ALIMERA SCIENCES INC
Form 10-K
March 03, 2017
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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, 2016
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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o

Non-accelerated filer o (Do not check if a smaller reporting company) Smaller reporting company x

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, 2016, 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 $45,721,956 based on the closing price of the registrant’s Common Stock, on June 30, 2016, as reported by the NASDAQ Global Market. For the purposes of this disclosure, shares of Common Stock held by each executive officer, director and stockholder known by the registrant to be affiliated with such individuals based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 1, 2017 there were 64,862,904 shares of the registrant’s Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant’s proxy statement with respect to the registrant’s 2016 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, 2016, 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 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 Alimera Sciences, Inc.'s (we, our, Alimera or the Company) 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, but not limited to, "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "contemplates," "predict," "project," "target," "likely," "potential," "will," "would," "should," "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to:

- uncertainty as to our ability to achieve profitability and positive cash flow through the commercialization of ILUVIEN® in the European Economic Area (EEA), the United States (U.S.) and other regions of the world where we sell ILUVIEN;
- our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility;
- dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality;
- uncertainty as to the pricing and reimbursement guidelines for ILUVIEN or any future products or product candidates, including ILUVIEN in new markets;
- our ability to successfully commercialize ILUVIEN following regulatory approval in additional markets;
- delay in or failure to obtain regulatory approval of ILUVIEN in additional countries or any future products or product candidates;
- the extent of government regulations; and
- our need to raise additional financing.

All written and verbal 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 publicly any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult 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.

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 complete discussion 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 the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

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ITEM 1. BUSINESS

Overview

Alimera Sciences, Inc., and its subsidiaries (we, Alimera or the Company), is a pharmaceutical company that specializes in the commercialization, research and development of prescription ophthalmic pharmaceuticals. We are presently focused 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 been 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. In the fourth quarter of 2016, we requested approval to modify our protocol to cap enrollment in the study due to our post market safety surveillance not showing any unexpected safety signals. Although we have not received formal regulatory approval, the Medicines & Healthcare products Regulatory Agency (MHRA) has agreed to allow us to suspend enrollment, pending approval of our protocol amendment. As of December 31, 2016, 548 patients were enrolled in this study.

We launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015.

In addition, we have entered into various agreements under which distributors will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in numerous countries in the Middle East, Italy, Australia, New Zealand and Canada. In the third quarter of 2016, our Middle East distributor launched ILUVIEN and initiated named patient sales in the Middle East.

ILUVIEN is an intravitreal implant that treats patients by delivering a continuous microdose of the non-proprietary corticosteroid fluocinolone acetonide (FAc) in the eye, which lasts for up to 36 months. We believe that corticosteroids provide the best option in the treatment of DME because of 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 and mitigate the typical corticosteroid related side effects. ILUVIEN, which is non-bioerodable, provides consistent delivery as a result of its constant surface area. This provides a sustained therapeutic effect on DME, and an adverse event profile that is predictable and manageable by a retinal physician. Other corticosteroid options for DME 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 vision loss in DME patients and subsequently for other indications for which ILUVIEN is proven safe and effective. We are led by an executive team with 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.

Business Strategy

We are presently focused 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 launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015. We have approval in 14 additional countries in the EEA and we are pursuing opportunities to sell ILUVIEN in some of these countries, including Austria

and Ireland. In Italy, our distributor plans to launch ILUVIEN in 2017. 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.

Pursue Approval in Additional Countries. We plan to pursue regulatory approval for ILUVIEN, directly or with a partner, in other countries. In addition to the distribution agreements for the Middle East and Italy, we entered into agreements to distribute ILUVIEN in Australia, New Zealand and Canada. Pursuant to these agreements, our distributors will assist us in obtaining approval or seek approval with our oversight in those countries. In addition,

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under a Mutual Recognition Procedure (MRP) available in the EEA, we can submit ILUVIEN for approval in any or all of the remaining 12 European Union (EU) countries where we do not have marketing approval.

- Assess the Effectiveness of ILUVIEN for Additional Retinal Diseases. We believe that ILUVIEN has the potential to address additional retinal diseases including, among others, Non-Proliferative Diabetic Retinopathy (NPDR), retinal vein occlusion (RVO), dry aged-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. Toward that end, we intend 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 estimated prevalence of diabetes worldwide in 2015 increased to 415 million people and is expected to increase to 642 million people by 2040 according to the U.S. Centers for Disease Control and Prevention (CDC).

According to the CDC, the number of Americans diagnosed with diabetes was approximately 22.0 million people in 2014 and continues to increase each year. In addition to diagnosed cases, the CDC most recently estimated in 2012 that an additional 8.1 million Americans with diabetes are undiagnosed and are therefore not being monitored and treated to control their disease and prevent systemic and ophthalmic complications. In the EEA countries in which ILUVIEN has received marketing authorizations, according to the International Diabetes Foundation, Diabetes Atlas, Seventh Edition, 2015 Update, there are approximately 17.2 million diagnosed diabetics and 10.5 million diabetics that 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, 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 growth of new blood vessels. These new blood vessels are abnormal and fragile, growing along the retina and along the surface of the clear, vitreous gel that fills the inside of the eye. By themselves, these blood vessels do not cause symptoms or vision loss. However, these blood vessels have thin, fragile walls that are prone to leakage and hemorrhage.

Diabetic Macular Edema

DME, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition is called DME. 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.

DME has been demonstrated to be mediated by multiple cytokines in various studies where cytokine levels are measured inside the eye. Of the currently approved pharmacotherapies to treat DME, only corticosteroids, including the corticosteroid in ILUVIEN, affect multiple cytokines.

As the incidence of diabetes continues to increase worldwide, the incidence of DME and other complications is predicted to rise as well. 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.

