ALIMERA SCIENCES INC
Form 10-K
March 02, 2018
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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, 2017
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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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. (Check one):

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	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, 2017, 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 $81,912,112 based on the closing price of the registrant’s Common Stock, on June 30, 2017, 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 28, 2018 there were 69,985,666 shares of the registrant’s Common Stock issued and outstanding.

EXPLANATORY NOTE

The registrant met the accelerated filer requirements as of the end of its fiscal year ended December 31, 2017 pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended. However, pursuant to Rule 12b-2 and SEC Release No. 33-8876, the registrant (as a smaller reporting company transitioning to the larger reporting company system based on its public float as of June 30, 2017) is not required to satisfy the larger reporting company disclosure requirements until its first Quarterly Report on Form 10-Q for the fiscal year ending December 31, 2018 and thus remains eligible to use the scaled disclosure requirements applicable to smaller reporting companies under Item 10 of Regulation S-K under the Securities Act of 1933, as amended, in this Annual Report on Form 10-K.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant’s proxy statement with respect to the registrant’s 2018 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, 2017, 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:

- 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.
- 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 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. 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 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, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom. In the U.S., 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. We received regulatory approval to cease enrollment in the study from the Medicines & Healthcare products Regulatory Agency (MHRA) in July 2017 due to our post market safety surveillance not showing any unexpected safety signals, and enrollment was capped at 562 patients.

We commercially market ILUVIEN 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.

In addition, we have entered into various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in several countries in the Middle East, as well as Italy, Spain, France, Canada, Australia and New Zealand. In the third quarter of 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 the second quarter of 2017. Our Spanish distributor began selling on a named patient basis in 2017 and is currently pursuing reimbursement at the national level. Our French distributor is currently pursuing reimbursement at the national level.

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.

ILUVIEN is 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. 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 microdose makes it the only approved drug therapy 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 and mitigates the typical corticosteroid related side effects. 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, with an adverse event profile a retinal physician can predict and manage. Other corticosteroid options for DME and NIPU provide a higher initial daily dose but then rapidly decline, requiring frequent reinjection by the physician to maintain or reestablish the therapeutic effect. 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.

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 filed for a new indication for ILUVIEN for NIPU in the 17 EEA countries as part of this strategy. Our executive team has extensive development and commercialization expertise with ophthalmic products. We intend to capitalize on our management's experience and expertise to market ILUVIEN, and other potential eye care products, when, where and if such drugs receive regulatory approval.

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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 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 the second quarter of 2017. Our Spanish distributor began selling on a named patient basis in 2017 and is currently pursing reimbursement at the national level. In addition, outside the EEA, our distributor launched in the Middle East and began selling ILUVIEN in the United Arab Emirates in the second half of 2016. Our French distributor is currently pursuing reimbursement at the national level.

- Pursue Approval in Additional Countries. We plan to pursue regulatory approval for ILUVIEN, directly or with a partner, in other countries. We have entered into agreements to distribute ILUVIEN in Canada, Australia and New Zealand. Pursuant to these agreements, our distributors will assist us in obtaining approval or seek approval with our oversight 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.

- 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 other countries where we have the license to use ILUVIEN to treat uveitis in the remaining countries in the EU, the Middle East and Africa.

- 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. In Europe, in which ILUVIEN has received marketing authorizations, the IDF estimates that there are approximately 58.0 million people 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 (also called background retinopathy) develops first and causes increased capillary permeability, micro aneurysms, hemorrhages, exudates (when fluid leaks into spaces between vessels), macular ischemia (lack of oxygen) and macular edema (thickening of the retina caused by fluid leakage from capillaries). Proliferative retinopathy is an advanced stage of diabetic retinopathy which, in addition to characteristics of non-proliferative retinopathy, results in the

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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 (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. DME is the most common cause of vision loss among people with diabetic retinopathy and about half of all 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 flucoinolone 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. A majority of 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 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. In addition, these therapies have safety profiles that include an increased risk of endophthalmitis, a serious eye infection that must be treated with high doses of antibiotics. This risk of endophthalmitis is associated with any intravitreal injection. There is evidence that intravitreal

anti-VEGF therapy affects systemic VEGF levels, which may have cardiovascular complications.

Intravitreal corticosteroid therapies are also used to treat DME. Short-acting corticosteroids typically have peak effects within six months, and there is a need for repeated injections, albeit less frequent than anti-VEGF therapies. Otherwise, macular edema will reoccur and the therapeutic effect of the corticosteroids will be lost. 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

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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, ILUVIEN is a long-term 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.

Because of the bolus nature of anti-VEGF and shorter duration corticosteroid injections, the daily drug therapy delivered to the eye is often inconsistent.

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.

ILUVIEN

Overview

Our only commercial product is ILUVIEN, a sustained release corticosteroid intravitreal implant. “Intravitreal” refers to the space inside the eye behind the lens that contains the jelly-like substance called vitreous. 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 (μg) 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.

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We believe that ILUVIEN is a unique therapeutic option to treat retina disease because ILUVIEN has been shown to deliver 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. Further, 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.

ILUVIEN has received marketing authorization in the U.S., Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom. In the U.S., 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.

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.

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.

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.
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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

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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, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom. In the U.S., 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. We received regulatory approval to cease enrollment in the study from the Medicines & Healthcare products Regulatory Agency (MHRA) in July 2017 due to our post market safety surveillance not showing any unexpected safety signals, and enrollment was capped at 562 patients.

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

Uveitis

We do not currently have a regulatory license for ILUVIEN to treat uveitis in the EEA. 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 being conducted to assess the safety and efficacy of the equivalent of the ILUVIEN insert for the treatment of posterior uveitis. These studies are 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. These two trials form the basis of our regulatory submission in Europe for NIPU. We received formal acceptance of our Type II variation submission for ILUVIEN, which was submitted through the Mutual Recognition Procedure with the MHRA in the United Kingdom as the Reference Member State. 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.

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 in the first quarter of 2017 and in Ireland in the fourth quarter of 2017.Our Italian distributor launched ILUVIEN in Italy in the second quarter of 2017. Our Spanish distributor began selling on a named patient basis in 2017 and is currently pursing reimbursement at the national level. 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.

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Sales and Marketing

As of December 31, 2017, we had a U.S. field force of approximately 43 persons, consisting of sales personnel, reimbursement specialists, payor relations directors and other positions. As of December 31, 2017, we had a European field force of approximately 15 persons, consisting of personnel in Germany, Portugal and the United Kingdom. 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 from our distributors.

In the fourth quarter of 2016, after failing to negotiate a reasonable price with the French government, we decided to close operations in France, which was completed in 2017. In August 2017, we signed a distribution agreement with a third party to serve as our exclusive distributor in France. Currently, our French distributor is pursuing reimbursement at the national level. They will handle promotion, marketing and commercial activities in France for ILUVIEN.

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.

We have various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for commercialization of ILUVIEN in numerous countries in the Middle East, Italy, Spain, France, Canada, Australia and New Zealand. Pursuant to these agreements, our distributors 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.

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

•the quality release testing of ILUVIEN in the EEA (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 0.19 mg 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

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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 Tijuana, Mexico facility. We purchased certain equipment at 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, 2017 and 2016 were generated from product sales primarily in the U.S., Germany, Portugal and the United Kingdom. In the U.S., two large pharmaceutical distributors accounted for 73% and 75% of our consolidated revenues for the years ended December 31, 2017 and 2016, 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. We believe that the following drugs provide competition to ILUVIEN:

- Lucentis (ranibizumab injection), marketed by Genetech (Roche) in the U.S. and Novartis in the rest of the world and Avastin (bevacizumab), an oncology product marketed by the Roche group, are both antibodies that inhibit VEGF signaling pathways. Lucentis is currently approved for the treatment of DME, the treatment of diabetic retinopathy in patients with DME, the treatment of neovascular wet AMD and the treatment of macular edema following RVO in the U.S. In the EEA, the indications are similar except for 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 who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.
- Humira (adlimumab), marketed by Abbvie, is a TNF-blocker. It works by targeting and blocking a specific source of inflammation that plays a role in non-infectious uveitis. In the EEA, Humira is indicated for the

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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.

In addition, a number of other companies, including Alcon/ Novartis, Ampio Pharmaceuticals, Aerpio, Allegro and pSivida, are developing drug therapies or sustained delivery platforms for the treatment of retinal diseases.

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

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

Licenses and Agreements

pSivida US, Inc.

We entered into an agreement with pSivida for the use of FAc in pSivida's proprietary insert technology in 2005, which we have amended a number of times. In July 2017, we amended and restated this agreement with pSivida 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 pSivida for the use of steroids, including FAc, in pSivida'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 pSivida'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 pSivida's proprietary insert technology in connection with indications for diseases outside of the eye.

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 pSivida effective July 1, 2017. This royalty amount will increase to 6% upon the earliest of December 12, 2018 or the receipt of the first marketing approval for ILUVIEN for the treatment of NIPU. 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 the year ended December 31, 2017, we recognized approximately $621,000 of royalty and profit share expense. During the year ended December 31, 2016, we recognized approximately $254,000 of 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.

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 the third quarter of 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 the year ended December 31, 2017.

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

(a) fail twice to cure our breach of an obligation to make certain payments to pSivida following receipt of written notice of the breach;
(b) fail to cure other breaches of material terms of our agreement with pSivida 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;

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(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 pSivida in writing of our decision to abandon our license with respect to a certain product using pSivida's proprietary insert technology. We were not in breach of our agreement with pSivida as of December 31, 2017.

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 $304,000 as of our last renewal in October 2017.

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. We received regulatory approval to cease enrollment in the study from the MHRA in July 2017 due to our post market safety surveillance not showing any unexpected safety signals, and enrollment was capped at 562 patients.

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.

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Foreign Regulations

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

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

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, 2017, 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 pSivida. Pursuant to our agreement with pSivida, 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 pSivida, we also license two European patents from pSivida. 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 pSivida 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 are licensed to us from pSivida 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 have built a research and development organization that includes extensive expertise with ophthalmic product development. We operate cross-functionally and are led by an experienced research and development management team. We also access relevant market information and key opinion leaders in creating target product profiles and, when appropriate, as we advance our programs to commercialization. We engage third parties to conduct our clinical and preclinical research as we do not have research laboratories in house. In addition, we use multiple clinical sites to conduct our clinical trials. We do not depend substantially any one of these sites for our clinical trials nor do any of them conduct a major portion of our clinical trials.

We invested $4.2 million and $2.1 million in research and development during the years ended December 31, 2017 and 2016, 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 pSivida. Assuming we reach profitability, we expect to continue to develop stable formulations of ILUVIEN or any future products or product candidates, to test such formulations in preclinical studies for toxicology, safety and efficacy and to conduct clinical trials for each future product candidate. We anticipate funding these clinical trials ourselves, but we

may engage collaboration partners at certain stages of clinical development. As we obtain results from these clinical trials, we may elect to discontinue or delay them for certain products or product candidates or programs in order to focus our resources on more promising products or product candidates or programs. Completion of these clinical trials by us or our future collaborators may take several years or more, with the length of time generally varying with the type, complexity, novelty and intended use of a product candidate.

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Employees

As of December 31, 2017, we had 126 employees (118 of whom were full-time), with 28 of these employees engaged in research, development, regulatory and medical affairs activities, 25 of these employees engaged in administrative support, finance, legal and information technology and 73 of these employees engaged in sales and marketing activities.

Corporate Information

We are a Delaware corporation incorporated on June 4, 2003. Our principal executive office is located at 6120 Windward Parkway, Suite 290, Alpharetta, Georgia 30005 and our telephone number is (678) 990-5740. Our website address is www.alimerasciences.com. The information contained in our website, or that can be accessed through our website, is not part of this report and should not be considered part of this report.

Available Information

We file annual, quarterly and current reports, proxy statements, and other documents with the Securities and Exchange Commission (SEC) under the Securities Exchange Act of 1934, as amended (the Exchange Act). The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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/Corporate Governance Committee are available through our website at www.alimerasciences.com.

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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

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 distributor in France will launch ILUVIEN in that country in 2018, 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.

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., Germany, 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.

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 (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)) and
-

the quality release testing of ILUVIEN in the European Economic Area (EEA) (AndersonBrecon Limited trading as Packaging Coordinators, Inc. (PCI)).

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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 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 procedure 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.
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 entered into agreements 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.

