organizations (CROs) for clinical and data management services to be performed in connection with the five-year, post-authorization, open label registry study in patients treated with ILUVIEN per the labeled indication in the EEA. Since May 2013, the company has entered into twelve additional agreements for work with these CROs. For the years ended December 31, 2018 and 2017, the Company incurred $141,000 and $101,000, respectively, of expense associated with these agreements. As of December 31, 2018 and 2017, $4,000 and $67,000, respectively, is included in accrued expenses

(Note 8). As of December 31, 2018, the Company expects to incur an additional $210,000 of expense associated with these agreements through December 31, 2019.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2019, the Company is party to four agreements with annual salaries ranging from $332,000 to $525,000. 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

12. 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 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 $2.66 (Conversion Price). The initial Conversion Price was subject to adjustment based on certain customary price-based anti-dilution adjustments. These adjustment features lapsed in September 2014. 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 $10.00 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 unit sold in the preferred stock financing included a warrant to purchase 0.30 shares of Series A Preferred Stock at an exercise price equal to $44.00 per share. At the election of the holder of a warrant, the warrant could have been exercised for the number of shares of common stock then issuable upon conversion of the Series A Preferred Stock that would otherwise be issued upon such exercise at the then-effective Conversion Price. The rights to exercise these warrants expired on October 1, 2017.

These warrants were considered derivative instruments because the agreements provided for settlement in Series A Preferred Stock shares or common stock shares at the option of the holder, an adjustment to the warrant exercise price for common shares at some point in the future, and contain anti-dilution provisions whereby the number of shares for which the warrants were exercisable and/or the exercise price of the warrants was subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. Therefore, the warrants were recorded as a liability at issuance. The warrant anti-dilution provisions lapsed in September 2014. During 2017, the Company recorded a gain of $188,000 as a result of the change in fair value of the warrants

In 2014, 6,015,037 shares of common stock were issued pursuant to the conversion of 400,000 shares of Series A Convertible Preferred Stock. As of December 31, 2018, there were 600,000 shares of Series A Convertible Preferred Stock issued and outstanding.

Series B Convertible Preferred Stock

On December 12, 2014, the Company closed a preferred stock financing in which it sold 8,291.873 shares of Series B Convertible Preferred Stock (Series B Preferred Stock) for a purchase price of $6,030 per share, or an aggregate purchase price of $50,000,000, prior to the payment of approximately $432,000 of related issuance costs. The Company issued an additional 124.378 shares of Series B Preferred Stock as a subscription premium to the purchasers. On September 4, 2018, all of the outstanding shares of Series B Preferred Stock were exchanged for shares of Series C Convertible Preferred Stock (see below).

The powers, preferences and rights of the Series B Preferred Stock were set forth in the certificate of designation for the Series B 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 B Preferred Stock was convertible into 1,000 shares of the Company's common stock at any time at the option of the holder, provided that the holder was prohibited from converting Series B Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together

with its affiliates, would own more than 9.98% of the total number of shares of the Company's common stock then issued and outstanding. The Series B Preferred Stock ranked junior to the Company's existing Series A Preferred Stock and senior to the Company's common stock, with respect to rights upon liquidation. The Series B Preferred Stock ranked junior to all existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions), the Series B Preferred Stock did not have voting rights. The Series B Preferred Stock was not redeemable at the option of the holder. The Series B Preferred Stock was not subject to any price-based or other anti-dilution protections and did not provide for any accruing dividends.

The Company determined that the conversion option of the Series B Preferred Shares represented a beneficial conversion feature, as the conversion feature had intrinsic value to the holder on the commitment date as a result of the subscription

premium. Therefore, the Company recorded a beneficial conversion feature of $750,000 as an increase in additional paid in capital. Because the Series B Preferred Stock was immediately convertible into common stock at the option of the holder at issuance, the Company immediately accreted the full value of the beneficial conversion feature to the carrying value of the Series B Preferred Stock on that date.