Current Treatments for DME

Anti-vascular endothelial growth factor (VEGF) therapies are the current standard of care for the treatment of DME. Lucentis and Eylea 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. having been proven efficacious in patients suffering from DME. Off-label injections and anti-VEGF oncology therapy are also used to treat DME. However, anti-VEGF therapies are limited by a need for multiple and frequent injections to maintain a therapeutic effect. Further, many patients either do not achieve a response or

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achieve an insufficient response from these anti-VEGF therapies. In addition, these therapies have safety profiles which include an increased risk of endophthalmitis, a serious eye infection that must be treated with high doses of antibiotics.

Intravitreal corticosteroid therapies are also used to treat DME. Ozurdex, a short acting corticosteroid, is marketed for the treatment of vision loss associated with DME in the EEA and for the treatment of DME in the U.S. Intravitreal injections of triamcinolone, an off label corticosteroid, and Avastin are also used to treat DME via intravitreal injections. Corticosteroids have historically been associated with significant increases in IOP, which may increase the risk of glaucoma and the acceleration of cataract formation. Like anti-VEGF antibody therapy, these shorter duration corticosteroids are limited by a need for multiple and frequent injections to maintain a therapeutic effect.

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, however, its primary benefit is to prevent or slow vision loss. Further, this is a destructive procedure that has undesirable side effects including partial loss of peripheral and night vision.

ILUVIEN

Overview

Our only commercial product is ILUVIEN, a sustained release corticosteroid intravitreal implant for the treatment of DME. "Intravitreal" refers to the space inside the eye behind the lens that contains the jelly-like substance called vitreous. DME is a disease of the retina which affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN consists of a tiny non-bioerodable polyimide tube with a permeable membrane cap on one end and an impermeable silicone cap on the other end that is filled with 190mg 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-bioerodable, provides consistent delivery as a result of its constant surface area which allows it to deliver a continuous microdose of FAc over 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.

Based on data from our FAME Study (described below), our current post-market study in Europe and our real world experience with ILUVIEN, we believe ILUVIEN is a unique therapeutic option for DME that improves vision while mitigating side effects associated with the continuous, multi-year, intravitreal delivery of corticosteroids, especially elevated IOP. We believe that the uniqueness of this therapeutic option rests on the following reasons:

- ILUVIEN delivers FAc. The active pharmaceutical ingredient in ILUVIEN is FAc, which has demonstrated efficacy in the treatment of DME in clinician’s real world experience and in the two completed Phase 3 pivotal clinical trials, collectively referred to as our FAME Study, over multiple years.
- ILUVIEN delivers a continuous daily microdose of steroid to the eye. The delivery mechanism of ILUVIEN provides lower daily and aggregate exposure to corticosteroids than other intraocular dosage forms currently available.
- ILUVIEN has shown to provide sustained sub-microgram levels of FAc through in vitro release kinetics and in vivo over time. The results of our FAME Study demonstrated that ILUVIEN provides a sustained, therapeutic effect in the treatment of DME patients for up to 36 months.

Fluocinolone Acetonide

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, NPDR, RVO, dry AMD and wet AMD. However, FAc shares many of the same side effects as other

corticosteroids currently available for intraocular use, including increased IOP, which may increase the risk of glaucoma, and the acceleration of cataract formation.

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ILUVIEN for Other Diseases of the Eye

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, there are 16 million adults affected with RVO around the world. In September 2009, Allergan, Inc. (Allergan) introduced Ozurdex (a short duration corticosteroid) as the first approved product for macular edema following branch or RVO. The U.S. Food and Drug Administration's (FDA) approval of Ozurdex provides additional evidence that corticosteroids work effectively to treat RVO.
- Moderately severe to severe 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 risk of severe vision loss, blindness and retinal detachment increase when diabetic retinopathy progresses from NPDR to PDR.
- Dry AMD. Dry AMD patients account for 90% of AMD patients, with the greatest unmet need among these patients being a treatment for geographic atrophy (GA) 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 GA, we believe these results support the exploration of ILUVIEN to treat this condition.
- Wet AMD. The size of the wet AMD market was $2 billion in 2008 according to VisionGain, an independent competitive intelligence organization. According to American Academy of Ophthalmology, more than 11 million people in America are affected by AMD and are now benefiting from advanced treatment options such as anti-VEGF agents and photodynamic therapy (PDT). Anti-VEGF antibodies require persistent dosing to maintain a therapeutic effect which is a burden on both the patient and the physician. Estimates as of March 2015 of the global cost of visual impairment due to AMD is $343 billion, including $255 billion in direct health care costs according to BrightFocus Foundation. We believe ILUVIEN has the potential to be synergistic with the market leading anti-VEGF antibody therapies in the treatment of wet AMD given that corticosteroids have been shown to suppress the production of VEGF.

ILUVIEN Regulatory Status

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 in Europe, we committed to conduct a five-year, post-authorization, open label registry study in 800 patients treated with ILUVIEN. In the fourth quarter of 2016, we requested approval to modify our protocol to cap enrollment in the study due to our post market safety surveillance not showing any unexpected safety signals. Although we have not received formal regulatory approval, the MHRA has agreed to allow us to suspend enrollment, pending approval of our protocol amendment. As of December 31, 2016, 548 patients were enrolled in this study.

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

Commercialization

ILUVIEN is the only intraocular therapy to treat DME designed to deliver a continuous microdose of FAc over 36 months enabling the physician to treat DME consistently and continuously every day. 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 launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015. We plan to launch ILUVIEN in Austria and Ireland in 2017. Our distributor in the Middle East launched ILUVIEN in the United Arab Emirates in the

fourth quarter of 2016. In Italy, our distributor plans to launch ILUVIEN in 2017. 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 ILUVIEN being administered as a standalone therapy, we do not foresee the use of ILUVIEN as precluding the administration of other

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therapies in conjunction with ILUVIEN. Our commercialization strategy in any geography is subject to and dependent upon the regulatory approval of ILUVIEN in any jurisdiction.