The terms of our Loan and Security Agreement 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

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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, 2017, we had approximately $24.1 million in cash and cash equivalents. Whether this amount will be sufficient to fund our operations and support our growth will be determined by many factors, some of which are beyond our control, and we may need monies 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., Germany, the United Kingdom and Portugal and any other countries where we sell ILUVIEN directly,
- expenses relating to the commercialization of ILUVIEN;
- our research, development and general and administrative expenses;
- the level of success of the commercialization of ILUVIEN by our distributors in Italy, Spain the Middle East;
- 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.

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ILUVIEN and any future products or product candidates may not be commercially viable if in the U.S. 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 ILUVEN, 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 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, which could ultimately affect the timing of payments to us, which would adversely affect our working capital requirements.

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 EEA 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 (persons who have had an artificial lens implanted after the natural eye lens has been removed). 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

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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 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.

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 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 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 Medicines and Healthcare Regulatory Agency (MHRA). Because of Brexit, we will 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

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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. It is likely that 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.

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.

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 on our own in the U.S., Germany, the United Kingdom and Portugal, and to a lesser extent, in Ireland and Austria. 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 generate some revenues for us in 2018, if they are able to continue to successfully commercialize ILUVIEN in those territories, but the amount of that revenue will be minimal compared to the revenue generated in geographic locations where we sell ILUVIEN directly.

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As of December 31, 2017, we had 126 employees, 81 of whom were located in the U.S. and 45 of whom were located in the United Kingdom, Germany and Portugal. As of December 31, 2017, our commercial U.S. organization included 43 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;
- our inability to obtain sufficient levels of pricing and reimbursement in each jurisdiction; 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. We do not have experience in a commercial operation of this size. 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.

We may not be able to obtain regulatory approval for ILUVIEN for the Non-Infectious Posterior Uveitis (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 operations could be negatively affected.

On December 12, 2017, we filed a Type II Variation of 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 sixteen 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 seventeen 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-market safety or efficacy study of ILUVIEN for NIPU in pediatric patients and the general population. 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, it would have a material adverse effect on our business, operations and financial condition.

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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. 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 distributor will sell ILUVIEN in Italy and Spain in 2018. 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 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., 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.

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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 pSivida to intellectual property relating to ILUVIEN. Our ability to pursue the development and commercialization of ILUVIEN depends upon the continuation of our license from pSivida. This license imposes various commercialization, milestone payment, royalty payments, insurance and other obligations on us, including the right by pSivida to audit. If we fail to comply with these obligations, pSivida may have the right to terminate the license. Our license rights to pSivida's proprietary insert technology could revert to pSivida if we:

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

(b) fail to cure other breaches of material terms of our agreement with pSivida 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 pSivida in writing of our decision to abandon our license with respect to a certain product using pSivida's proprietary delivery device.

If our license with pSivida, 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 business may be adversely affected.

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.

pSivida has filed for regulatory approval in the U.S. for a drug to treat uveitis with fluocinolone acetonide (FAc), the active pharmaceutical ingredient in ILUVIEN. pSivida's drug also uses the same insert technology as ILUVIEN, but with their own inserter. If pSivida or another party that licenses the technology from pSivida obtains regulatory approval and subsequently commercializes this drug, our business may suffer.

Our license agreement with pSivida permits pSivida to develop a drug to treat posterior segment uveitis using the technology of the polyimide insert, but not the ILUVIEN inserter. pSivida has conducted clinical trials with such a drug for the treatment of NIPU and has filed a New Drug Application with the FDA in the first quarter of 2018 for this

drug (Uveitis Drug). If pSivida receives approval for the Uveitis Drug and they or another party commercializes the Uveitis Drug in the U.S., similarities of the Uveitis Drug to ILUVIEN may create confusion in the market place. In addition, pSivida may seek or receive pricing or reimbursement that is lower than ILUVIEN, which could ultimately result in lower reimbursement levels for ILUVIEN. This

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potential market place confusion or any impact to our reimbursement for ILUVIEN could have a material adverse effect on our revenues, business and operations.

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;
- are more accepted 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.

We believe that ILUVIEN competes with other products that have been or are being developed for the treatment of DME. Currently, DME is treated with biological anti-vascular endothelial growth factor (VEGF) agents, corticosteroids and laser photocoagulation.

Three biological anti-VEGF agents are used to treat DME:

Lucentis is currently approved for the treatment of DME, the treatment of diabetic retinopathy in patients with DME, the treatment of neovascular wet age-related macular degeneration (AMD) and the treatment of macular edema following retinal vein occlusion (RVO) in the U.S. In the EEA, the approval does not include diabetic retinopathy in patients with DME. Lucentis is marketed in the U.S. by Genentech and in the EEA by Novartis.

Eylea is currently approved for the treatment of DME, the treatment of diabetic retinopathy in patients with DME, the treatment of neovascular wet AMD and the treatment of macular edema following RVO in the U.S. In the EEA, the approval does not include diabetic retinopathy in patients with DME. Eylea is marketed in the U.S. by Regeneron and in the EEA by Bayer.

Avastin, an oncology product marketed by the Roche Group, is used off label by retinal specialists in both the U.S. and in certain countries of the EEA in the treatment of numerous retinal diseases, including DME, but is not formulated or approved for any ophthalmic use.

Two other drugs that are not biological anti-VEGF agents are also used to treat DME:

Ozurdex, which is within the corticosteroid class, is currently approved in the U.S. for the treatment of DME and in the EEA for visual impairment due to DME in patients who are pseudophakic or who are considered insufficiently responsive to, or are unsuitable for, non-corticosteroid therapy. Ozurdex is also indicated for macular edema resulting from RVO and for uveitis in the U.S. and the EEA. Ozurdex is marketed in the U.S. and EEA by Allergan.

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

In addition, retinal specialists are currently using laser photocoagulation to treat DME, and may continue to use these therapies in competition with ILUVIEN. Other laser, surgical or pharmaceutical treatments for DME may also compete against ILUVIEN. These competitive therapies may result in pricing pressure, even if ILUVIEN is otherwise viewed as a preferable therapy.

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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. We do not have the right to develop and sell pSivida'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, which pSivida retained. Further, our agreement with pSivida permits pSivida 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.

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 a competitive area. Several more established companies are also pursuing strategies to license or acquire products in the ophthalmic field. These established companies may have a competitive advantage over us due to their size, cash resources and greater development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable products or product candidates include the following:

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

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

If we are unable to develop suitable potential product candidates through internal research programs or by obtaining rights to novel therapeutics from third parties, our business may suffer.

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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 C. Daniel Myers, our Chief Executive Officer, Richard Eiswirth, our President and Chief Financial Officer, Philip Ashman, Ph.D., our EEA Senior Vice President and EEA Managing Director, Dave Holland, our Senior Vice President of Sales and Marketing and Kenneth Green, Ph.D., our Senior Vice President, Chief Scientific Officer and Global Head of Research and Development. These executives have significant ophthalmic, regulatory industry, sales and marketing, operational and/or corporate finance experience. The loss of any such executives or any other principal member of our management team may impair our ability to identify, develop and market ILUVIEN and any future ophthalmic products or product candidates.

In addition, our growth will require us to hire a significant number of qualified technical, commercial and administrative personnel. We face intense competition from other companies and research and academic institutions for the qualified personnel we need in our business. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain or grow our operations.

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

We launched ILUVIEN in Germany and the United Kingdom in 2013, and in the U.S. and Portugal in 2015. 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, 2017, we had accumulated a deficit of $399.1 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. Although we believe we may be cash flow positive in late 2018, we cannot assure you that we will be profitable, or cash flow positive, even if we successfully commercialize ILUVIEN or future products or product candidates. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

Our 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;

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- 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.

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

As of December 31, 2017, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $121.4 million and $161.8 million, respectively, which expire at various dates beginning in 2020 through 2037, 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 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.

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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,
- 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.

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

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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, 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 the deployment of harmful malware, ransomware, malicious websites, denial-of-service attacks, 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 system failure, accident or security breach to date that has affected our business, we cannot assure that our and our vendors' data protection efforts and our and our vendors' investment in information technology will prevent 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, it could result in a material disruption of our business operations, including, distribution and manufacturing.

For example, we sell ILUVIEN in the U.S. primarily to two distributors and in Europe utilize 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, 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

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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 73% and 75% of our consolidated revenues for the years ended December 31, 2017 and 2016, respectively.

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 pSivida, pSivida 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 or 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 pSivida 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. As of December 31, 2017, the patent rights relating to ILUVIEN licensed to us from pSivida included seven U.S. patents that expire between March 2019 and August 2027, two European patents expiring in April of 2021 and October of 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 pSivida 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 pSivida. 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 proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and

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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 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.

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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

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., Germany, the United Kingdom, Portugal, Ireland and Austria;
- 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;

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- 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.

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.

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, 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 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. The failure to maintain our listing on the Nasdaq Global Market could harm the liquidity of our common stock and could have an adverse effect on the market price of our common stock.

Holders of our Series A Convertible Preferred Stock have the ability to control 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, assuming the exercise of the outstanding warrants to purchase shares of our Series A Convertible Preferred 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 B 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

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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 have the right to sell shares of our common stock through an at-the-market offering. For example, in 2017, we sold a total of 4,203,015 shares of common stock at a weighted average price of $1.43 per share pursuant to an at-the-market offering through Cowen and Company, LLC (Cowen), which has expired. We entered into a new at-the-market offering with HC Wainwright in the fourth quarter of 2017. Pursuant to our sales agreement with HC Wainwright, we could sell additional shares of common stock in the future if we determined it was appropriate or necessary to do so, which could cause a significant reduction in the market price of our common stock.

In addition to our outstanding common stock, as of December 31, 2017, we are obligated to issue a total of 11,595,510 shares of common stock upon the exercise of outstanding common stock options granted under our equity incentive plans. Upon the exercise of these options, in accordance with their respective terms, these shares obtained by exercise may be resold freely, subject to restrictions imposed on our affiliates under the SEC’s Rule 144. If significant sales of these shares occur in short periods, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

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

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

To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. See the preceding risk factor for the descriptions of public offerings we conducted in 2016 and 2017. 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 restricted stock units (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, 2018, 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 December 31, 2017, we have reserved 414,689 shares of our common stock for issuance under our 2010 Employee Stock Purchase Plan. The number of shares eligible for purchase is replenished as of January 1st of each year in an amount equal to the shares purchased under the plan in the preceding year. As such, on January 1, 2018, an additional 79,733 shares became available for future issuance under our 2010 Employee Stock Purchase Plan.

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

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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 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;

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- 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 6,100 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 1,000 square feet of office space in each of Berlin, Germany, and Lisbon, Portugal. Our leases for these facilities in Germany and Portugal expire in 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 alleges breach of a letter agreement pursuant to which we had engaged Cantor Fitzgerald to assist us in obtaining bank or loan financing. Cantor Fitzgerald alleges that our agreement in October 2016 with Hercules Capital, Inc. (Hercules) to restructure and amend our existing $35 million debt facility with Hercules and to secure an additional $10 million in debt financing requires the payment to Cantor Fitzgerald of an advisory fee of 2% of $45 million, or $900,000, plus expenses of $24,890. Cantor Fitzgerald seeks 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 allege 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 seek compensatory and other damages, arising from, among other things, our additional out-of-pocket costs incurred as a result of Cantor Fitzgerald's breach.

Both parties have answered each other's complaint and counterclaims and have denied liability. Discovery has concluded and the parties have submitted a summary judgment schedule to the Court. No trial date has been set, and we do not expect a trial date to be set until the second quarter of 2018 at the earliest. We are not able to predict the outcome of this litigation.

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. The following table sets forth, for the periods indicated, the range of high and low sale prices of our common stock as reported by Nasdaq.

Year Ended December 31, 2017	High	Low
First quarter 2017	$1.72	$1.10
Second quarter 2017	$1.70	$1.26
Third quarter 2017	$1.65	$1.25
Fourth quarter 2017	$1.46	$1.14

Year Ended December 31, 2016	High	Low
First quarter 2016	$2.75	$1.49
Second quarter 2016	$5.15	$1.21
Third quarter 2016	$2.40	$1.01
Fourth quarter 2016	$1.54	$1.03

Stockholder Data

As of February 28, 2018, there were 32 holders of record of our common stock, and there were 69,985,666 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 2015, 2016 and 2017, we did not sell any shares of stock that were not registered under the Securities Act of 1933, as amended, other than those sales previously reported in a Current Report on Form 8-K.

ITEM 6. 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, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom. In the U.S., 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.

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.

We commercially market ILUVIEN 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.

In addition, we have entered into various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in several countries in the Middle East, as well as Italy, Spain, France, Canada, Australia and New Zealand. In the third quarter of 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 the second quarter of 2017. Our Spanish distributor began selling on a named patient basis in 2017 and is currently pursing reimbursement at the national level.