On September 4, 2018, following the closing of the exchange of all outstanding shares of Series B Preferred Stock for shares of Series C Convertible Preferred Stock, the Company filed with the Delaware Secretary of State a Certificate of Elimination of Series B Convertible Preferred Stock of Alimera Sciences, Inc., which eliminated from the Company's amended and restated certificate of incorporation, as amended, the Alimera Sciences, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock. As a result, all shares of the Company's preferred stock previously designated as Series B Convertible Preferred Stock were eliminated and returned to the status of authorized but unissued shares of preferred stock, without designation as to series.

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 the outstanding approximately 8,416 shares of Series B Preferred Stock. Under the Exchange Agreement, the holders of Series B Preferred Stock exchanged their shares of Series B Preferred Stock for an aggregate of 10,150 shares of Series C Convertible Preferred Stock, par value $0.01 per share (Series C Preferred Stock). The powers, preferences and rights of the Series C Preferred Stock are set forth in the certificate of designation filed by the Company with the Delaware Secretary of State as part of the Company's certificate of incorporation, as amended. All of the outstanding shares of Series B Preferred Stock were canceled in the exchange. The Company incurred approximately $122,000 in legal costs related to the Exchange Agreement.

The 10,150 issued and outstanding shares of Series C Preferred Stock have an aggregate stated value of $10,150,000 and are convertible into shares of the Company's common stock at $1.00 per share, or 10,150,000 shares of the Company's common stock in total, at any time at the option of the holder, provided that the holder will be prohibited from converting shares of Series C Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of the Company's common stock then issued and outstanding. The Series C Preferred Stock is not redeemable at the option of the holder. In the event of a liquidation, dissolution or winding up of the Company and in the event of certain mergers, tender offers and asset sales, the holders of the Series C Preferred Stock will receive the greater of (a) the liquidation preference equal to $10,150,000 in the aggregate, plus any declared but unpaid dividends, or (b) the amount such holders would receive had all shares of the Series C Preferred Stock been converted into the Company's common stock immediately before such event. With respect to rights upon liquidation, the Series C Preferred Stock ranks junior to the Company's Series A Preferred Stock and senior to the Company's common stock. The Series C Preferred Stock ranks junior to all existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions), the Series C Preferred Stock does not have voting rights. The Series C Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends.

The Company determined that the Exchange Agreement resulted in an extinguishment of the Series B Preferred Stock. As a result, the Company recognized a gain of $38,330,000 on the extinguishment of preferred stock during 2018. As of the transaction date, the Company made an assessment of the fair market value of the Series C Preferred Stock and calculated the value to be $11,239,000, prior to the payment of approximately $122,000 of related transaction costs. This Company recorded this gain within stockholders' equity and as an increase to earnings available to stockholders for 2018. The $38,330,000 gain on extinguishment of preferred stock was derived by the difference in the fair market value of the Series C Preferred Stock and the carrying value of the Series B Preferred Stock.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

13. 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 17). 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,			
	2018		2017	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period	11,595,510	$ 2.90	10,804,412	$ 3.22
Grants	2,111,375	1.07	2,336,300	1.25
Forfeitures	(1,257,967)	2.54	(1,544,473)	2.63
Exercises	(1,563)	1.06	(729)	1.49
Options outstanding at year end	12,447,355	2.63	11,595,510	2.90
Options exercisable at year end	9,138,544	3.09	8,085,064	3.25
Weighted average per share fair value of options granted during the year	$ 0.71		$ 0.94	

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, 2018:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
				(In thousands)
Outstanding	12,447,355	$ 2.63	6.25 years	$ —
Exercisable	9,138,544	3.09	5.37 years	—
Outstanding, vested and expected to vest	12,044,311	2.67	6.16 years	—