Sales and Marketing

We began building our U.S. commercial infrastructure in the fourth quarter of 2014 following the FDA approval of ILUVIEN with the addition of sales management, field sales representatives, payor relations specialists, reimbursement support specialists and other positions. As of December 31, 2016, we had a U.S. field force of approximately 45 persons, including sales personnel, reimbursement specialists, and payor relations directors.

In late 2012 and early 2013 we established a core management team for our European operations based in the United Kingdom. In November 2012, we entered into a master services agreement with Quintiles Commercial Europe Limited. Under the agreement, Quintiles Commercial Europe Limited and its affiliates (collectively, Quintiles Commercial) provided certain services to us in relation to the commercialization of ILUVIEN, in France, Germany and the United Kingdom. In December 2013 and January 2014, respectively, we transitioned our German and United Kingdom country manager positions in-house. In April 2015, we terminated the project orders associated with France and Germany and transitioned the covered positions employed by Quintiles Commercial to our payroll. In July 2015, we terminated the remaining project orders associated with the United Kingdom and transitioned the covered positions employed by Quintiles Commercial to our payroll. As of December 31, 2015 all of the agreements with Quintiles Commercial had been terminated.

In the fourth quarter of 2016, after unsuccessfully negotiating with the French government to obtain an appropriate price, we decided to close operations in France. We expect the closing of operations to be completed in early 2017. We are continuing to evaluate our options to enter the French market, including potential distributor relationships.

As of December 31, 2016, we had a European management team, local management teams and commercial personnel in France, Germany, Portugal and the United Kingdom totaling 31 persons, three of which are consultants.

We are developing our medical marketing, promotion and communication materials to ensure that influential retinal specialists are presenting our ILUVIEN data, clinician’s real world data and messages at key retina meetings in the U.S. and EEA.

In addition, we have entered into various agreements under which distributors will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in numerous countries in the Middle East, Italy, Australia, New Zealand and Canada, Pursuant to these agreements, our distributors will assist us in obtaining approval or seek approval with our oversight in those countries. In Italy, our distributor plans to launch ILUVIEN in 2017. Our distributor in the Middle East began sales in the United Arab Emirates in the fourth quarter of 2016, although these sales were not significant. We expect that our distributors may be able to sell ILUVIEN in the future in the other territories which we have distribution agreements.

Manufacturing

We do not have an in-house manufacturing capability for our products and as a result we will 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 the implementation of our quality system to ensure that they produce active pharmaceutical ingredients (APIs) and finished drug products in accordance with current Good Manufacturing Practices (cGMPs) 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 the manufacturer of FAc, the API in ILUVIEN (FARMABIOS SpA/Byron Chemical Company Inc.), the manufacturer of the components of the ILUVIEN applicator (FlexMedical or an affiliate of Flextronics International, Ltd. (Flextronics)), the manufacturer of ILUVIEN (Alliance Medical Products Inc., a Siegfried Company (Alliance)) and the manufacturer for 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 190mg of FAc and 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, one of the third-party contract manufacturers of ILUVIEN.

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In February 2010, we entered into a commercial manufacturing agreement with Alliance whereby Alliance agreed to manufacture and package ILUVIEN for us at its Irvine, California facility. The agreement was amended and restated in February 2016. Certain equipment at Alliance's facility was purchased by us and is used solely for the purpose of allowing Alliance to manufacture and package ILUVIEN for us. Under the amended and restated agreement, we are also responsible for supplying Alliance with the ILUVIEN applicator and the API. 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. Unless terminated earlier in accordance with the provisions thereof, the agreement, as amended, has a remaining term of five years through February 2021 and will automatically renew for successive terms of one year unless either party delivers written notice of non-renewal to the other at least 12 months prior to the end of the then current term.

In February 2012, we entered into a commercial manufacturing agreement with Flextronics whereby Flextronics agreed to manufacture the components of the ILUVIEN applicator for us at its Tijuana, Mexico facility. Certain equipment at Flextronics' facility was purchased by us and is used solely for the purpose of allowing Flextronics to manufacture the components of the ILUVIEN applicator for us. Unless terminated earlier in accordance with the provisions thereof, our agreement with Flextronics had an initial term of three years and 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 is aligned in two segments: U.S. and International. Financial information about our business segments can be found in the section entitled "Results of Operations - Segment Review" of Item 7 of Part I of this annual report on Form 10-K and Note 18 of the accompanying consolidated financial statements in this annual report on Form 10-K.

Customers

Our revenues for the fiscal years ended December 31, 2015 and 2016 were generated from product sales primarily in the U.S., Germany, Portugal and the United Kingdom. Because we sell to only two large pharmaceutical distributors in the U.S., they accounted for 75% and 68% of our consolidated revenues for the years ended December 31, 2016 and 2015, respectively.

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 antibodies, short duration corticosteroids and laser photocoagulation or other therapies that may be approved in the future. There are other companies working to develop other drug therapies and sustained delivery platforms for DME and other indications. We believe that the following companies provide competition to ILUVIEN:

- Roche's products Lucentis (ranibizumab injection) and Avastin (bevacizumab) are both antibodies that inhibit VEGF signaling pathways. Lucentis is marketed in the EEA by Novartis. 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, an oncology product, 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.
- Regeneron's Eylea (aflibercept), an anti-VEGF inhibitor, is approved for the treatment of DME, the treatment of diabetic retinopathy in patients with DME, neovascular wet AMD and RVO in the U.S. As with Lucentis, in the EEA, the indication does not include diabetic retinopathy. Eylea is marketed in the EEA by Bayer.
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Allergan’s product Ozurdex (dexamethasone intravitreal implant), 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 affecting the posterior segment of the eye in the U.S. In the EEA, the indication for DME is for visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.