We amended and restated our license agreement with pSivida 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. 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 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 pSivida effective July 1, 2017. This royalty amount will increase to 6% upon the earliest of December 12, 2018 or the receipt of the first marketing approval for ILUVIEN for the treatment of NIPU. 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 the year ended December 31, 2017, we recognized approximately $374,000 of royalty 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, 2017, we had accumulated a deficit of $399.1 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 and, through our distributors, in the Middle East, Italy and Spain;
- continue to seek regulatory approval of ILUVIEN in other jurisdictions and for other indications;
- 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, 2017, we had approximately $24.1 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.

We used the proceeds of the 2018 Loan Agreement loan to refinance the previous loan agreement with Hercules Capital, Inc. (Hercules Term 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 9 of our notes to consolidated financial statements below.)

Our revenues for the fiscal years ended December 31, 2017 and 2016 were generated from product sales primarily in the U.S., Germany, Portugal and the United Kingdom. In the U.S., two large pharmaceutical distributors accounted for 73% and 75% of our consolidated revenues for the years ended December 31, 2017 and 2016, respectively. These 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

	Years Ended December 31,	
	2017	2016
	(In thousands)	
NET REVENUE	$35,912	$34,333
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(3,438)	(2,344)
GROSS PROFIT	32,474	31,989
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	12,844	12,375
GENERAL AND ADMINISTRATIVE EXPENSES	13,039	15,263
SALES AND MARKETING EXPENSES	23,210	29,431
DEPRECIATION AND AMORTIZATION	2,684	2,767
RECOVERABLE COLLABORATION COSTS	(2,851)	—
OPERATING EXPENSES	48,926	59,836
NET LOSS FROM OPERATIONS	(16,452)	(27,847)
INTEREST EXPENSE AND OTHER	(5,579)	(5,178)
UNREALIZED FOREIGN CURRENCY GAIN (LOSS), NET	5	(40)
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	(2,564)
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	188	2,627
NET LOSS BEFORE TAXES	(21,838)	(33,002)
PROVISION FOR TAXES	(163)	(172)
NET LOSS	$(22,001)	$(33,174)
NET LOSS PER SHARE — Basic and diluted	$(0.33)	$(0.63)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	66,993,649	52,801,603

Revenue

We began generating revenue from ILUVIEN in 2013, but do not expect positive cash flow from operations until late 2018, if at all. 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.

Net revenue increased by approximately $1.6 million, or 5%, to approximately $35.9 million for the year ended December 31, 2017, compared to approximately $34.3 million for the year ended December 31, 2016. The increase was primarily attributable to increased sales volume in the U.S. and international segments, offset by the timing of the ordering of our two large U.S. 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 pSivida 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 pSivida (before July 1, 2017). Additionally, revenue from our international distributors fluctuates depending on the timing of the shipment of ILUVIEN to the distributor and the distributors' sales of ILUVIEN to their customers.

Cost of goods sold, excluding depreciation and amortization increased by approximately $1.1 million, or 48%, to approximately $3.4 million for the year ended December 31, 2017, compared to approximately $2.3 million for the year ended December 31, 2016. The increase was primarily attributable to increases of approximately $370,000 in profit share and royalty expenses payable to pSivida and $310,000 of costs associated with certain parts used to manufacture ILUVIEN that were no longer unusable.

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Gross profit increased by approximately $500,000, or 2%, to approximately $32.5 million for the year ended December 31, 2017, compared to approximately $32.0 million for the year ended December 31, 2016. Gross margin was 90% and 93% for the years ended December 31, 2017 and 2016, respectively. The change in gross margin was primarily impacted by profit share expense and royalty expense, in each case, payable to pSivida.

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. However, once we reach profitability, we expect to incur a large percentage of our research, development and medical affairs expenses in support of our current and future technical, preclinical and clinical development programs. These expenditures are subject to numerous uncertainties in terms of both their timing and their total cost to completion.We expense both internal and external development costs as they are incurred.

Research, development and medical affairs expenses increased by approximately $400,000, or 3%, to approximately $12.8 million for the year ended December 31, 2017, compared to approximately $12.4 million for the year ended December 31, 2016. The increase was primarily attributable to a $2.9 million non-cash charge as in-process research and development expense for the additional rights to uveitis acquired from pSivida in 2017, offset by decreases of approximately $810,000 in costs associated with our five-year, post-authorization, open label European registry study of patients treated with ILUVIEN for which enrollment was terminated in early 2017, $710,000 in personnel costs, $430,000 of costs related to maintaining the U.S. and international registrations of ILUVIEN, $400,000 in scientific communication costs and $300,000 in costs associated with improving the ILUVIEN applicator.

General and Administrative Expenses

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

General and administrative expenses decreased by approximately $2.3 million, or 15%, to approximately $13.0 million for the year ended December 31, 2017, compared to approximately $15.3 million for the year ended December 31, 2016. The decrease was primarily attributable to decreases of approximately (a) $1.1 million in personnel costs and related travel and entertainment, which includes accrued shut down costs for our French operations incurred in 2016, (b) $960,000 for certain one-time costs associated with pursuing alternative debt options in 2016, including contingent advisory fees and (c) $350,000 in costs paid to pSivida in 2016.

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 decreased by approximately $6.2 million, or 21%, to approximately $23.2 million for the year ended December 31, 2017, compared to approximately $29.4 million for the year ended December 31, 2016. The decrease was primarily attributable to decreases of approximately $2.6 million in personnel costs primarily due to unfilled sales territories in the U.S., $2.3 million in marketing costs directly related to our cost saving plan we implemented in late 2016 and $900,000 in market access costs.

Recoverable Collaboration Costs

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

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Operating Expenses

As a result, total operating expenses decreased by approximately $10.9 million, or 18%, to approximately $48.9 million for the year ended December 31, 2017, compared to approximately $59.8 million for the year ended December 31, 2016. The decrease was primarily attributable to decreases of approximately $6.2 million in sales and marketing expenses and $2.3 million in general and administrative expenses, offset by an increase in the value of the Euro and British Pound Sterling, which affected operating expenses in our international segment.

Interest Expense and Other

Interest expense consists primarily of interest and amortization of deferred financing costs and debt discounts associated with our Note Payable under the Hercules Term Loan Agreement. As discussed in Note 9, we entered into a new loan facility with Solar Capital Ltd. on January 5, 2018 and refinanced the Hercules Term Loan Agreement with the proceeds. Interest income consists primarily of interest earned on our cash, cash equivalents and investments.

Interest expense and other. Interest expense and other increased by approximately $400,000, or 8%, to approximately $5.6 million for the year ended December 31, 2017, compared to approximately $5.2 million for the year ended December 31, 2016. The increase was primarily attributable to the increasing interest rate on our Hercules Term Loan Agreement, which increased with increases in the U.S. Prime Rate.

Loss on early extinguishment of debt

We recorded a loss on early extinguishment of debt of approximately $2.6 million for the year ended December 31, 2016, as a result of the Second Loan Amendment to our Hercules Term Loan Agreement.

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) 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 the years ended December 31, 2017 and 2016, we recognized gains of approximately $190,000 and $2.6 million, respectively, related to decreases in the fair value of our derivative warrant liability. The change in fair value was due to decreases in the fair market value of our underlying common stock during the years ended December 31, 2017 and 2016 and the time remaining to exercise the warrants. The rights to exercise these warrants expired on October 1, 2017.

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

We calculated net loss per share in accordance with ASC 260, Earnings Per Share. We had a net loss for both periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive. Dilutive common stock equivalents would include the dilutive effect of convertible securities, common stock options, warrants for convertible securities and warrants for common stock equivalents. Common stock equivalent securities that would potentially dilute basic EPS in the future, but were not included in the computation of diluted EPS because to do so would have been anti-dilutive, totaled approximately 31,681,900 and 34,550,161 for the years ended December 31, 2017 and 2016, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods of net loss because of their anti-dilutive effect. Therefore, for the years ended December 31, 2017 and 2016, the weighted average shares used to calculate both basic and diluted loss per share are 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 2017 or 2016.

U.S. Segment

	Years Ended December 31,	
	2017	2016
	(In thousands)	
NET REVENUE	$26,146	$25,765
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(2,482)	(1,694)
GROSS PROFIT	23,664	24,071
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	5,780	7,183
GENERAL AND ADMINISTRATIVE EXPENSES	7,580	8,918
SALES AND MARKETING EXPENSES	16,588	21,252
OPERATING EXPENSES	29,948	37,353
NET LOSS FROM OPERATIONS	$(6,284)	$(13,282)

U.S. Segment - Year ended December 31, 2017 compared to the year ended December 31, 2016

Net Revenue. Net revenue increased by approximately $300,000, or 1%, to approximately $26.1 million for the year ended December 31, 2017, compared to approximately $25.8 million for the year ended December 31, 2016. The increase was primarily attributable to a 12% increase in end user demand, offset by the timing of orders from our two large U.S. distributors, which increased inventory levels in 2016 and decreased inventory levels in 2017.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $800,000, or 47%, to approximately $2.5 million for the year ended December 31, 2017 compared to approximately $1.7 million for the year ended December 31, 2016. The increase was primarily attributable to increases of approximately $310,000 of profit share expense and royalty expense, in each case payable to pSivida and $310,000 of costs associated with certain parts used to manufacture ILUVIEN that were no longer usable.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately $1.4 million, or 19%, to approximately $5.8 million for the year ended December 31, 2017, compared to approximately $7.2 million for the year ended December 31, 2016. The decrease was primarily attributable to decreases of approximately $670,000 in personnel costs, $400,000 in scientific communication costs, $310,000 of costs related to maintaining the U.S. registration of ILUVIEN and $150,000 in costs associated with improving the ILUVIEN applicator.

General and administrative expenses. General and administrative expenses decreased by approximately $1.3 million, or 15%, to approximately $7.6 million for the year ended December 31, 2017, compared to approximately $8.9 million for the year ended December 31, 2016. The decrease was primarily attributable to decreases of approximately $960,000 for certain one-time costs associated with pursuing alternative debt options in 2016, including contingent advisory fees, $320,000 in bonus expense as we granted restricted stock unit awards to our non-field personnel in lieu of a cash bonus program in 2017, which expense is recorded in our Other segment and $270,000 in costs incurred with our third-party manufacturers of ILUVIEN. These decreases were offset by an increase of $250,000 in legal, professional fees and insurance premiums as well as increases in other various general and administrative expenses.

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Sales and marketing expenses. Sales and marketing expenses decreased by approximately $4.7 million, or 22%, to approximately $16.6 million for the year ended December 31, 2017, compared to approximately $21.3 million for the year ended December 31, 2016. The decrease was primarily attributable to decreases of approximately $2.1 million in personnel costs due to unfilled sales territories in the U.S., $1.6 million in marketing costs directly related to our cost saving plan we implemented in late 2016 and $550,000 in market access costs.

International Segment

	Years Ended December 31,	
	2017	2016
	(In thousands)	
NET REVENUE	$9,766	$8,568
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(956)	(650)
GROSS PROFIT	8,810	7,918
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	3,314	4,289
GENERAL AND ADMINISTRATIVE EXPENSES	2,605	3,517
SALES AND MARKETING EXPENSES	5,394	7,021
OPERATING EXPENSES	11,313	14,827
NET LOSS FROM OPERATIONS	$(2,503)	$(6,909)

International Segment - Year ended December 31, 2017 compared to the year ended December 31, 2016

Net Revenue. Net revenue increased by approximately $1.2 million, or 14%, to approximately $9.8 million for the year ended December 31, 2017, compared to approximately $8.6 million for the year ended December 31, 2016. The increase was primarily attributable to the increased value of the British pound sterling and the Euro as compared to the U.S. dollar and to increased sales to our international distributors.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $310,000, or 48%, to approximately $960,000 for the year ended December 31, 2017, compared to approximately $650,000 for the year ended December 31, 2016. The increase was primarily attributable to increased sales volume and profit share expense and royalty expense payable to pSivida.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately $1.0 million, or 23%, to approximately $3.3 million for the year ended December 31, 2017, compared to approximately $4.3 million for the year ended December 31, 2016. The decrease was primarily attributable to decreases of approximately $810,000 in costs associated with our five-year, post-authorization, open label European registry study of patients treated with ILUVIEN for which enrollment was terminated in early 2017 and $110,000 of costs related to maintaining our international registrations of ILUVIEN.