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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,	
	2018	2017
Risk-free interest rate	2.63 %	2.06 %
Volatility factor	72.60 %	90.49 %
Grant date fair value of common stock options	$0.71	$0.94
Weighted-average expected life	6.02 years	6.02 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,	
	2018	2017
	(In thousands)	
Sales and marketing	$ 685	$ 907
Research, development and medical affairs	565	643
General and administrative	2,130	2,510
Total employee stock-based compensation expense related to stock options	$ 3,380	$ 4,060

As of December 31, 2018, there was approximately $2,993,000 of total unrecognized compensation cost related to outstanding stock option awards that will be recognized over a weighted average period of 2.25 years. The total fair value of shares vested during 2018 was approximately $3,400,000.

The total estimated fair value of options granted during the years ended December 31, 2018 and 2017 was $2,268,000 and $2,186,000, respectively. The total estimated intrinsic value of options exercised was less than $1,000 for both the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, the Company was authorized to grant options to purchase up to an additional 263,498 shares under the 2010 Equity Incentive Plan. The Company's 2010 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year equal to the lesser of: (1) 2,000,000 shares of common stock; (2) 4% of the shares of common stock outstanding at that time; and (3) such other amount as our board of directors may determine. On January 1, 2019, an additional 2,000,000 shares became available for future

issuance under the 2010 Plan. These additional shares from the annual increase under the 2010 Plan are not included in the foregoing discussion.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Restricted Stock Units

A summary of RSU transactions under the plans are as follows:

	Years Ended December 31,			
	2018		2017	
	RSUs	Weighted Average Grant Date Fair Value	RSUs	Weighted Average Grant Date Fair Value
Restricted stock units outstanding at beginning of period	839,285	$ 1.21	—	$ —
Grants	1,091,712	1.15	964,720	1.21
Vested units	(839,285)	1.21	—	—
Forfeitures	(191,460)	1.15	(125,435)	1.18
Restricted stock units outstanding at year end	900,252	1.15	839,285	1.21

As of December 31, 2018, there was approximately $169,000 of total unrecognized compensation cost related to outstanding RSUs that will be recognized during the first quarter of 2019.

Employee stock-based compensation expense related to RSUs recognized in accordance with ASC 718 was $1,002,000 and $883,000 for the years ended December 31, 2018, and 2017, respectively.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

14. COMMON STOCK WARRANTS

The Company has issued warrants to purchase common stock to various members of the board of directors, third parties for services, and lenders. Warrants to purchase a total of 1,795,663 shares of common stock were outstanding as of December 31, 2018 and 2017. As of December 31, 2018, the exercise prices ranged from $1.09 to $11.00 per share. The warrants are exercisable for a period between 5 and 10 years from the issuance date.

In connection with Alimera UK entering into the Hercules Loan Agreement (Note 10), the Company entered into the 2014 Warrant, which granted Hercules the right to purchase up to 285,016 shares of the Company's common stock at an exercise price of $6.14 per share. The Company amended the 2014 Warrant a number of times to increase the number of shares issuable upon exercise to 1,258,993 and decrease the exercise price to $1.39 per share. The right to exercise this warrant expires 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 458,716 shares of the Company's common stock at an exercise price of $1.09 per share. The right to exercise this warrant expires on October 20, 2021.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

15. CONCENTRATIONS AND CREDIT RISK

For the years ended December 31, 2018 and 2017, there were three customers within the U.S. segment. Two of these customers, which are large pharmaceutical distributors, accounted for approximately 69% and 73%, respectively, of the Company's total consolidated revenues. These two customers accounted for approximately 73% and 81% of the Company's consolidated accounts receivable as of December 31, 2018 and 2017, respectively.