In addition, there are a number of other companies, including Ampio Pharmaceuticals, Aerpio, Allegro and pSivida, which are developing drug therapies or sustained delivery platforms for the treatment of DME.

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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.

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 in February 2005, and a subsequent amendment in March 2008, to obtain a worldwide exclusive license to develop and sell ILUVIEN for delivery to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis). This agreement also provides us with a worldwide non-exclusive license to develop and sell pSivida's proprietary delivery device to deliver other corticosteroids to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis) 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 delivery device in connection with indications for diseases outside of the eye or for the treatment of uveitis.

Our license rights to pSivida's proprietary delivery device could revert to pSivida if we were to (i) fail twice to cure our 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 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; (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 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 (iv) we notify pSivida in writing of our decision to abandon our license with respect to a certain product using pSivida's proprietary delivery device. We were not in breach of our agreement with pSivida as of December 31, 2016.

The agreement provides that after commercialization of ILUVIEN, pSivida will be entitled to 20% of the net profits and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN as defined in the amended and restated agreement. In connection with this arrangement we are entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits. As of December 31, 2016 and 2015, pSivida owed us $25.8 million and $21.6 million, respectively, in commercialization costs. Due to the uncertainty of future net profits from ILUVIEN, we have fully reserved these amounts in the accompanying consolidated financial statements. As of December 31, 2016 we owed pSivida approximately $240,000 for their portion of net profits on a cash basis, as defined in the amended and restated agreement, from the fourth quarter of 2016.

In the second quarter of 2016, pSivida disputed portions of our claimed commercialization costs for the year ended December 31, 2014. As part of this dispute, pSivida notified us that it disagreed with approximately $1.3 million of the $13.0 million in commercialization costs receivable that we had reported as of December 31, 2014 and claimed incremental profit sharing payments of $136,000 for the year ended December 31, 2014. We are disputing pSivida's assertions using the alternative dispute resolution mechanism under the pSivida Agreement. If pSivida's assertions were to prevail in the alternative dispute resolution mechanism and their assertions were then applied to the commercialization cost calculations for the year ended December 31, 2015 and the year ended December 31, 2016, then we believe the commercialization costs receivable from pSivida would be reduced from $21.6 million to $18.5 million as of December 31, 2015 and from $25.8 million to $21.2 million as of December 31, 2016. If pSivida's assertions were to prevail in the alternative dispute resolution mechanism, the impact on our statements of operations for the year ended December 31, 2015 and the year ended December 31, 2016 would be immaterial.

As a result of the FDA's approval of ILUVIEN in September 2014, we paid pSivida a milestone payment of $25.0 million (the pSivida Milestone Payment) in October 2014.

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Government Regulation

General Overview

Government authorities in the U.S. and other countries extensively regulate among other things the research, development, testing, quality, efficacy, safety (pre- and post-marketing), manufacturing, labeling, storage, record-keeping, advertising, promotion, export, import, marketing and distribution of pharmaceutical products.

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 is currently projected to be $585,000.

Post-Marketing Requirements.

There are post-marketing safety surveillance requirements that are required to be met to continue marketing an approved product. Adverse experiences with the product must be reported to the FDA and could result in imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety and/or efficacy of the product occur following approval. The FDA may also, at its discretion, 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.

With respect to product advertising and promotion of marketed products, the FDA imposes a number of complex regulations which include, among others, 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 penalties, including the issuance of warning letters directing the sponsor to correct deviations from FDA standards, a requirement that future advertising and promotional materials are pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

The manufacturing facility that produces our product must maintain compliance with cGMP and is subject to periodic inspections by the FDA. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal and regulatory action, including Warning Letters, seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties.

Foreign Regulations

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

Under the EU regulatory system, applications for drug approval may be submitted either in a centralized or decentralized procedure. Under the centralized procedure, a single application to the European Medicines Evaluation Agency, if approved, would permit marketing of the product throughout the EU (currently 27 member states). We chose to pursue the decentralized procedure in Austria, France, Germany, Italy, Portugal, Spain and the United Kingdom due to our limited resources. 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

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be requested to recognize the original authorization. Pursuant to this procedure, we obtained marketing authorizations in Belgium, the Czech Republic, Denmark, Finland, Ireland, Luxembourg, the Netherlands, Norway, Poland and Sweden.

Third-party reimbursement and pricing controls

In the EU, U.S. 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 PPACA), is expected to significantly change the way healthcare is financed by both governmental and private insurers. The provisions of the PPACA became effective beginning in 2010, although the new presidential administration and Congress is actively working to repeal it and replace it with a different health care law. 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 PPACA 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 PPACA or its replacement may have a significant effect on our profitability in the future. We cannot predict whether the PPACA will continue or what other laws or proposals will be made or adopted, or what impact these efforts may have on us.

In addition, other legislative changes have been proposed and adopted in the U.S. since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, which will remain in effect until 2024 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, increased the statute of limitations period for the government to recover overpayment to providers from three to five years. 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.

More recently, the new presidential administration and the U.S. Congress have indicated they may seek to replace the PPACA and related legislation with new healthcare legislation. There is uncertainty with respect to the impact these potential changes may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the PPACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

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 such 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 certain intellectual property relating to ILUVIEN is licensed to us by third-party collaborators, we are dependent on our collaborators' ability to obtain and maintain such protection. Where we have conducted our own research, our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets,

know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of December 31, 2016, we owned or had licensed six U.S. utility patents, one U.S. design patent and two U.S. patent applications as well as numerous foreign counterparts to many of these patents and patent applications relating to ILUVIEN or the ILUVIEN applicator. We licensed two European patents from pSivida directed to our low-dose device and have an application pending directed to our applicator system for ILUVIEN. We licensed our 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 (other than uveitis). 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

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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 licensed to us from pSivida include six U.S. patents that expire between March 2019 and August 2027 and counterpart filings to these patents in a number of other jurisdictions. Two European patents are licensed to us from pSivida directed to our low-dose device that expire in April of 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 developed by us. 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 utilize multiple clinical sites to conduct our clinical trials; however, we are not substantially dependent upon any one of these sites for our clinical trials nor do any of them conduct a major portion of our clinical trials.