General and administrative expenses. General and administrative expenses decreased by approximately $900,000, or 26%, to approximately $2.6 million for the year ended December 31, 2017, compared to approximately $3.5 million for the year ended December 31, 2016. The decrease was primarily attributable to a reduction of $630,000 in personnel costs and related travel and entertainment, which includes accrued shut down costs for our French operations incurred in 2016 and $150,000 in costs paid to pSivida in 2016.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately $1.6 million, or 23%, to approximately $5.4 million for the year ended December 31, 2017, compared to approximately $7.0 million for the year ended December 31, 2016. The decrease was primarily attributable to a decrease of approximately $700,000 in marketing costs, $520,000 of personnel costs and $350,000 in market access costs.

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Other Segment

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, increased by approximately $100,000, or 18%, to $5.0 million for the year ended December 31, 2017, compared to $4.9 million for the year ended December 31, 2016.

Depreciation and amortization decreased by approximately $100,000, or 3%, to approximately $2.7 million for the year ended December 31, 2017, compared to approximately $2.8 million for the year ended December 31, 2016.

In July 2017, we acquired the license rights to uveitis from pSivida 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 pSivida'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 in the third quarter of 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. As a result, there was no impact on our operating loss or net loss for the year ended December 31, 2017.

Liquidity and Capital Resources

Since inception, we have incurred recurring losses, negative cash flow from operations and have accumulated a deficit of $399.1 million through December 31, 2017. 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. In 2015, we sold a total of 268,978 shares of our common stock at a weighted average price of $3.07 per share through our at-the-market offering, for total gross proceeds of approximately $825,000, reduced by approximately $100,000 of related commissions, issuance costs and placement agent fees. We used the net proceeds from this offering for general corporate purposes and working capital.

In 2016, we sold a total of 662,779 shares of our common stock at a weighted average price of $1.83 per share through our at-the-market offering, for total gross proceeds of approximately $1.2 million, reduced by approximately $60,000 of related commissions, issuance costs and placement agent fees. In 2017, we sold 4,203,015 shares of our common stock at a weighted average price of $1.43 per share through our 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.

In August 2016, we closed an underwritten public offering pursuant to which we sold and issued 18,900,000 shares of our common stock at a price to the public of $1.40 per share, resulting in gross proceeds of $26,460,000, offset by payments of approximately $1.3 million of related issuance costs. We used the net proceeds from this offering for general corporate purposes and working capital.

In October 2017, we entered into a sales agreement with H.C. Wainwright & Co., LLC (HCW) to offer shares of our common stock from time to time through HCW, as our sales agent, for the offer and sale of the shares up to an aggregate offering price of $25.0 million. We have no obligation to sell shares under this sales agreement with HCW and we currently do not have plans to sell shares under this agreement. The Sales Agreement provides that HCW will

be entitled to compensation for its services in an amount up to 3.0% of gross proceeds from the sale of Placement Shares, and also provided HCW with customary indemnification rights.

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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 previous Hercules Term Loan Agreement and for related expenses. We expect to use the remaining loan proceeds to provide additional working capital for general corporate purposes. (See Note 9 of our notes to consolidated financial statements below.)

As of December 31, 2017, we had approximately $24.1 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 in the first quarter of 2017 and in Ireland in the fourth quarter of 2017. Due to the limited revenue generated by ILUVIEN to date, 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 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.

For the year ended December 31, 2017, cash used in our operations of $12.8 million was primarily due to our net loss of $21.9 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 the year ended December 31, 2016, cash used in our operations of $25.1 million was primarily due to our net loss of $33.2 million, which is subject to further adjustment for non-cash items. These items included approximately $2.6 million for a non-cash gain for the change in the value of our derivative warrant liability, charges of approximately $4.9 million for stock compensation expense, $2.8 million of depreciation and amortization expense and $1.0 million of amortization costs associated with our debt discount. Further reducing cash from operations was an increase in accounts receivable of $4.1 million. This reduction was offset by a $2.1 million increase in accounts payable, accrued expenses and other current liabilities and a $1.0 million decrease in inventory. Accounts receivable increased primarily due to an increase in U.S. sales volume as ILUVIEN continued to gain market acceptance during the year ended December 31, 2016. Accounts payable, accrued expenses and other current liabilities increased primarily due to increases of $600,000 in amounts payable for one-time fees associated with pursuing alternative debt options, including contingent advisory fees, $540,000 in accrued costs associated with closing operations in France, $390,000 in amounts payable to the investigators and CROs in our ongoing clinical studies and $220,000 in accrued compensation expenses including commissions in the three months ended December 31, 2016 that were earned by, but not paid to, our sales force.

For the year ended December 31, 2017, net cash used in our investing activities was approximately $240,000, which was primarily due to the purchase of manufacturing equipment and software.

For the year ended December 31, 2016, net cash used in our investing activities was approximately $190,000, which was primarily due to the purchase of property and equipment, primarily the purchase of accounts payable software and leasehold improvements.

For the year ended December 31, 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 by

$180,000 of related commissions, issuance costs and placement agent fees.

For the year ended December 31, 2016, net cash provided by our financing activities was approximately $25.4 million. In August 2016, we closed an underwritten public offering in which we sold and issued 18,900,000 shares of our common stock at a price to the public of $1.40 per share, resulting in gross proceeds of $26,460,000. In June and July 2016, we sold a total of 662,779 shares of our common stock through our at-the-market offering, resulting in total gross proceeds of $1.2 million. Offsetting these increases were payments of approximately $1.3 million relating to common stock issuance costs, $1.1 million associated with the amendments of our Hercules Term Loan Agreement and $230,000 in payments on capital leases.

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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.

Product Revenue

We recognize revenue from our product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss have passed to the customer, the price is fixed or determinable, and collection from the customer is reasonably assured. Title passes generally upon receipt by the customer. Precise information regarding the receipt of product by the customer is not always readily available. In these cases, we estimate the date of receipt based upon shipping policies by geographic location. Our shipping policies require delivery within 24 hours of shipment in most instances. Taxes that are collected from customers and remitted to governmental authorities, primarily in Europe, are not included in revenue.

In the U.S., we sell ILUVIEN to a limited number of pharmaceutical distributors who in turn sell the product downstream to physician offices, pharmacies and hospitals. Revenue is recorded net of provisions for estimated rebates, wholesaler chargebacks, distribution related fees, and other deductions. Calculating these provisions involves management’s estimates and judgments. We review our estimates of rebates, chargebacks and other applicable provisions each period and record any necessary adjustments in the current period’s net product sales.

In the international segment, in countries where we sell direct we recognize revenue at the time of sale to hospitals, pharmacies, and physician practices. Revenue is recorded net of provisions for contractual rebates, cash discounts, and other deductions. In countries where we utilize a distributor, we recognize revenue in accordance with the terms of the respective distributor agreements, which may reflect revenue recognition upon the initial purchase of product by the distributor or upon sale to the end user at which time we recognize royalty revenue, or both. From time to time, we may recognize milestone revenue as it is earned.

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 due to 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. In the event that 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, 2017, we had federal NOL carry-forwards of approximately $121.4 million and state NOL carry-forwards of approximately $161.8 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 and the state NOL carry-forwards will expire at various dates between 2020 and 2037.

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, 2017 and December 31, 2016 are approximately $52,000 and $59,000, respectively. Both balances relate to research and development tax credits. In accordance with ASC 740-10, such attributes are reduced 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 2014 to 2017 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

From time to time, the Financial Accounting Standards Board (FASB) or other standard setting bodies issue accounting pronouncements that we adopt as of the specified effective date. Unless otherwise discussed, we believe that the recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Adoption of New Accounting Standards

In August 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. ASU 2014-15 requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The adoption of this guidance did not have a material impact on our financial statements.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. This update requires entities to measure inventory at the lower of cost and net realizable value. Net realizable value is the

estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. This ASU is

effective for annual reporting periods beginning after December 15, 2016 and interim periods within those years. The adoption of this guidance did not have a material impact on our financial statements.

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 adoption of this guidance did not have a material impact on our 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 adoption of this guidance did not have a material impact on our financial statements.

Accounting Standards Issued but Not Yet Effective

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB has subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards are effective for interim and annual periods beginning on January 1, 2018. The new standards are required to be adopted using either a full-retrospective or a modified-retrospective approach. We will adopt these standards using the modified-retrospective approach beginning in 2018. We have completed our impact assessment and do not anticipate a material impact to net revenue in our Consolidated Statements of Operations, accounting policies, business processes, internal controls or disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This standard requires all leases with durations greater than twelve months to be recognized on the balance sheet and is effective for interim and annual reporting periods beginning after December 15, 2018, although early adoption is permitted. The primary effect of adoption will be the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. In addition, the standard will require that we update our systems, processes and controls we use to track, record and account for our lease portfolio. We are currently in the process of evaluating the impact of the adoption on our financial statements.

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ITEM 7A. QUALITATIVE AND QUANTITATIVE 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 65 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, 2017.

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, 2017, 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, 2017.

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, 2017 and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for the year ended December 31, 2017, has issued an attestation report on the Company's internal control over financial reporting, which is included on page 57.

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 2017 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 Shareholders
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, 2017, 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, 2017, 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, 2017, and our report dated March 2, 2018 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.

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

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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

March 2, 2018

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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 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of fiscal year ended December 31, 2017 (2018 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 2018 Proxy Statement and is incorporated herein by reference, except that information required by Item 407(e)(5) of Regulation S-K will be deemed furnished in this Form 10-K and will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

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 2018 Proxy Statement and is incorporated herein by reference.

Equity Compensation Plan Information

The following table provides information as of December 31, 2017, 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	12,434,795	(1)	$ 2.90	(2)	1,452,407	(3)
Equity compensation plans not approved by security holders	—		—		—	
Total	12,434,795		$ 2.90		1,452,407	

(1) Of these shares, 10,971,913 were subject to options then outstanding under the 2010 Plan, 566,838 were subject to options then outstanding under the 2005 Plan, 56,759 were subject to options then outstanding under the 2004 Plan and 839,285 were outstanding restricted stock units.

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

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(3) Represents 1,037,718 shares of common stock available for issuance under our 2010 Plan and 414,689 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, 2018, 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, 2018, an additional 79,733 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 2018 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 2018 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.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
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, 2017 and 2016, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, 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, 2017, 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 March 2, 2018 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 3 to the consolidated financial statements, the Company has incurred recurring losses, negative cash flows from operations, and has an accumulated deficit of $399,075,000 as of December 31, 2017. These conditions, along with the other matters as set forth in Note 3, 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 3. 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.

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

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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
March 2, 2018

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ALIMERA SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS
AS OF DECEMBER 31, 2017 AND 2016

	December 31, 2017	2016
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 24,067	$ 30,979
Restricted cash	34	31
Accounts receivable, net	11,435	13,839
Prepaid expenses and other current assets	2,278	2,107
Inventory (Note 4)	1,508	446
Total current assets	39,322	47,402
NON-CURRENT ASSETS:		
Property and equipment, net	1,410	1,787
Intangible asset, net	18,664	20,604
Deferred tax asset	528	436
TOTAL ASSETS	$ 59,924	$ 70,229
CURRENT LIABILITIES:		
Accounts payable	$ 5,905	$ 4,986
Accrued expenses (Note 7)	3,582	3,758
Derivative warrant liability	—	188
Capital lease obligations	184	191
Total current liabilities	9,671	9,123
NON-CURRENT LIABILITIES:		
Note payable (Note 9)	34,365	33,084
Capital lease obligations — less current portion	203	274
Other non-current liabilities	766	2,162
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $.01 par value — 10,000,000 shares authorized at December 31, 2017 and 2016:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 600,000 issued and outstanding at December 31, 2017 and 2016; liquidation preference of $24,000 at December 31, 2017 and 2016	19,227	19,227
Series B Convertible Preferred Stock, 8,417 authorized and 8,416.251 issued and outstanding at December 31, 2017 and 2016; liquidation preference of $50,750 at December 31, 2017 and 2016	49,568	49,568
Common stock, $.01 par value — 150,000,000 shares authorized, 69,146,381 shares issued and outstanding at December 31, 2017 and 64,862,904 shares issued and outstanding at December 31, 2016	691	649
Additional paid-in capital	341,622	330,781
Common stock warrants	3,707	3,707
Accumulated deficit	(399,075)	(377,074)
Accumulated other comprehensive loss — foreign currency translation adjustments	(821)	(1,272)
TOTAL STOCKHOLDERS' EQUITY	14,919	25,586
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 59,924	$ 70,229