For the years ended December 31, 2018 and 2017 one of the Company's third-party manufacturers of ILUVIEN comprised approximately 13.7% and 10.5%, respectively, of the Company's total purchases, and there were no other vendors that comprised more than 10% of the Company's total purchases. The Company relies on a single manufacturer for ILUVIEN, a single manufacturer for the ILUVIEN applicator and a single active pharmaceutical ingredient manufacturer for ILUVIEN's active pharmaceutical ingredient.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

16. INCOME TAXES

On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (2017 Tax Act). The more significant attributes of the 2017 Tax Act impose a repatriation tax on accumulated earnings of foreign subsidiaries, implement a territorial tax system together with a current tax on certain foreign earnings and lower the general corporate income tax rate to 21%.

Following guidance provided by SEC Staff Accounting Bulletin No. 118, which in March 2018 was codified by the FASB in ASU 2018-05, Income Taxes (Topic 740) the Company remeasured certain net deferred and other tax liabilities based on the tax rate at which they are expected to reverse, which is now 21% instead of 35%. The net impact of the 2017 Tax Act was $0 due to a full valuation allowance recorded against the U.S. deferred tax assets. During 2018, the Company continued to analyze other provisions of the 2017 Tax Act and as of December 31, 2018, we have completed our accounting for the effects of the 2017 Tax Act.

The components of net loss before taxes are as follows:

	Years Ended December 31,	
	2018	2017
	(In thousands)	
United States	$(2,908)	$(1,890)
Foreign	(13,368)	(19,948)
Loss before provision for income taxes	$(16,276)	$(21,838)

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,	
	2018	2017
	(In thousands)	
Current expense (benefit):		
Federal	$—	$—
State	—	—
Foreign	759	255
Current income tax expense	759	255
Deferred expense (benefit):		
Federal	256	549
State	411	3,330
Foreign	(654)	(92)
	13	3,787
Valuation allowance	(666)	(3,879)
Deferred income tax benefit	(653)	(92)
Total income tax expense	$106	$163

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	Years Ended December 31,	
	2018	2017
	(In thousands)	
Valuation allowance at beginning of period	$(41,485)	$(55,968)
Income tax provision	(666)	(3,879)
U.S. Tax Reform	—	18,362
Valuation allowance at end of period	$(42,151)	$(41,485)

Worldwide net deferred tax assets and liabilities are as follows:

	December 31,	
	2018	2017
Deferred tax assets	(In thousands)	
Depreciation and amortization	$55	$ 44
Other deferred tax assets	1,382	707
NOL carry-forwards	34,217	33,980
Research and development costs	813	1,340
Equity compensation	4,485	3,686
Collaboration agreement receivable reserves	2,381	2,256
Valuation allowance	(42,151)	(41,485)
Total deferred tax assets	$1,182	$ 528

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

	Years Ended December 31,			
	2018		2017	
	Amount	Percent	Amount	Percent
	(in thousands, except percentages)			
Federal tax benefit at statutory rate	$(3,463)	21.0 %	$(7,425)	34.0 %
State tax — net of federal benefit	1	—	(3,783)	17.3
Permanent items and other	528	(3.2)	686	(3.1)
Foreign rate differential	2,946	(17.9)	6,880	(31.5)
U.S. tax reform	—	—	18,362	(84.1)
Deferred rate change	(438)	2.7	(212)	1.0
Other	(134)	0.8	138	(0.6)
Change in valuation allowance	666	(4.0)	(14,483)	66.3
Total tax expense (benefit)	$106	(0.6)%	$163	(0.7)%

The change in state taxes in 2017, net of federal benefit, was a result of the Company filing additional state income tax returns in 2017. This resulted in approximately $3.8 million of state NOLs being generated. During 2018, there was no additional impact of the one-time, non-cash deferred rate change as a result of the 2017 Tax Act. The U.S. corporate tax rate change and state NOLs are fully offset by a valuation allowance recorded against U.S. federal and state income taxes; therefore, the overall impact of these items is zero to income tax expense.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	Years Ended December 31,	
	2018	2017
	(In thousands)	
Balance of uncertain tax positions at beginning of period	$ 52	$ 59
Gross increases - tax positions in current period	13	4
Gross increases - tax positions in prior period	10	—
Gross decreases - tax positions in prior period	(7)	(11)
Settlements	—	—
Lapse of statute of limitations	—	—
Balance of uncertain tax positions at end of period	$ 68	$ 52