We invested $2.1 million and $2.4 million in research and development during the years ended December 31, 2016 and 2015, respectively.

Employees

As of December 31, 2016, we had 125 employees with 28 of these employees engaged in research, development, regulatory and medical affairs activities, 24 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, 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.

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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 report, including the consolidated financial statements and the related notes appearing at the end of this annual report on Form 10-K, 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 Dependence on ILUVIEN and Our Business

We are dependent on the commercial success of our lead product, ILUVIEN, which in the near term will depend almost entirely on our ability to successfully commercialize ILUVIEN on our own in the U.S., Germany, Portugal and the United Kingdom, and on our distributors ability to generate revenues in other countries, which may not be significant or may never occur.

We are a pharmaceutical company with only one product available for commercial sale in a limited number of markets. We launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and the U.S. and Portugal in the first quarter of 2015. We anticipate that our distributors in Italy and the Middle East may generate some revenues for us in 2017 if they are able to successfully commercialize ILUVIEN in those territories. We also anticipate launching ILUVIEN directly in Austria and Ireland in 2017.

In the fourth quarter of 2016, through our Middle Eastern distributor, we received from the Health Authority in Abu Dhabi (HAAD) a reimbursement code for ILUVIEN to allow for reimbursement in the Emirate of Abu Dhabi. As a result, our distributor in the Middle East has begun limited named patient sales in the United Arab Emirates in late 2016. In February of 2017, we announced that the Italian government had published a change in the reimbursement status of ILUVIEN, allowing ILUVIEN to be hospital-administered and that ILUVIEN should be fully reimbursed for pseudophakic patients. The timing of the commercial launch of ILUVIEN in any country is dependent upon each specific country’s pricing and reimbursement timelines. Because we do not currently have any products or product candidates available for sale or in clinical development other than ILUVIEN, our future success is dependent upon our successful and our distributors successful commercialization of ILUVIEN for the treatment of DME.

If we or our distributors do not successfully commercialize ILUVIEN in these countries our ability to generate revenue may be jeopardized and, consequently, 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 obtaining unfavorable pricing and/or reimbursement which could negatively affect our ability to increase revenues.

We incurred and expect to continue to incur significant expenses and to use a substantial portion of our cash resources for the continued commercial launch of ILUVIEN in the U.S., Germany, Portugal and the United Kingdom, continue to pursue the approval of and reimbursement for ILUVIEN in other countries and continue to grow our operational capabilities. This represents a significant investment in the commercial and regulatory success of ILUVIEN, which is uncertain.

ILUVIEN may not be commercially successful.

Market acceptance of and demand for ILUVIEN will depend on many factors, including, but not limited to:

- cost of treatment;
- pricing and availability of alternative products;
- our ability to obtain third-party coverage or reimbursement for ILUVIEN at appropriate levels;
- perceived prevalence and severity of adverse side effects associated with treatment;
- perceived efficacy relative to other available therapies;

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- relative convenience and ease of administration; and
- shifts in the medical community to new treatment paradigms or standards of care.

We have limited experience and information with regard to the market acceptance of ILUVIEN in the EEA or elsewhere. As a result, we may have to revise our estimates regarding the acceptance of ILUVIEN under our pricing structure, reevaluate and/or change the pricing for ILUVIEN.

Additionally, we may encounter unexpected or unforeseen delays in expanding our commercial launch in one or more countries in which ILUVIEN received or was recommended for marketing authorization. These delays may increase the cost of and the resources required for successful commercialization of ILUVIEN.

We may need alternative financing or additional capital to maintain our covenants under our $35.0 million debt facility, which we may be unable to obtain or which may be expensive or dilutive.

We may need to raise alternative or additional financing to maintain compliance with our debt covenants under our loan and security agreement with Hercules Technology Growth Capital, Inc. (Hercules), which Alimera Sciences Limited (Limited), our subsidiary, entered into in April 2014, and amended in November 2015, March 2016, May 2016 and October 2016 (the Term Loan Agreement). Under the Term Loan Agreement, Limited obtained a term loan in an aggregate principal amount of $35.0 million, with up to $10 million in additional financing upon our achievement of certain revenue milestones (Term Loan).

The Term Loan Agreement contains customary affirmative and negative covenants, including without limitation, covenants of minimum liquidity, minimum trailing six-month net revenue and adjusted EBITDA, and events of default in connection with these covenants.

Under the Term Loan Agreement, if we maintain $35.0 million in liquidity, including cash and eligible accounts receivable, and we have not been and are not in breach of the Term Loan Agreement at the end of a month, the six-month trailing revenue covenant is waived for such month. As of December 31, 2016, our liquidity as defined under the Term Loan Agreement was $40.9 million, which consisted of $31.0 million in cash and cash equivalents, and 80% of our $12.4 million in eligible U.S. accounts receivable.

To secure the performance of our obligations under the Term Loan Agreement, Limited pledged all of its assets to Hercules. Our or Limited’s failure to comply with the covenants under the Term Loan Agreement could result in an event of default, the acceleration of our debt and the loss of our assets. We and certain of our subsidiaries are guarantors of the obligations of Limited to the lender under the Term Loan Agreement (Guaranties). Pursuant to the Guaranties, we and these subsidiaries granted the lender a first priority security interest in substantially all of our respective assets.