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	Years Ended December 31,	
	2017	2016
	(In thousands, except share and per share data)	
NET REVENUE	$35,912	$34,333
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(3,438)	(2,344)
GROSS PROFIT	32,474	31,989
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	12,844	12,375
GENERAL AND ADMINISTRATIVE EXPENSES	13,039	15,263
SALES AND MARKETING EXPENSES	23,210	29,431
DEPRECIATION AND AMORTIZATION	2,684	2,767
RECOVERABLE COLLABORATION COSTS	(2,851)	—
OPERATING EXPENSES	48,926	59,836
NET LOSS FROM OPERATIONS	(16,452)	(27,847)
INTEREST EXPENSE AND OTHER	(5,579)	(5,178)
UNREALIZED FOREIGN CURRENCY GAIN (LOSS), NET	5	(40)
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	(2,564)
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	188	2,627
NET LOSS BEFORE TAXES	(21,838)	(33,002)
PROVISION FOR TAXES	(163)	(172)
NET LOSS	$(22,001)	$(33,174)
NET LOSS PER SHARE — Basic and diluted	$(0.33)	$(0.63)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	66,993,649	52,801,603

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	Years Ended December 31,	
	2017	2016
	(In thousands)	
NET LOSS	$(22,001)	$(33,174)
OTHER COMPREHENSIVE INCOME (LOSS)		
Foreign currency translation adjustments	451	(124)
TOTAL OTHER COMPREHENSIVE INCOME (LOSS)	451	(124)
COMPREHENSIVE LOSS	$(21,550)	$(33,298)

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, 2017 AND 2016

	Common Stock		Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Additional Paid-In Capital	Common Stock Warrants	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
	(In thousands, except share data)										
BALANCE — December 31, 2015	45,005,833	$450	600,000	$19,227	8,416	$49,568	$299,376	$2,747	$(343,900)	$(1,148)	$26,320
Issuance of common stock, net of issuance costs	19,645,539	197	—	—	—	—	26,225	—	—	—	26,422
Exercise of stock options	211,532	2	—	—	—	—	291	—	—	—	293
Modification of common stock warrants	—	—	—	—	—	—	—	590	—	—	590
Issuance of common stock warrants	—	—	—	—	—	—	—	370	—	—	370
Stock-based compensation	—	—	—	—	—	—	4,889	—	—	—	4,889
Net loss	—	—	—	—	—	—	—	—	(33,174)	—	(33,174)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	(124)	(124)
BALANCE — December 31, 2016	64,862,904	649	600,000	19,227	8,416	49,568	330,781	3,707	(377,074)	(1,272)	25,586
Issuance of common stock, net of issuance costs	4,282,748	42	—	—	—	—	5,859	—	—	—	5,901
Exercise of stock options	729	—	—	—	—	—	1	—	—	—	1
Stock-based compensation	—	—	—	—	—	—	4,981	—	—	—	4,981
Net loss	—	—	—	—	—	—	—	—	(22,001)	—	(22,001)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	451	451
BALANCE — December 31,	69,146,381	$691	600,000	$19,227	8,416	$49,568	$341,622	$3,707	$(399,075)	$(821)	$14,919

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See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	Years Ended December 31,	
	2017	2016
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(22,001)	$(33,174)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,684	2,767
Inventory reserve	34	104
Unrealized foreign currency transaction loss	(5)	40
Amortization of debt discount	1,416	1,038
Deferred taxes (benefit)	(92)	(213)
Loss on early extinguishment of debt	—	2,564
Stock compensation expense	4,981	4,889
Change in fair value of derivative warrant liability	(188)	(2,627)
Changes in assets and liabilities:		
Accounts receivable	2,610	(4,096)
Prepaid expenses and other current assets	(67)	556
Inventory	(1,052)	1,000
Accounts payable	644	1,073
Accrued expenses and other current liabilities	(271)	1,035
Other long-term liabilities	(1,567)	(55)
Net cash used in operating activities	(12,874)	(25,099)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(238)	(186)
Net cash used in investing activities	(238)	(186)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	1	292
Proceeds from sale of common stock	6,084	27,763
Payment of issuance cost of common stock	(183)	(1,341)
Payment of debt issuance costs (Note 9)	—	(1,069)
Payments on capital lease obligations	(182)	(227)
Changes in restricted cash	3	6
Net cash provided by financing activities	5,723	25,424
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS	477	(235)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(6,912)	(96)
CASH AND CASH EQUIVALENTS — Beginning of year	30,979	31,075
CASH AND CASH EQUIVALENTS — End of year	$24,067	$30,979
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$4,117	$3,958
Cash paid for income taxes	$74	$193
Supplemental schedule of noncash investing and financing activities:		
Property and equipment acquired under capital leases	$282	$76

Note payable end of term payment accrued but unpaid	$1,400	$1,400

There were no dividend payments made for the years ended December 31, 2017 and 2016.

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, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom. In the U.S., 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. In the fourth quarter of 2016, the Company requested approval to modify its protocol to cap enrollment in the study due to its post market safety surveillance not showing any unexpected safety signals. The Company received regulatory approval to cap enrollment in the study from the Medicines & Healthcare products Regulatory Agency (MHRA) in July 2017. As of December 31, 2017, 562 patients were enrolled in this study.

The Company commercially markets ILUVIEN in the U.S., Germany, the United Kingdom, Portugal, Austria and Ireland. The Company began selling ILUVIEN in Austria in the first quarter of 2017 and in Ireland in the fourth quarter of 2017.

In addition, the Company has entered into various agreements under which distributors will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in several countries in the Middle East, as well as France, Italy, Spain, Australia, New Zealand and Canada. In the third quarter of 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 the second quarter of 2017. As of December 31, 2017, the Company has recognized sales of ILUVIEN to the Company's distributors in the Middle East, Italy and Spain.

In July 2017, the Company amended its license with pSivida US, Inc. (pSivida) 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 8). 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.

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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 all 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 $24,067,000 and $30,979,000 as of December 31, 2017 and 2016, respectively, with approximately 93.0% and 92.0% of these balances, respectively held in U.S. based financial institutions. In addition, under its loan and security agreement with Hercules Capital, Inc. (Hercules), the Company was required to maintain minimum balances in specific bank accounts as collateral which are recorded as restricted cash (see Note 9).

Product Revenue — The Company recognizes revenue from its product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss have passed to the customer, the price is fixed or determinable, and collection from the customer is reasonably assured. Title passes generally upon receipt by the customer. Precise information regarding the receipt of product by the customer is not always readily available. In these cases, the Company estimates the date of receipt based upon shipping policies by geographic location. The Company's shipping policies require delivery within 24 hours of shipment in most instances. Taxes that are collected from customers and remitted to governmental authorities, primarily in Europe, are not included in revenue.

In the U.S., the Company sells ILUVIEN to a limited number of pharmaceutical distributors who in turn sell the product downstream to pharmacies and physician practices. Revenue is recorded net of provisions for estimated rebates, wholesaler chargebacks, distribution related fees, and other deductions. Calculating these provisions involves management's estimates and judgments. The Company reviews its estimates of rebates, chargebacks and other applicable provisions each period and records any necessary adjustments in the current period's net product sales.

In the international segment, the Company sells ILUVIEN to hospitals, pharmacies and physician practices. Revenue is recorded net of provisions for contractual rebates, cash discounts, and other deductions. Additionally, in the international segment, the Company recognizes royalties from corporate partners based on third-party sales of ILUVIEN, and these royalties are recorded in accordance with contract terms when third-party results are reliably measurable and collectability is reasonably assured. Corporate partner revenues are composed mainly of royalties, license fees, and milestones earned.

Accounts Receivable and Allowance for Doubtful Accounts — Accounts receivable are generated through sales primarily to 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. Provisions for doubtful accounts are charged to operations at the time management determines these 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, 2017 and 2016, the Company had no reserve for doubtful accounts.

Inventory — Inventories are stated at the lower of cost or market 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 6).

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, four years; software and information technology hardware, three years; and office equipment and leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease life.

Impairment — Property and equipment and definite lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When indicators of impairment are present, the Company evaluates the carrying amount of such assets in relation to the operating performance and future estimated undiscounted net cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. The assessment of the recoverability of assets will be impacted if estimated future operating cash flows are not achieved.

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 $4,216,000 and $2,146,000 for the years ended December 31, 2017 and 2016, respectively. During the year ended December 31, 2017, the Company expensed $2,851,000 of in-process Research and Development Expense in connection with the New Collaboration Agreement (see Note 8).

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 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.

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 do 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 agreements provide for settlement in Series A Convertible Preferred Shares or common 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 are exercisable and/or the exercise price of the

warrants are subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The warrant exercise price no longer can be adjusted at some point in the future. The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying common stock. Such financial instruments are initially recorded at fair value with subsequent changes in fair value recorded as a component of change in fair value of derivative warrant liability in the consolidated statements of operations in each reporting period. If these instruments subsequently meet the requirements for equity classification, the Company reclassifies the fair value to equity. As of December 31, 2016, these warrants represented the only outstanding derivative instruments issued or held by the Company. The rights to exercise these warrants expired on October 1, 2017.

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

Earnings Per Share (EPS) — Basic EPS is calculated in accordance with ASC 260, Earnings per Share by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated in accordance with ASC 260 by adjusting weighted average common shares outstanding for the dilutive effect of common stock options, warrants, convertible preferred stock and accrued but unpaid convertible preferred stock dividends. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive. Common stock equivalent securities that would potentially dilute basic EPS in the future, but were not included in the computation of diluted EPS because to do so would have been anti-dilutive, were as follows:

	Years Ended December 31,	
	2017	2016
Series A convertible preferred stock	9,022,556	9,022,556
Series B convertible preferred stock	8,416,251	8,416,251
Series A convertible preferred stock warrants	—	4,511,279
Common stock warrants	1,795,663	1,795,663
Stock options	11,595,510	10,804,412
Restricted stock units	839,285	—
Total	31,669,265	34,550,161

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 since it is not reviewed by the Company's chief operating decision maker. The Company has three reportable segments, U.S., International and

Other.

Modification of Segment Footnote — The Company modified its segment footnote for the year ended December 31, 2016 for an immaterial change and removed, within the segment footnote, certain non-cash expenses including $4,889,000 of stock-based compensation expense and $2,767,000 of depreciation and amortization from the Company's U.S. and International segments. These amounts are appropriately classified as Other within the segment footnote of these consolidated financial statements. Additionally, in the Company's Annual Report on Form 10-K filing for the year ended December 31, 2016, the Company disclosed that the Company's chief operating decision maker separately managed and evaluated each segment primarily upon net loss from operations. The modification made in these consolidated financial statements clarifies that the chief operating decision maker manages and evaluates each segment based on net loss from operations adjusted for certain non-cash items, such as stock-based compensation expense and depreciation and amortization.

Adoption of New Accounting Standards — In August 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The adoption of this guidance did not have a material impact on the Company's financial statements.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. This update requires entities to measure inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. This ASU is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those years. The adoption of this guidance did not have a material impact on the Company's financial statements.

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 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 adoption of this guidance did not have a material impact on the Company's financial statements.

Accounting Standards Issued but Not Yet Effective — In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB has subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards are effective for interim and annual periods beginning on January 1, 2018. The new standards are required to be adopted using either a full-retrospective or a modified-retrospective approach. We will adopt these standards using the modified-retrospective approach beginning in 2018. We have completed our impact assessment and do not anticipate a material impact to net revenue in our Consolidated Statements of Operations, accounting policies, business processes, internal controls or disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This standard requires all leases with durations greater than twelve months to be recognized on the balance sheet and is effective for interim and annual reporting periods beginning after December 15, 2018, although early adoption is permitted. The primary effect of adoption will be the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. In addition, the standard will require that we update our systems, processes and controls we use to track, record and account for our lease portfolio. The Company is currently in the process of evaluating the impact of the adoption on the Company's financial statements.

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

3. 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 $399,075,000 from the Company's inception through December 31, 2017. As of December 31, 2017, the Company had approximately $24,067,000 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.

During the year ended December 31, 2017, the Company raised $6,001,000 of additional equity via the Company's at-the-market offering facility, which expired on August 13, 2017, for operations and to ensure compliance with its debt covenants. In management's opinion, the uncertainty regarding the Company's future revenues, and its ability to maintain compliance with its debt covenants raises doubt about the Company's ability to continue as a going concern without access to alternate or additional debt or equity financing, over the course of the next twelve months.

In particular, the Company must maintain compliance with the covenants of its debt agreement (see Note 9). To meet the Company's future working capital needs, the Company may need to raise additional debt or equity financing. The Company may be able to access capital under the Company's current at-the-market offering facility, which has $25,000,000 of remaining availability. 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 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)

4. INVENTORY

Inventory consisted of the following:

	December 31,	
	2017	2016
	(In thousands)	
Component parts (1)	$ 404	$ 115
Work-in-process (2)	587	18
Finished goods	517	313
Total inventory	1,508	446

(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.