Included in the balance of unrecognized tax benefits as of December 31, 2018 and 2017 are approximately $68,000 and $52,000, 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 2014 to 2017 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, 2018 and 2017, the Company had federal net operating loss (NOL) carry-forwards of approximately $122,455,000 and $121,413,000, and state NOL carry-forwards of approximately $153,333,000, and $161,753,000 respectively, subject to further limitation based upon the final results of our Internal Revenue Code (IRC) sections 382 and 383 analyses. These NOLs are available to reduce future income unless otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2029 and 2037, the Company's federal NOL created in 2018 will carry forward indefinitely and the state NOL carry-forwards will expire at various dates between 2020 and 2038.

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 IRC 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.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

As of December 31, 2018, the Company had cumulative book losses in foreign subsidiaries of approximately $126,648,000. 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.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

17. 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 $274,000 and $187,000 for the years ended December 31, 2018 and 2017, respectively. The Company may also make an annual discretionary profit-sharing contribution. No such discretionary contributions were made during the years ended December 31, 2018 and 2017, respectively.

In April 2010, the Company established an Employee Stock Purchase Plan (the Purchase Plan). Under the Company's Purchase Plan, eligible employees can participate and purchase common stock semi-annually through accumulated payroll deductions. The Purchase Plan is administered by the Company's board of directors or a committee appointed by the Company's board of directors. Under the Purchase Plan 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 Purchase Plan 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 2,500 shares of common stock per purchase period. The value of the shares purchased in any calendar year may not exceed $25,000.

The Purchase Plan was effective upon the completion of the Company's initial public offering in 2010, at which time a total of 494,422 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 91,649 and 79,733 shares of the Company's common shares were acquired through the Purchase Plan during the years ended December 31, 2018 and 2017, respectively. As such, on January 1, 2019 and 2018, respectively, an additional 91,649 and 79,733 shares became available for future issuance under the Purchase Plan. 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 Purchase Plan, the Company recorded $31,000 and $38,000 of compensation expense for the years ended December 31, 2018 and 2017, respectively.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

18. SEGMENT INFORMATION

For the years ended December 31, 2018 and 2017, there were three customers within the U.S. segment. Two of these customers, which are large pharmaceutical distributors, accounted for 69% and 73% of the Company's consolidated revenues for the years ended December 31, 2018 and 2017, respectively. These same two customers within the U.S. segment accounted for approximately 73% and 81% of the Company's consolidated accounts receivable at December 31, 2018 and 2017, 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 segment is separately managed and is evaluated primarily upon segment income or loss from operations. Non-cash items, including stock-based compensation expense and depreciation and amortization, are categorized as Other within the tables below.

The following table presents a summary of the Company's reporting segments for the years ended December 31, 2018 and 2017:

	Year Ended December 31, 2018			
	U.S.	International	Other	Consolidated
	(In thousands)			
NET REVENUE	$32,337	$ 14,633	$ —	$ 46,970
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(3,246)	(1,433)	—	(4,679)
GROSS PROFIT	29,091	13,200	—	42,291
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	6,457	3,946	871	11,274
GENERAL AND ADMINISTRATIVE EXPENSES	8,147	3,259	3,119	14,525
SALES AND MARKETING EXPENSES	16,569	5,910	1,038	23,517
DEPRECIATION AND AMORTIZATION	—	—	2,645	2,645
OPERATING EXPENSES	31,173	13,115	7,673	51,961
SEGMENT LOSS FROM OPERATIONS	(2,082)	85	(7,673)	(9,670)
OTHER INCOME AND EXPENSES, NET			(6,606)	(6,606)
NET LOSS BEFORE TAXES				$ (16,276)