In the event that we are unable to meet the liquidity requirement under the Term Loan Agreement and we are not in a position to meet the trailing six-month revenue requirement, we may determine that we need alternative financing, which may not be available or may be very expensive or we may need to raise funds on terms not favorable to us or our stockholders in order to meet the liquidity requirement.

Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline significantly and may cause us to raise funds on terms not favorable to us or our stockholders. Insufficient funds may require us to delay, scale back or eliminate some or all of our activities, and if we are unable to obtain additional funding, there may be substantial doubt about our ability to continue as a going concern, which

could cause significant reputational damage and impact our ability to sell ILUVIEN.

In an event of default, Hercules may call the Term Loan, which could require us to pay back the entire amount owed and pay an early termination fee, or if they do not call the Term Loan, we may have to pay an increased rate of interest, pay additional monetary amounts in exchange for a waiver or modification of the Term Loan, or grant additional equity or warrant coverage and agree to further restrictions on our operations that could hinder us in the future. For example, in January of 2016 we did not meet the revenue requirement and in June of 2016 we did not meet the liquidity requirements under the then existing terms of the Term Loan Agreement. While these violations were waived by Hercules, we were required to pay additional monies to Hercules and modify the terms of a warrant previously issued to Hercules. In conjunction with the first waiver, we paid an amendment fee of $350,000 and agreed to increase the payment that will be made when the Term Loan ends to $1.4 million. In conjunction with the second waiver, we agreed to pay a fee of $350,000 and paid a weekly ticking fee of 0.05% multiplied by the outstanding principal amount of the Term Loan, in addition to the normal interest payments we were making, until we raised $15.0 million in equity,

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which we did in August of 2016. The warrant was modified in conjunction with the first and second waiver to increase the number of shares that may be purchased under the warrant and reduce the exercise price. Although Hercules waived each of these defaults, there can be no assurance that it will do so with respect to any future default.

We rely 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. Our business would be seriously harmed if any of these third-parties are not able to satisfy our demand and alternative sources are not available.

We do not have, nor currently intend to have, in-house manufacturing capability and depend completely on a single third-party manufacturer for the manufacture of the ILUVIEN implant (Alliance Medical Products, Inc., a Siegfried Company (Alliance)), a single third-party manufacturer for the manufacture of the ILUVIEN applicator (FlexMedical or an affiliate of Flextronics International, Ltd. (Flextronics)), a single third-party manufacturer for the manufacture of ILUVIEN's active pharmaceutical ingredient (FARMABIOS SpA./Byron Chemical Company Inc. (FARMABIOS)) and a single third-party manufacturer for the quality release testing of ILUVIEN in the EEA (AndersonBrecon Limited trading as Packaging Coordinators, Inc. (PCI)). Although we have agreements for the manufacture of the ILUVIEN implant (with Alliance), the manufacture of the ILUVIEN applicator (with Flextronics), for the supply of ILUVIEN's active pharmaceutical ingredient (with FARMABIOS) and for the quality release testing of ILUVIEN in the EEA (with PCI), if any of the third-party manufacturers breach their agreements or are unable to meet their contractual or quality requirements or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with them or get them approved by the applicable regulatory authorities, such as the U.S. Food and Drug Administration (FDA), in a timely manner. Further, all of our manufacturers rely on additional third-parties for the manufacture of component parts. For example, in the third quarter of 2016, we did not have ILUVIEN that was labeled for the German and Portuguese markets. We were able to sell the United Kingdom labeled ILUVIEN in Germany and Portugal during this period and the effect was not material on our operations. 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, and impact our ability to fulfill demand for ILUVIEN, which may be material in the future and affect our revenue, operations and cash flow.

Materials necessary to manufacture ILUVIEN may not be available on commercially reasonable terms, or at all, which may delay the development, regulatory approval and commercialization of ILUVIEN.

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 at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. If our manufacturers are unable to obtain these materials in sufficient amounts, the commercialization of ILUVIEN would be hampered or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of ILUVIEN. 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 we are unable to obtain these supplies, our ability to manufacture ILUVIEN for commercial sale would be delayed, significantly impacting our ability to generate revenue from the sale of ILUVIEN.

The terms of our Term Loan Agreement require us to meet certain operating covenants and place restrictions on our operating and financial flexibility.

The Term Loan Agreement contains certain operating covenants and restricts our operating and financial flexibility. The Term Loan is secured by a lien covering all of our assets, other than our intellectual property. The Term Loan Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to meet certain six-month trailing revenue requirements, satisfy certain financial covenants, including maintaining at least $35.0 million in a combination of cash and eligible accounts receivable and certain adjusted EBITDA, maintaining our legal existence and governmental approvals, delivering certain financial reports and maintain insurance coverage. Negative covenants include, among others, restrictions on transferring any part of our business or property, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets and other financial covenants, in each case subject to customary exceptions.

In order to maintain compliance with these covenants, we must ensure that our activities will not violate the terms of the affirmative or negative covenants, which may cause us to delay expenditures or reduce costs, all of which may reduce our future revenue growth. In an event of default under our Term Loan Agreement, including failure to satisfy our operating covenants, Hercules may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to raise additional financing, renegotiate the Term Loan Agreement on terms less favorable to us or to immediately cease operations. Any

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declaration by Hercules of an event of default could cause adverse publicity, could significantly harm our business and prospects and could cause the price of our common stock to decline significantly. Further, if we are liquidated, Hercules' right to repayment would be senior to the rights of our stockholders.

We may need to raise additional capital to fund our operations and support our growth, and if we do not do so, we may be unable to successfully commercialize ILUVIEN.