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31,	
	2017	2016
	(In thousands)	
Furniture and fixtures	$392	$391
Office equipment	864	838
Automobiles	663	762
Software	1,122	973
Leasehold improvements	482	460
Manufacturing equipment	1,088	997
Total property and equipment	4,611	4,421
Less accumulated depreciation and amortization	(3,201)	(2,634)
Property and equipment — net	$1,410	$1,787

Depreciation and amortization expense associated with property and equipment totaled $744,000 and $822,000 for the years ended December 31, 2017 and 2016, respectively.

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

6. 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 pSivida a milestone payment of $25,000,000 (the pSivida Milestone Payment) in October 2014 (see Note 8).

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 $18,664,000 and $20,604,000 as of December 31, 2017 and 2016, respectively, and amortization expense was $1,940,000 and $1,946,000 for the years ended December 31, 2017 and 2016, respectively.

The estimated remaining amortization as of December 31, 2017 is as follows (in thousands):

Years Ending December 31	
2018	$1,940
2019	1,940
2020	1,946
2021	1,940
2022	1,940
Thereafter	8,958
Total	$18,664

7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2017	2016
	(In thousands)	
Accrued clinical investigator expenses	$696	$1,122
Accrued compensation expenses	511	1,020
Accrued rebate, chargeback and other revenue reserves	305	809
Accrued End of Term Payment (see Note 9)	1,400	—
Other accrued expenses	670	807
Total accrued expenses	$3,582	$3,758

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

8. LICENSE AGREEMENTS

pSivida Agreement

The Company entered into an agreement with pSivida for the use of fluocinolone acetonide (FAc) in pSivida's proprietary insert technology in February 2005. This agreement was subsequently amended a number of times (as amended, the pSivida Agreement). The pSivida 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 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, as defined by the 2008 Agreement. In connection with the 2008 Agreement, the Company was entitled to recover 20% of commercial losses associated with ILUVIEN, as defined in the pSivida Agreement, that could be offset in any future quarter out of payments of pSivida's share of net profits (the Future Offset). As of December 31, 2016, the total Future Offsets available to reduce future net profit payments to pSivida, as defined in the 2008 Agreement, was $24,475,000. In connection with the New Collaboration Agreement discussed below, the Company and pSivida agreed to cap the Future Offset amount as of June 30, 2017 at $25,000,000. The Future Offset was not previously reflected on the Company's balance sheet due to the uncertainty of future realizability.

New Collaboration Agreement - Second Amended and Restated Collaboration Agreement

On July 10, 2017, the Company and pSivida entered into a Second Amended and Restated Collaboration Agreement (the New Collaboration Agreement), which amends and restates the pSivida Agreement.

Prior to entering into the New Collaboration Agreement, the Company held the worldwide license from pSivida for the use of pSivida'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 allows the Company to also pursue an indication for posterior uveitis for ILUVIEN in those territories.

The New Collaboration Agreement converts 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 pSivida July 1, 2017. This royalty amount will increase to 6% upon the earliest of December 12, 2018 or the receipt of the first marketing approval for ILUVIEN for the treatment of NIPU. The Company will pay an additional 2% royalty on global net revenues and other related consideration in excess of $75,000,000 in any year. During the year ended December 31, 2017, the Company recognized approximately $621,000 of royalty and profit share expense, which is included in cost of goods sold, excluding depreciation and amortization. As of December 31, 2017, approximately $184,000 of this royalty and profit share expense was included in the Company's accounts payable. During the year ended December 31, 2016, the Company recognized approximately $254,000 of profit share expense.

The New Collaboration Agreement did not require an upfront cash payment by the Company. In connection with the New Collaboration Agreement, the Company agreed to forgive $10,000,000 of the total $25,000,000 of the Future Offset at the amendment date. Following the signing of the New Collaboration Agreement, the Company retains a right to recover up to the remaining $15,000,000 of the Future Offset. The Company will be able to recover up to $15,000,000 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. 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 pSivida the difference in cash.

The Company valued the transaction utilizing a present value analysis at approximately $2,851,000. Because there was no approved indication for ILUVIEN for uveitis at the time, the Company expensed the $2,851,000 as a non-cash charge as in-process Research and Development Expense in the third quarter of 2017. The Company 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 the Company's operating loss or net loss for the year ended December 31, 2017.

General Discussion of pSivida Agreement

The Company's license rights to pSivida's proprietary insert technology could revert to pSivida if the Company were to (i) fail twice to cure its breach of an obligation to make certain payments to pSivida following receipt of written notice thereof; (ii) fail to cure other breaches of material terms of the pSivida 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 pSivida in writing of its decision to abandon its license with respect to a certain product using pSivida's proprietary insert technology.

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

9. LOAN AGREEMENTS

Hercules Loan Agreement

2014 Loan Agreement

In April 2014, Alimera Sciences Limited (Limited), a subsidiary of the Company, entered into a loan and security agreement (2014 Loan Agreement) with Hercules providing for a term loan of up to $35,000,000 (2014 Term Loan), which Limited and Hercules amended in November 2015 (the First Loan Amendment), March 2016 (the Second Loan Amendment), May 2016 (the Third Loan Amendment), October 2016 (the Fourth Loan Amendment) and May 2017 (the Fifth Loan Amendment and, collectively with the 2014 Loan Agreement, the First Loan Amendment, the Second Loan Amendment, the Third Loan Amendment and the Fourth Loan Amendment, the Hercules Term Loan Agreement). Under the 2014 Loan Agreement, Hercules made an advance in the initial principal amount of $10,000,000 to Limited at closing to provide Limited with additional working capital for general corporate purposes and to repay a 2013 term loan with Silicon Valley Bank. Hercules made an additional advance of $25,000,000 to Limited in September 2014, following the approval of ILUVIEN by the FDA to fund the pSivida Milestone Payment. The 2014 Loan Agreement provided for interest only payments through November 2015. Interest on the 2014 Term Loan accrued at a floating per annum rate equal to the greater of (i) 10.90%, or (ii) the sum of (A) 7.65%, plus (B) the prime rate. Following the interest only period the 2014 Term Loan was due and payable to Hercules in equal monthly payments of principal and interest through May 1, 2018.

First Loan Amendment

In November 2015, Limited and Hercules amended the 2014 Loan Agreement to extend the interest only payments through May 2017. In connection with the First Loan Amendment, Limited paid to Hercules an amendment fee of $262,500 and agreed to make an additional payment of $1,050,000, equal to 3% of the 2014 Term Loan at the time of the final payment (End of Term Payment).

Limited and the Company, on a consolidated basis with the Company’s other subsidiaries (the Consolidated Group), agreed to customary affirmative and negative covenants and events of default in connection with these arrangements. The occurrence of an event of default could result in the acceleration of Limited’s obligations under the Hercules Term Loan Agreement and an increase to the applicable interest rate and would have permitted Hercules to exercise remedies with respect to the collateral under the Hercules Term Loan Agreement. In connection with the First Loan Amendment, Limited agreed to covenants regarding certain revenue thresholds and a liquidity threshold.

Second Loan Amendment

In January 2016, the revenue threshold covenant was not met by the Consolidated Group and as a result, in March 2016, Limited and Hercules entered into the Second Loan Amendment, which further amended certain terms of the 2014 Loan Agreement. In conjunction with the Second Loan Amendment, Hercules waived this covenant violation. The Second Loan Amendment adjusted the revenue covenant to a rolling three-month calculation, first measured for the three months ended May 31, 2016. In addition, the Second Loan Amendment increased the liquidity covenant. Upon execution of the Second Loan Amendment, Limited paid Hercules an amendment fee of $350,000 and agreed to increase the End of Term Payment to $1,400,000 from $1,050,000, which was scheduled to be paid in May 2018. The Company concluded that the Second Loan Amendment resulted in a substantial modification of the terms of debt when considered with the First Loan Amendment in accordance with the guidance in ASC 470-50, Debt. As a result, the Company accounted for the Second Loan Amendment as an extinguishment and recognized a loss on early extinguishment of debt of approximately $2,564,000 within the consolidated statement of operations for the year ended December 31, 2016. The loss on early extinguishment consisted primarily of the unamortized debt discount associated with the warrant and debt issuance costs incurred prior to the Second Loan Amendment, the incremental fair value of the warrant as a result of modifying the terms of the warrant and the debt issuance costs of $360,000 paid to Hercules for the Second Loan Amendment.

Third Loan Amendment and July 2016 Waiver

In May 2016, Limited and Hercules entered into the Third Loan Amendment to expand the definition of liquidity to allow for the inclusion of cash of up to $2,000,000 in bank accounts outside of the U.S. and the United Kingdom. In July 2016, Limited obtained a waiver of the requirements of the liquidity covenant (the Waiver) because the Consolidated Group was not in compliance with the liquidity covenant as of June 30, 2016. The Waiver cured the default of the liquidity covenant then existing under the Hercules Term Loan Agreement and decreased the liquidity requirement. In addition,

the Waiver modified the three-month revenue covenant so that it was not measured at July 31, 2016 and reduced the three-month revenue target to be measured at August 31, 2016. Following execution of the Waiver, Limited incurred a weekly ticking fee equal to 0.05% multiplied by the outstanding principal amount through the closing of the Company's public offering in August 2016 (Note 13), totaling $65,000. Further, Limited paid Hercules a fee of $350,000 associated with the Waiver.

Fourth Loan Amendment

In October 2016, Limited entered into the Fourth Loan Amendment with Hercules, which further amended certain terms of the Hercules Term Loan Agreement. Pursuant to the terms of the Fourth Loan Amendment, Hercules agreed to provide up to an additional $10,000,000 to Limited with (i) the first $5,000,000 to have been available at Limited's option through June 30, 2017 subject to (A) the Consolidated Group's achievement of $12,000,000 in trailing three month net product revenue and (B) no event of default having occurred since October 20, 2016 (the Effective Date) and (ii) the second $5,000,000 to have been available at Limited's option through December 31, 2017 subject to (X) the Consolidated Group's achievement of $15,000,000 in trailing three month net product revenue, (Y) no event of default having occurred since the Effective Date and (Z) the prior $5,000,000 having been advanced to Limited (the Additional Advances and, together with the 2014 Term Loan, the Term Loan). The Consolidated Group did not achieve the trailing three-month net product revenue threshold prior to June 30, 2017 and as a result the additional $10,000,000 was not available to Limited.

The Fourth Loan Amendment provided for interest only payments through November 30, 2018 (the Interest-Only Period). Pursuant to the Fourth Loan Amendment, interest on the Term Loan was to accrue 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 Term Loan was to bear "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 Term Loan so as to increase the outstanding principal balance of the Term Loan on each payment date for the Term Loan, which amount was to be payable when the aggregate outstanding principal amount of the Term Loan matured. The Term Loan was scheduled to be due and payable to Hercules in 24 equal monthly payments of principal and interest following the Interest-Only Period beginning on December 1, 2018 and was to mature in full on November 1, 2020. The interest rate on the Hercules Term Loan Agreement was 12.0% as of December 31, 2017.

Limited paid Hercules a facility charge of $337,500 and reimbursed Hercules for legal and diligence fees incurred in connection with the Fourth Loan Amendment, which provided that if Limited were to prepay the Term Loan, it would pay Hercules a prepayment penalty (i) if such amounts were prepaid in any of the first 12 months following the Effective Date, equal to 3.0% of the principal amount of the Term Loan being repaid, (ii) if such amounts were prepaid after 12 months but prior to 24 months following the Effective Date, equal to 2.0% of the principal amount of the Term Loan being repaid, and (iii) if such amounts were prepaid at any time thereafter, equal to 1.0% of the principal amount of the Term Loan being repaid.

The Consolidated Group also agreed to customary affirmative and negative covenants, including, without limitation, covenants relating to minimum liquidity, minimum trailing six-month net revenue and adjusted EBITDA and events of default in connection with these arrangements. The occurrence of an event of default could have resulted in the acceleration of Limited's obligations under the Hercules Term Loan Agreement, as amended by the Fourth Loan Amendment and an increase to the applicable interest rate and would permit Hercules to exercise remedies with respect to the collateral under the Hercules Term Loan Agreement, as amended by the Fourth Loan Amendment. In the event that the Company maintained $35,000,000 in liquidity, including cash and eligible accounts receivable, at the end of the month and had not been and was not in breach of the amended debt facility, the six-month trailing revenue covenant would have been waived for such month.