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Year Ended December 31, 2017			
	U.S.	International	Other	Consolidated
	(In thousands)			
NET REVENUE	$26,146	$ 9,766	$ —	$ 35,912
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(2,482)	(956)	—	(3,438)
GROSS PROFIT	23,664	8,810	—	32,474
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	5,780	3,314	3,750	12,844
GENERAL AND ADMINISTRATIVE EXPENSES	7,580	2,605	2,854	13,039
SALES AND MARKETING EXPENSES	16,588	5,394	1,228	23,210
DEPRECIATION AND AMORTIZATION	—	—	2,684	2,684
RECOVERABLE COLLABORATION COSTS	—	—	(2,851)	(2,851)
OPERATING EXPENSES	29,948	11,313	7,665	48,926
SEGMENT LOSS FROM OPERATIONS	(6,284)	(2,503)	(7,665)	(16,452)
OTHER INCOME AND EXPENSES, NET			(5,386)	(5,386)
NET LOSS BEFORE TAXES				$ (21,838)

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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 Quarterly Report on Form 10-Q, as filed on November 9, 2018, and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Registrant, as amended (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, as filed on November 5, 2015, and incorporated herein by reference)
4.4	Warrant to Purchase Stock dated October 14, 2010 issued to Silicon Valley Bank (filed as Exhibit 4.1 to the Registrant's Current Report, as filed on October 18, 2010, and incorporated herein by reference)
4.5	Warrant to Purchase Stock dated October 14, 2010 issued to MidCap Funding III, LLC (filed as Exhibit 4.2 to the Registrant's Current Report, as filed on October 18, 2010, and incorporated herein by reference)
4.6	Warrant to Purchase Stock dated May 16, 2011 issued to MidCap Funding III, LLC (filed as Exhibit 4.1 to the Registrant's Current Report, as filed on May 17, 2011, and incorporated herein by reference)
4.7	Warrant to Purchase Stock dated May 16, 2011 issued to Silicon Valley Bank (filed as Exhibit 4.2 to the Registrant's Current Report, as filed on May 17, 2011, and incorporated herein by reference)
4.8.A	Warrant to Purchase Shares of Series A Preferred issued to Sofinnova Venture Partners VIII, L.P. (filed as Exhibit 4.10.A to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)
4.8.B	Warrant to Purchase Shares of Series A Preferred issued to Growth Equity Opportunities Fund III, LLC (filed as Exhibit 4.10.B to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)
4.8.C	Warrant to Purchase Shares of Series A Preferred issued to Micro Cap Partners, L.P. (filed as Exhibit 4.10.C to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)
4.8.D	Warrant to Purchase Shares of Series A Preferred issued to Palo Alto Healthcare Master Fund, L.P. (filed as Exhibit 4.10.D to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)
4.8.E	Warrant to Purchase Shares of Series A Preferred issued to Palo Alto Healthcare Master Fund II, L.P. (filed as Exhibit 4.10.E to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)
4.9	Registration Rights Agreement dated October 2, 2012 between the Registrant and Palo Alto Healthcare Master Fund, L.P., Palo Alto Healthcare Master Fund II, L.P., Micro Cap Partners, L.P., Sofinnova Venture Partners VIII L.P. and Growth Equity Opportunities Fund III, LLC (filed as Exhibit 4.11 to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)

4.10	Amendment No. 1 to Warrant to Purchase Stock dated May 7, 2013 by and between Silicon Valley Bank and the Registrant (filed as Exhibit 4.10 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013, and incorporated herein by reference)
4.11	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)
4.12	Warrant Agreement dated as of April 24, 2014 issued to Hercules Technology Growth Capital, Inc. (filed as Exhibit 4.11 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
4.13	Amendment No. 1 to Warrant Agreement dated November 2, 2015 by and among the Registrant and Hercules Technology Growth Capital, Inc. (filed as Exhibit 4.13 to the Registrant's Annual Report on Form 10-K, as filed on March 15, 2016, and incorporated herein by reference)
4.14	Amendment No. 2 to Warrant Agreement dated March 14, 2016 by and among the Registrant and Hercules Technology Growth Capital, Inc. (filed as Exhibit 4.14 to the Registrant's Quarterly Report on Form 10-Q, as filed on May 6, 2016, and incorporated herein by reference)