We do not expect to have positive cash flow from operations until later in 2017, if at all. As of December 31, 2016, we had approximately $31.0 million in cash and cash equivalents. We may need to raise additional funds to fund our operations and support our growth. The actual amount of funds that we may need to raise, if any, 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 but are not limited to:

- the level of success of the commercialization of ILUVIEN in the U.S., Germany, Portugal, the United Kingdom and any other territories we may launch in,
- expenses relating to the commercialization of ILUVIEN;
- the level of success of the commercialization of ILUVIEN by our distributors in Italy and the Middle East;
- the timing of approvals, if any, of ILUVIEN 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 amount of our research, development and medical affairs, marketing and general and administrative expenses;
- the need and cost of conducting additional clinical trials for ILUVIEN;
- 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 do so, we may not be able to commercialize ILUVIEN successfully. If we are unable to obtain additional funds on a timely basis or on terms favorable to us, we may be required to cease or reduce further commercialization of ILUVIEN,

If we seek to raise additional capital it may be difficult to obtain on commercially reasonable terms, may further restrict our operations and could result in additional dilution to our stockholders.

We do not expect to have positive cash flow from operations until later in 2017, if at all. As of December 31, 2016, we had approximately $31.0 million in cash and cash equivalents. We may need to raise alternative or additional financing to maintain compliance with our debt covenants under the Term Loan Agreement, as discussed above in these risk factors. We may need to raise alternative or additional financing to fund our operations and support growth, as discussed above in these risk factors. 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 be dependent upon our stock being quoted on the

NASDAQ Global 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. In the event additional financing is needed or advisable, 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, or 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 example, under our Term Loan Agreement, we and certain of our subsidiaries are subject to a variety of affirmative and negative

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covenants, including revenue requirements, adjusted EBITDA requirements, liquidity requirements, limitations on the disposition of assets, limitations on incurring additional debt, required financial reporting, and other requirements.

ILUVIEN and any future products or product candidates may not be commercially viable if we fail to obtain or maintain an adequate level of reimbursement for these products from any of the following: governments, private insurers, the Medicare program or other third-party payers. The market for our products may also be limited by the indications for which their use or frequency of administration may be reimbursed.

Our revenue from sales of ILUVIEN in the countries in which ILUVIEN has received or been recommended for marketing authorization is dependent upon the pricing and reimbursement guidelines adopted in each of such countries, which levels 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.

We have established list pricing or developed estimates of anticipated pricing in countries in which ILUVIEN has received or been recommended for marketing authorization. These estimates are our expectations, which are based upon the burden of DME, the lack of any approved therapies for DME, our perception of the overall cost to benefit ratio of ILUVIEN and the current pricing of therapies to treat DME and other retinal diseases such as age related macular degeneration and retinal vein occlusion. However, due to numerous factors beyond our control, including efforts to provide for containment of health care costs, one or more countries may not support our estimated level of governmental pricing and reimbursement for ILUVIEN, particularly in light of the ongoing budget crises faced by a number of countries, which would negatively impact anticipated revenue from ILUVIEN.

The availability and levels of reimbursement by governmental and other third-party payers affect the market for products such as ILUVIEN and others that we may develop. These third-party payers continually attempt to contain or reduce the costs of health care by challenging the prices charged for medical products and services.

In many countries, the pricing of prescription pharmaceuticals is subject to governmental control. In the U.S., we obtained approvals for payment for ILUVIEN from private insurers, including managed care organizations, and from the Medicare and Medicaid programs, but the payment amount for ILUVIEN could be modified in the future, and the types of patients for which ILUVIEN is reimbursed could be reduced to a smaller subset of patients. 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 new 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 which allow us to gauge the impact of such potential reforms, if any, on our business and operations. These reforms could significantly reduce payments from Medicare and Medicaid over the next ten years. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling of payments or the imposition of enrollment limitations on new providers, may change the availability, methods and rates of reimbursements from Medicare, private insurers and other third-party payers for ILUVIEN and our future product candidates. Some of these changes and proposed changes 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 also could be adversely affected if retinal specialists are not reimbursed for the cost of the procedure in which they administer ILUVIEN on a basis satisfactory to the administering retinal specialists.

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.

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. Our business also could be adversely affected if retinal specialists are not reimbursed by Medicare for the cost of the procedure in which they administer ILUVIEN on a basis satisfactory to the administering retinal specialists. If the local contractors that administer the Medicare program are slow to reimburse retinal specialists for ILUVIEN, the retinal specialists may pay us more slowly, which would adversely affect our working capital requirements.

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 of 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

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patients. The negotiation for this reimbursement change took more than 15 months. To obtain reimbursement or pricing approval at a level that we feel is appropriate in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of ILUVIEN to other available therapies. Limitations on reimbursement could be imposed at the national, regional or local level or by fiscal intermediaries in each country either through the initial authorization process or at some point in the future. For example, in November 2016, we began a review process with The National Institute for Health and Care Excellence (NICE) in the United Kingdom. This review could result in beneficial or detrimental changes to the limitations on the use of ILUVIEN in England and Wales. Our business could be materially adversely affected if such limitations are imposed.

In addition, due to price referencing within the EEA and certain other countries, existing pricing in our current markets could be negatively impacted 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.

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

We expect to experience pricing pressures in connection with the sale of ILUVIEN and any future products or product candidates 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 and additional legislative proposals, and the economic health of companies. 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.

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 manufacture and packaging of pharmaceutical products such as ILUVIEN and any future product candidates are regulated by the FDA and similar foreign regulatory agencies and must be conducted in accordance with the FDA's current Good Manufacturing Practice (cGMP) and comparable requirements of foreign regulatory agencies. There are a limited number of manufacturers that operate under these cGMP regulations which are both capable of manufacturing ILUVIEN and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of ILUVIEN or any future products or product candidates, 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 which could significantly and adversely affect our business. Any significant delays in the manufacture of ILUVIEN or the quality of the product could materially harm our business and prospects.