Fifth Loan Amendment

In May 2017, Limited entered into the Fifth Loan Amendment with Hercules, which further amended and clarified certain terms of the Hercules Term Loan Agreement. The amendment was not material.

October 2017 Waiver

For September 2017, the Consolidated Group did not meet the six-month revenue covenant required under the Hercules Term Loan Agreement. As a result, the Consolidated Group was required to demonstrate it had $35,000,000 in liquidity as of the last business day in September 2017. On the last business day in September 2017, the Consolidated Group was not able to demonstrate it had $35,000,000 in liquidity. However, the Consolidated Group was able to demonstrate that it had $35,000,000 in liquidity on the business day immediately before the last business day in September 2017, the first business day in October 2017 and the last business day in October 2017. As a result, Hercules waived the Company’s non-compliance with the $35,000,000 liquidity requirement at the end of September 2017.

General Discussion of the Hercules Term Loan Agreement

Pursuant to the Hercules Term Loan Agreement, Limited's obligations to Hercules were secured by a first-priority security interest in substantially all of Limited's assets, excluding intellectual property. Hercules also maintained a negative pledge on Limited's intellectual property requiring Hercules' consent prior to the sale of such intellectual property. The Company and certain of the Company's other subsidiaries were guarantors of the obligations of Limited to Hercules under the Hercules Term Loan Agreement pursuant to separate guaranty agreements between Hercules and each of Limited and such subsidiaries (Guaranties). Pursuant to the Guaranties, the Company and these subsidiaries granted Hercules a first-priority security interest in substantially all of their respective assets excluding intellectual property. The Hercules Term Loan Agreement also placed limitations on the Company's ability to declare or pay any dividend or distribution on any shares of capital stock.

2014 Warrant

In connection with Limited entering into the 2014 Loan Agreement, the Company issued a warrant to Hercules 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). Sixty percent of the 2014 Warrant was exercisable at the closing in April 2014 and the remaining forty percent became exercisable upon the funding of the additional $25,000,000 to Limited in September 2014.

The Company agreed to amend the 2014 Warrant in connection with the First Loan Amendment to increase the number of shares issuable upon exercise to 660,377 and decrease the exercise price to $2.65 per share. Upon entering into the Second Loan Amendment, the Company agreed to further amend the 2014 Warrant to increase the number of shares issuable upon exercise to 862,069 and decrease the exercise price to $2.03 per share. In connection with the July 2016 Waiver, the Company agreed to further amend the 2014 Warrant to increase the number of shares issuable upon exercise to 1,258,993 and decrease the exercise price to $1.39 per share.

2016 Warrant

In connection with Limited entering into the Fourth Loan Amendment, the Company agreed to issue a new warrant to Hercules (the 2016 Warrant) to purchase up to 458,716 shares of the Company's common stock at an exercise price of $1.09 per share, which was equal to $500,000 divided by the lowest volume-weighted average sale price for a share of the Company's common stock reported over any ten consecutive trading days during the period commencing on and including September 23, 2016 and ending on the earlier to occur of (i) December 30, 2016 (inclusive of such date), and (ii) the second trading day immediately preceding the date of closing of a merger event (as defined in the 2016 Warrant).

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 in its capacity as a Lender (each a "Lender" and 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 Term Loan Agreement and 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 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;

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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 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.

As noted above, the total fees payable under the Exit Fee Agreement may not exceed $2,000,000.

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

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 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 Lender does, however, maintain a negative pledge on the property of the Company and all of its subsidiaries, including the Company’s intellectual property, requiring the Lender’s consent for any liens (other than typical permitted liens) on or the sale of such property.

Fair Value of Debt

As of December 31, 2017 and 2016, 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, 2017 and 2016.

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10. COMMITMENTS AND CONTINGENCIES

Term Note Payable — Under the Hercules Term Loan Agreement (see Note 9), as of December 31, 2017, the Company was obligated to make future minimum principal payments, excluding (a) PIK Interest and (b) the $1,400,000 End of Term Payment that was scheduled to be paid in May 2018, as follows (in thousands):

Years Ending December 31	(In thousands)
2018	$ 1,300
2019	$ 16,526
2020	$ 17,174
Total	$ 35,000

As of December 31, 2017 and 2016, the Company had $363,000 and $336,000 accrued and unpaid interest payable under the Hercules Term Loan Agreement, respectively. On January 5, 2018, the Company used part of the proceeds of the 2018 Loan Agreement to repay (a) all outstanding principal, (b) all accrued and unpaid interest and (c) the $1,400,000 End of Term Payment owed under the Hercules Term Loan Agreement.

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, Limited 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 Germany and Portugal under leases that expire in June 2021 and March 2020, respectively. As of December 31, 2017, 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)
2018	$ 561
2019	533
2020	417
2021	301
Total	$ 1,812

Rent expense under all operating leases totaled approximately $499,000 and $544,000 for the years ended December 31, 2017 and 2016, respectively.

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, 2017, 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)
2018	262
2019	172
2020	95
Total	529
Less amount representing interest	(30)
Less amount representing executory costs	(112)
Present value of minimum lease payments	387

Less current portion	(184)
Non-current portion	$ 203

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Property and equipment under capital leases, which are included in property and equipment (Note 5), consisted of the following:

	December 31,	
	2017	2016
	(In thousands)	
Automobiles	$663	$762
Office equipment	63	63
Less accumulated depreciation	(311)	(342)
Total	$415	$483

Depreciation expense associated with property and equipment under capital leases was approximately $172,000 and $267,000 for the years ended December 31, 2017 and 2016, 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 for an initial term of six years. The agreement initially had an initial six-year term and automatically renewed for successive one-year periods unless either party delivered written notice of non-renewal to the other at least 12 months prior to the end of the then current term. In February 2016, the Company and the third party manufacturer amended and restated this agreement to extend the term to five years, at which point it will automatically renew for successive one-year periods unless either party delivers notice of non-renewal to the other party at least 12 months prior to 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 of 2013, nine additional agreements have been entered into for work with these CROs. For the years ended December 31, 2017 and 2016, the Company incurred $101,000 and $157,000, respectively, of expense associated with these agreements. As of December 31, 2017 and 2016, $67,000 and $76,000, respectively, is included in accrued expenses (Note 7). As of December 31, 2017, the Company expects to incur an additional $390,000 of expense associated with these agreements through December 31, 2019.

Employment Agreements — The Company is party to employment agreements with five executives. The agreements generally provide for annual salaries, bonuses and benefits and for the “at-will” employment of such executives. Effective January 1, 2018, the Company is party to five agreements with salaries ranging from $338,000 to $600,000. 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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11. 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 and warrants to purchase 300,000 shares of Series A Convertible Preferred Stock for gross proceeds of $40,000,000, prior to the payment of approximately $560,000 of related issuance costs. Each share of Series A Convertible Preferred Stock, including any shares of Series A Convertible Preferred Stock issued upon exercise of the warrants, 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 Convertible Preferred Stock shall automatically be converted into shares of common stock at the then-effective Conversion Price upon the occurrence of the later to occur of both (i) the Company receives and publicly announces the approval by the FDA of the Company's New Drug Application for ILUVIEN and (ii) 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 Convertible 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 Convertible 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 Convertible 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 Convertible Preferred Stock that would otherwise be issued upon such exercise at the then-effective Conversion Price. These warrants were considered derivative instruments because the agreements provided for settlement in Series A Convertible 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 are 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. These adjustment features lapsed in September 2014. As of December 31, 2016, the fair market value of the warrants was estimated to be $188,000. The Company recorded gains of $188,000 and $2,627,000 as a result of the change in fair value of the warrants during the years ended December 31, 2017 and 2016, respectively. The rights to exercise these warrants expired on October 1, 2017.

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, 2017, there were 600,000 shares of Series A Convertible Preferred Stock issued and outstanding.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 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 Convertible Preferred Stock as a subscription premium to the purchasers. Each share of Series B Convertible Preferred Stock is convertible into 1,000 shares of the Company's common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series B Convertible 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 Convertible Preferred Stock ranks junior to the Company's existing Series A Convertible Preferred Stock and senior to the Company's common stock, with respect to rights upon liquidation. The Series B Convertible 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 B Convertible Preferred Stock do not have voting rights. The Series B Convertible Preferred Stock is not redeemable at the option of the holder. The Series B Convertible Preferred Stock is not subject to any price-based or other anti-dilution protections and does not provide for any accruing dividends.

The Company determined that the conversion option of the Series B Convertible 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 Convertible 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 Convertible Preferred Stock on that date.

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

12. STOCK INCENTIVE PLANS

The Company has stock option and stock incentive plans which 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. These plans include RSUs, stock options and an employee stock purchase plan (ESPP). 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,			
	2017		2016	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period	10,804,412	$ 3.22	9,475,890	$ 3.43
Grants	2,336,300	1.25	2,195,250	2.05
Forfeitures	(1,544,473)	2.63	(581,497)	3.15
Exercises	(729)	1.49	(285,231)	1.41
Options outstanding at year end	11,595,510	2.90	10,804,412	3.22
Options exercisable at year end	8,085,064	3.25	7,363,400	3.29
Weighted average per share fair value of options granted during the year	$ 0.94		$ 1.55	

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, 2017:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
				(In thousands)
Outstanding	11,595,510	$ 2.90	6.60 years	$ —
Exercisable	8,085,064	3.25	5.68 years	—
Outstanding, vested and expected to vest	11,161,477	2.94	6.51 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,	
	2017	2016
Risk-free interest rate	2.06 %	1.57 %
Volatility factor	90.49 %	93.54 %
Grant date fair value of common stock options	$0.94	$1.55
Weighted-average expected life	6.02 years	5.99 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,	
	2017	2016
	(In thousands)	
Sales and marketing	$907	$1,109
Research, development and medical affairs	643	886
General and administrative	2,510	2,814
Total employee stock-based compensation expense	$4,060	$4,809

As of December 31, 2017, there was approximately $4,830,000 of total unrecognized compensation cost related to outstanding stock option awards that will be recognized over a weighted average period of 2.04 years. The total fair value of shares vested during the year ended December 31, 2017 was approximately $4,094,000.

The total estimated fair value of options granted during the years ended December 31, 2017 and 2016 was $2,186,000 and $3,410,000, respectively. The total estimated intrinsic value of options exercised during the years ended December 31, 2017 and 2016 was approximately $26 and $65,000, respectively.

As of December 31, 2017, the Company was authorized to grant options to purchase up to an additional 1,037,718 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, 2018, 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.

Restricted Stock Units

During the year ended December 31, 2017, the Company granted 964,720 restricted stock units (RSUs) to its employees in lieu of a cash bonus program for 2017. As of December 31, 2017, 839,285 RSUs were outstanding. During the year ended December 31, 2017, the Company recorded compensation expense related these RSUs of

approximately $883,000.

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

13. 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 were issued to purchase a total of 1,795,663 shares of common stock as of December 31, 2017 and 2016. As of December 31, 2017, 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 Limited entering into the 2014 Loan Agreement (Note 9), the Company entered into the 2014 Warrant to purchase up to 285,016 shares of the Company's common stock at an exercise price of $6.14 per share. Sixty percent of the warrants were exercisable at the closing in April 2014 and the remaining forty percent became exercisable upon the funding of the additional $25,000,000 to Limited in September 2014.

The Company agreed to amend the 2014 Warrant in connection with the First Loan Amendment to increase the number of shares issuable upon exercise to 660,377 and decrease the exercise price to $2.65 per share. Upon entering into the Second Loan Amendment, the Company agreed to further amend the 2014 Warrant to increase the number of shares issuable upon exercise to 862,069 and decrease the exercise price to $2.03 per share. In connection with the July 2016 Waiver, the Company agreed to further amend the 2014 Warrant to increase the number of shares issuable upon exercise to 1,258,993 and decrease the exercise price to $1.39 per share.

In connection with Limited entering into the Fourth Loan Amendment, the Company agreed to issue the 2016 Warrant to purchase up to 458,716 shares of the Company's common stock at an exercise price of $1.09 per share, which was equal to $500,000 divided by the lowest volume-weighted average sale price for a share of the Company's common stock reported over any ten consecutive trading days during the period commencing on and including September 23, 2016 and ending on the earlier to occur of (i) December 30, 2016 (inclusive of such date), and (ii) the second trading day immediately preceding the date of closing of a merger event (as defined in the 2016 Warrant).