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4.15	Amendment No. 3 to Warrant Agreement dated July 21, 2016 by and among the Registrant and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc. (filed as Exhibit 4.15 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 4, 2016, and incorporated herein by reference)
4.16	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)
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	Alimera Sciences, Inc. 2004 Incentive Stock Plan, as amended (filed as Exhibit 10.7 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)
10.3	Form of Option Certificate under the Alimera Sciences, Inc. 2004 Incentive Stock Plan (filed as Exhibit 10.7.A 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)
10.4	Alimera Sciences, Inc. 2005 Incentive Stock Plan (filed as Exhibit 10.8 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)
10.5	Form of Option Certificate under the Alimera Sciences, Inc. 2005 Incentive Stock Plan (filed as Exhibit 10.8.A 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)
10.6	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)
10.7	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)
10.7.A	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)
10.8	Management Cash Incentive Plan (filed as Exhibit 10.11 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)
10.9	Compensation Program for Non-Employee Directors (filed as Exhibit 10.12 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)
10.10‡	Amended and Restated Collaboration Agreement by and between pSivida, Inc. (f/k/a/Control Delivery Systems, Inc.) and Alimera Sciences, Inc., dated as of March 14, 2008 (filed as Exhibit 10.13 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16,

	2010, and incorporated herein by reference)
10.11*	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
10.13	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)
10.15	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)
10.16‡	Manufacturing 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)
10.17	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)

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10.18	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)
10.19	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 10.46)
10.20	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)
10.21	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)
10.22	Employment Contract 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)
10.29	Securities Purchase Agreement dated January 27, 2014 (filed as Exhibit 10.42 to the Registrant's Current Report, as filed on January 28, 2014, and incorporated herein by reference)
10.30	Loan and Security Agreement dated as of April 24, 2014 by and among Alimera Sciences Limited, the several banks and other financial institutions or entities from time to time parties thereto and Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.49 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
10.31	First Amendment to Loan and Security Agreement dated November 2, 2015 by and among Alimera Sciences Limited, Hercules Capital Funding Trust and Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.31 to the Registrant's Annual Report on Form 10-K, as filed on March 15, 2016, and incorporated herein by reference)
10.32	Unconditional Guaranty entered into as of April 24, 2014 by the Registrant in favor of Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.50 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
10.33	Unconditional Guaranty entered into as of April 24, 2014 by Alimera Sciences B.V. in favor of Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.51 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
10.34	Unconditional Guaranty entered into as of April 24, 2014 by AS C.V. in favor of Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.52 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
10.35	Sales Agreement dated September 22, 2014 (filed as Exhibit 10.53 to the Registrant's Current Report on Form 8-K, as filed on September 22, 2014, and incorporated herein by reference)
10.36†	Amended and Restated Employment Agreement, effective as of October 23, 2014, by and between the Registrant and C. Daniel Myers (filed as Exhibit 10.53 to the Registrant's Current Report on Form 8-K, as filed on October 23, 2014, and incorporated herein by reference)

10.37†	Amended and Restated Employment Agreement, effective as of October 23, 2014, by and between the Registrant and Richard S. Eiswirth, Jr. (filed as Exhibit 10.54 to the Registrant's Current Report on Form 8-K, as filed on October 23, 2014, and incorporated herein by reference)
10.38†	Amended and Restated Employment Agreement, effective as of October 23, 2014, by and between the Registrant and Kenneth Green, Ph.D. (filed as Exhibit 10.55 to the Registrant's Current Report on Form 8-K, as filed on October 23, 2014, and incorporated herein by reference)
10.39†	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)
10.40	Securities Purchase Agreement dated November 26, 2014 (filed as Exhibit 10.56 to the Registrant's Current Report on Form 8-K, as filed on November 28, 2014, and incorporated herein by reference)
10.41‡	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)