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

14. CONCENTRATIONS AND CREDIT RISK

For the years ended December 31, 2017 and 2016, there were three customers within the U.S. segment. Two of these customers, which are large pharmaceutical distributors, accounted for approximately 73% and 75%, respectively, of the Company's total consolidated revenues. These two customers accounted for approximately 81% and 90% of the Company's consolidated accounts receivable as of December 31, 2017 and 2016, respectively.

For the year ended December 31, 2017 one of the Company's third-party manufacturers of ILUVIEN comprised approximately 10.5% of the Company's total purchases. For the year ended December 31, 2016, there were no 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)

15. 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, implements a territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21%.

The Company remeasured certain net deferred and other tax liabilities based on the tax rates at which they are expected to reverse in the future. The estimated amount recorded related to the remeasurement of these balances was a net benefit of $0. The net estimated impact of the 2017 Tax Act is $0 due to a full valuation allowance recorded against the U.S. deferred tax assets.

The components of net loss before taxes are as follows:

	Years Ended December 31,	
	2017	2016
	(In thousands)	
United States	$(1,890)	$(8,516)
Foreign	(19,948)	(24,486)
Loss before provision for income taxes	$(21,838)	$(33,002)

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,	
	2017	2016
	(In thousands)	
Current expense (benefit):		
Federal	$—	$—
State	—	—
Foreign	255	385
Current income tax expense	255	385
Deferred expense (benefit):		
Federal	549	3,099
State	3,330	(858)
Foreign	(92)	(213)
	3,787	2,028
Valuation allowance	(3,879)	(2,241)
Deferred income tax benefit	(92)	(213)
Total income tax expense	$163	$172

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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,	
	2017	2016
	(In thousands)	
Valuation allowance at beginning of period	$(55,968)	$(53,727)
Income tax provision	(3,879)	(2,241)
U.S. Tax Reform	18,362	—
Valuation allowance at end of period	$(41,485)	$(55,968)

Worldwide net deferred tax assets and liabilities are as follows:

	December 31,	
	2017	2016
Deferred tax assets	(In thousands)	
Depreciation and amortization	$44	$ 12
Other deferred tax assets	707	1,164
NOL carry-forwards	33,980	38,183
Research and development costs	1,340	3,063
Equity compensation	3,686	4,660
Collaboration agreement receivable reserves	2,256	9,327
Valuation allowance	(41,485)	(55,968)
Total deferred tax assets	$528	$ 441
Deferred tax liabilities		
Other deferred tax liabilities	—	(5)
Total deferred tax liabilities	—	(5)
Net deferred tax assets and deferred tax liabilities	$528	$ 436

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

	Years Ended December 31,			
	2017		2016	
	Amount	Percent	Amount	Percent
Federal tax benefit at statutory rate	$(7,425)	34.0 %	$(11,219)	34.0 %
State tax — net of federal benefit	(3,783)	17.3	(10)	—
Permanent items and other	686	(3.1)	(225)	0.7
Foreign rate differential	6,880	(31.5)	8,470	(26.1)
U.S. tax reform	18,362	(84.1)	—	
Deferred rate change	(212)	1.0	825	(2.5)
Other	138	(0.6)	90	(0.3)
Change in valuation allowance	(14,483)	66.3	2,241	(6.3)
Total tax expense (benefit)	$163	(0.7)%	$172	(0.5)%

The change in state taxes, net of federal benefit, is 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. The impact of the deferred rate change as a result of the 2017 Tax Act is $18.4 million. 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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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	Years Ended December 31,	
	2017	2016
	(In thousands)	
Balance of uncertain tax positions at beginning of period	$ 59	$ 46
Gross increases - tax positions in current period	4	16
Gross increases - tax positions in prior period	—	13
Gross decreases - tax positions in prior period	(11)	(16)
Settlements	—	—
Lapse of statute of limitations	—	—
Balance of uncertain tax positions at end of period	$ 52	$ 59

Included in the balance of unrecognized tax benefits as of December 31, 2017 and 2016 are approximately $52,000 and $59,000, 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 deferred tax assets due to the history of operating losses, a valuation allowance has been established against the entire net 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. In the event that 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, 2017 and 2016, the Company had federal net operating loss (NOL) carry-forwards of approximately $121,413,000 and $104,944,000 and state NOL carry-forwards of approximately $161,753,000, and $83,270,000 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 and the state NOL carry-forwards will expire at various dates between 2020 and 2037.

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. 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, it 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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As of December 31, 2017, the Company had cumulative book losses in foreign subsidiaries of approximately $113,278,000. 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.

The 2017 Tax Act transitions the U.S. from a worldwide tax system to a territorial tax system. Under previous law, companies could indefinitely defer U.S. income taxation on unremitted foreign earnings. The 2017 Tax Act imposes a one-time transition tax on deferred foreign earnings of 15.5% for liquid assets and 8% for illiquid assets, payable in defined increments over eight years. Due to the cumulative book losses discussed above, this provision of the new law will have no impact on the Company.

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16. FAIR VALUE

The Company applies ASC 820, Fair Value Measurements in determining the fair value of certain assets and liabilities. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date. In determining fair value, the Company uses various valuation approaches. The hierarchy of those valuation approaches is broken down into three levels based on the reliability of inputs as follows:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access

Level 2 Valuations for which all significant inputs are observable, either directly or indirectly, other than level 1 inputs

Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement

There have been no changes in the methodologies used as of December 31, 2017 and 2016.

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

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Liabilities:				
Derivative warrant liability (2)	$—	$188	$—	$188
Liabilities measured at fair value	$—	$188	$—	$188

(1) The carrying amounts approximate fair value due to the short-term maturities of the cash equivalents.

(2) 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. Assumptions used are generally consistent with those disclosed for stock-based compensation (see Note 12).

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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 $187,000 and $287,000 for the years ended December 31, 2017 and 2016, respectively. The Company may also make an annual discretionary profit-sharing contribution. No such discretionary contributions were made during the years ended December 31, 2017 and 2016, 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 IPO, 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 79,733 and 82,760 shares of the Company's common shares were acquired through the Purchase Plan during the years ended December 31, 2017 and 2016, respectively. As such, on January 1, 2018 and 2017, respectively, an additional 79,733 and 82,760 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 $38,000 and $80,000 of compensation expense for the years ended December 31, 2017 and 2016, respectively.

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18. SEGMENT INFORMATION

For the years ended December 31, 2017 and 2016, there were three customers within the U.S. segment. Two of these customers, which are large pharmaceutical distributors, accounted for 73% and 75% of the Company's consolidated revenues for the years ended December 31, 2017 and 2016, respectively. These same two customers within the U.S. segment accounted for approximately 81% and 90% of the Company's consolidated accounts receivable at December 31, 2017 and 2016, 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, 2017 and 2016:

	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)
NET LOSS BEFORE TAXES				$ (21,838)

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

	Year Ended December 31, 2016			
	U.S.	International	Other	Consolidated
	(In thousands)			
NET REVENUE	$25,765	$ 8,568	$ —	$ 34,333
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(1,694)	(650)	—	(2,344)
GROSS PROFIT	24,071	7,918	—	31,989
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	7,183	4,289	903	12,375
GENERAL AND ADMINISTRATIVE EXPENSES	8,918	3,517	2,828	15,263
SALES AND MARKETING EXPENSES	21,252	7,021	1,158	29,431
DEPRECIATION AND AMORTIZATION	—	—	2,767	2,767
OPERATING EXPENSES	37,353	14,827	7,656	59,836
SEGMENT LOSS FROM OPERATIONS	(13,282)	(6,909)	(7,656)	(27,847)
OTHER INCOME AND EXPENSES, NET				(5,155)
NET LOSS BEFORE TAXES				$ (33,002)

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

19. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly financial data for years ended December 31, 2017 and 2016 are as follows (in thousands except per share data):

	March 31	June 30	September 30	December 31
	(In thousands, except share and per share data)			
2017				
NET REVENUE	$6,618	$10,368	$ 9,784	$9,142
COST OF GOOD SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(587)	(769)	(1,039)	(1,043)
GROSS PROFIT	6,031	9,599	8,745	8,099
LOSS FROM OPERATIONS	(5,511)	(1,378)	(3,825)	(5,738)
NET LOSS BEFORE TAXES	(6,709)	(2,713)	(5,262)	(7,154)
NET LOSS	(6,735)	(2,757)	(5,285)	(7,224)
NET LOSS PER SHARE — Basic and diluted	(0.10)	(0.04)	(0.08)	(0.10)
2016				
NET REVENUE	$5,801	$9,557	$ 8,298	$10,677
COST OF GOOD SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(378)	(556)	(486)	(924)
GROSS PROFIT	5,423	9,001	7,812	9,753
LOSS FROM OPERATIONS	(8,790)	(6,449)	(7,243)	(5,365)
NET LOSS BEFORE TAXES	(11,136)	(6,816)	(9,212)	(5,838)
NET LOSS	(11,145)	(6,858)	(9,245)	(5,926)
NET LOSS PER SHARE — Basic and diluted	(0.25)	(0.15)	(0.16)	(0.09)

As a result of the Company’s weighted averages shares outstanding changing from quarter to quarter, the quarterly per share data will not necessarily add to the annual total.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

20. SUBSEQUENT EVENT

As discussed in Note 9, on January 5, 2018, the Company entered into the 2018 Loan Agreement with Solar Capital. Under the 2018 Loan Agreement, the Company borrowed $40,000,000 as a term loan that matures on July 1, 2022.

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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 3.2 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)
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)
3.3	Certificate of Designation of Series A Convertible Preferred Stock (filed as Exhibit 3.5 to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (filed as Exhibit 3.6 to the Registrant's Current Report on Form 8-K, as filed on December 15, 2014, and incorporated herein by reference)
3.5	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.5 to the Registrant's Annual Report on Form 10-K, as filed on March 3, 2017, and incorporated herein by reference)
4.1	Second Amended and Restated Investor Rights Agreement, dated March 17, 2008, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.3 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.2	Second Amended and Restated Stock Sale Agreement, dated March 17, 2008, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.4 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.3	Omnibus Amendment, dated August 25, 2009, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.5 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, 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)

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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)
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)

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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 (filed as Exhibit 10.18 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)
10.12‡	Commercial Contract Manufacturing Agreement, between Alimera Sciences, Inc. and Alliance Medical Products, Inc., dated February 5, 2010 (filed as Exhibit 10.26 to Amendment No. 6 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 20, 2010, and incorporated herein by reference)
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)
10.14‡	Amendment to Manufacturing Agreement between Registrant and Alliance Medical Products, Inc. (filed as Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q, as filed on August 5, 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)
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)
10.23	Loan and Security Agreement dated May 7, 2013 between Silicon Valley Bank and Alimera Sciences Limited (filed as Exhibit 10.42 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
10.24	Security Agreement entered into as of May 7, 2013 by and between Silicon Valley Bank and the Registrant (filed as Exhibit 10.43 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
10.25	Unconditional Guaranty entered into as of May 7, 2013 by Alimera Sciences B.V. in favor of Silicon Valley Bank (filed as Exhibit 10.44 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
10.26	Unconditional Guaranty entered into as of May 7, 2013 by AS C.V. in favor of Silicon Valley Bank (filed as Exhibit 10.45 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)

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10.27	Unconditional Guaranty entered into as of May 7, 2013 by the Registrant in favor of Silicon Valley Bank (filed as Exhibit 10.46 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
10.28	Second Loan Modification Agreement entered into as of May 7, 2013 by and between Silicon Valley Bank and the Registrant (filed as Exhibit 10.47 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 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)
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)

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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)
21.1*	List of subsidiaries of the Registrant (including jurisdiction of organization and names under which subsidiaries do business)

23.1*	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
101.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 March 2, 2018.

ALIMERA SCIENCES, INC.

By: /s/ C. Daniel Myers
Name: C. Daniel Myers
Title: 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/ C. Daniel Myers C. Daniel Myers	Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2018
/s/ Richard S. Eiswirth, Jr. Richard S. Eiswirth, Jr.	President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 2, 2018
/s/ James R. Largent James R. Largent	Chairman of the Board of Directors	March 2, 2018
/s/ Glen Bradley, Ph.D. Glen Bradley, Ph.D.	Director	March 2, 2018
/s/ Mark J. Brooks Mark J. Brooks	Director	March 2, 2018
/s/ Brian K. Halak, Ph.D. Brian K. Halak, Ph.D.	Director	March 2, 2018
/s/ Garheng Kong, M.D., Ph.D. Garheng Kong, M.D., Ph.D.	Director	March 2, 2018
/s/ Peter J. Pizzo, III Peter J. Pizzo, III	Director	March 2, 2018
	Director	

/s/ Calvin W. Roberts, M.D. Calvin W. Roberts, M.D.	March 2, 2018

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