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10.42	Second Amendment to Loan and Security Agreement dated March 14, 2016 by and among Alimera Sciences Limited, Hercules Capital Funding Trust and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.42 to the Registrant's Quarterly Report on Form 10-Q, as filed on May 6, 2016, and incorporated herein by reference)
10.43	Third Amendment to Loan and Security Agreement dated May 26, 2016 by and among Alimera Sciences Limited, Hercules Capital Funding Trust and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.43 to the Registrant's Current Report on Form 8-K, as filed on May 27, 2016, and incorporated herein by reference)
10.44	Waiver by Hercules Capital, Inc. of Certain Defaults under Loan and Security Agreement dated July 21, 2016 (filed as Exhibit 10.45 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 4, 2016 and incorporated herein by reference)
10.45	Fourth Amendment to Loan and Security Agreement dated October 20, 2016 by and among Alimera Sciences Limited, Hercules Capital Funding Trust and Hercules Capital, Inc. f/k/a/ Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.45 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 4, 2016 and incorporated herein by reference)
10.46	(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)
10.47	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 United Kingdom (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)
10.48	2017 Amendment to Amended and Restated Collaboration Agreement dated May 3, 2017 by and between Alimera Sciences Inc. and pSivida US, Inc. (f/k/a pSivida, Inc.) (filed as Exhibit 10.48 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 8, 2017, and incorporated herein by reference)
10.49	Fifth Amendment to Loan and Security Agreement dated May 5, 2017 by and among Alimera Sciences Limited, Hercules Capital Funding Trust and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.49 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 8, 2017, and incorporated herein by reference)
10.50‡	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)
10.51	Common Stock Sales Agreement by and between Alimera Sciences, Inc. and H.C. Wainwright & Co., LLC dated October 20, 2017 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on October 20, 2017, and incorporated herein by reference)
10.52‡	Loan and Security Agreement dated as of January 5, 2017, 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 10.1 to the Registrant's Current Report on Form 8-K, as filed January 8, 2018, and incorporated herein by reference)

10.53	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)
10.54	Series B Preferred Stock Exchange Agreement, dated as of September 4, 2018, by and among Alimera Sciences, Inc., and Deerfield Special Situations Fund, L.P., Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Deerfield Private Design Fund III, L.P. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on September 5, 2018 and incorporated herein by reference)
10.55	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)
10.56	Succession and Consulting Agreement, dated as of November 28, 2018, by and between Alimera Sciences, Inc. and Kenneth Green, Ph.D. (filed as exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed November 29, 2018, and incorporated herein by reference)
21.1*	List of subsidiaries of the Registrant (including jurisdiction of organization and names under which subsidiaries do business)

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

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† Compensation Arrangement.
‡ Confidential treatment has been granted with respect to certain portions of this document.
* Filed herewith.

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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 February 25, 2019.

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)	February 25, 2019
/s/ J. Philip Jones J. Philip Jones	Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2019
/s/ C. Daniel Myers C. Daniel Myers	Chairman of the Board of Directors	February 25, 2019
/s/ James Largent James Largent	Lead Independent Director	February 25, 2019
/s/ Mark J. Brooks Mark Brooks	Director	February 25, 2019
/s/ Brian K. Halak Brian K. Halak, Ph.D.	Director	February 25, 2019
/s/ Garheng Kong Garheng Kong, M.D., Ph.D.	Director	February 25, 2019
/s/ Peter J. Pizzo, III Peter J. Pizzo, III	Director	February 25, 2019
/s/ Calvin W. Roberts Calvin W. Roberts, M.D.	Director	February 25, 2019
/s/ Mary T. Szela Mary T. Szela	Director	February 25, 2019