Changes in certain aspects of the manufacturing process or procedure will require prior FDA review and/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 in our own facility or at the facility of another third-party, we would need to ensure that the new facility and the manufacturing process are in compliance with cGMP and comparable foreign regulations. Any such new facility will also be subject to inspection. In addition, we have to demonstrate that

the product made at any such new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA or a foreign regulatory agency may require clinical testing as a way to prove equivalency of the product manufactured at any new facility as compared to the old facility, which would result in additional costs and delay.

Furthermore, we need 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, we will be required to consistently produce in commercial quantities and of specified quality in a reproducible manner and document our 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.

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

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Our and our 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. 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 and biologicals, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, and other potential purchasers of drugs and biologicals. 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 put in place a Compliance Program to assist with monitoring and complying with these activities and we continually 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 such actions or asserting our rights, those actions could have a significant and material adverse impact 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.

Failure to successfully manage our international operations could harm our business, operating results and financial condition.

Our international operations require significant management attention and financial resources. In addition, there are many risks inherent in international business activities including, but not limited to:

- 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

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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 impact 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, Portugal and the United Kingdom. We launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013, and the U.S. and Portugal in the first quarter of 2015. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources. We anticipate that our distributors in Italy and the Middle East may generate some revenues for us in 2017, if they are able 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.

As of December 31, 2016, we had 125 employees, 77 of whom were located in the U.S. and 48 of whom were located in the United Kingdom, Germany, Portugal and France. We began building our U.S. commercial infrastructure in the fourth quarter of 2014 following the FDA approval of ILUVIEN in the third quarter of 2014 with the addition of sales management, field sales representatives, payor relations specialists, reimbursement support specialists and other positions. As of December 31, 2016, our commercial U.S. organization included 45 employees. As our development and 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;
- the inability of market access personnel 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, but not limited to, 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

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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.

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 jurisdiction where we have received regulatory approval but 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., Portugal, Germany and the United Kingdom. We plan to sell ILUVIEN in Austria and Ireland in 2017. Our distributor plans to launch ILUVIEN in Italy in 2017. 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 may be revoked. If our license in any of these countries is revoked, we will need to pursue marketing authorization for any of these countries. We intend to continue to pursue market authorizations for ILUVIEN internationally in additional jurisdictions. In order to market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements.

The research, testing, manufacturing and marketing of drug products are subject to extensive regulation by U.S. federal, state and local government authorities, including the FDA and similar entities in other countries. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval or approval in the seventeen EEA countries in which ILUVIEN has received marketing authorization. To obtain regulatory approval of a product, we must demonstrate to the satisfaction of the regulatory agencies that, among other things, the product is safe and effective for its intended use. In addition, we must show that the manufacturing facilities used to produce the products are in compliance with cGMP regulations or their equivalent in the jurisdiction in which we are seeking approval.

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, where drugs are regulated, 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 from those which we do;

- they may not approve of our manufacturing processes;
- a drug candidate may not be safe or effective;
- they may conclude that the drug candidate does not meet quality standards for stability, quality, purity and potency; and
- they may change their approval policies or adopt new regulations.

The applicable regulatory authorities may make requests or suggestions regarding conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval. For example, the regulatory authorities may not approve

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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.

We may not be able to file for regulatory approvals, may not receive necessary approvals to commercialize ILUVIEN in any additional market or we may be unable to maintain regulatory approvals in certain EEA countries. The failure to obtain these approvals or maintain regulatory approvals in certain EEA countries if they are revoked, could harm our business materially. 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 EEA member states where ILUVIEN has already received marketing authorization. The withdrawal of an approval could harm our business materially.

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, subsequently withdraw approval or take other actions against us or ILUVIEN that would be adverse to our business, including withdrawal of approval if we are unable to commercialize ILUVIEN within certain time periods.

Regulatory agencies generally approve products for particular indications. If any such 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 IOP. Either of these indications may limit the use of ILUVIEN to a segment of the DME population. Product approvals, once granted, may be withdrawn if problems occur after initial marketing. 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 EEA member states where ILUVIEN has already received marketing authorization. The marketing, distribution and manufacture of ILUVIEN will be subject to regulation. We will need to comply with facility registration and product listing requirements of the FDA and similar entities in other countries and adhere to the FDA’s Quality System Regulations. Noncompliance with applicable FDA and similar entities’ requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of ILUVIEN, total or partial suspension of production, refusal of regulatory agencies to grant approvals, withdrawal of approvals by regulatory agencies or criminal prosecution. We would also need to maintain compliance with federal, state and foreign laws regarding sales incentives, referrals and other programs.

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, profit sharing, insurance and other obligations on us, including the right by pSivida to audit the commercialization costs of ILUVIEN incurred by us. If we fail to comply with these obligations, pSivida may have the right to terminate the license. Our license rights to pSivida’s proprietary delivery device could revert to pSivida if we (i) fail twice to cure our 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 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; (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 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 (iv) notify pSivida in writing of our decision to abandon our license with respect to a certain product using pSivida's proprietary delivery device. If the license with pSivida, or any other current or future material license agreement were terminated, we would not be able 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 and conditions 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 by various regulatory authorities in

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European. In addition to approval required for new formulations, any new indication for an approved product also requires regulatory approval. If we are not able to obtain regulatory approval for any desired future indications for our products, including ILUVIEN, our ability to effectively market and sell our products, including ILUVIEN, 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 are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict 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 could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

If we fail to maintain proper and effective internal control over financial reporting or if the interpretations, estimates or judgments utilized in preparing our financial statements prove to be incorrect, 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 would require us to continue to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff. Moreover, if we are not able 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, the Securities and Exchange Commission (SEC) or other regulatory authorities, which would require additional financial and management resources.

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 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. Our interpretations, estimates and judgments are based 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. In the event that 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. The need to restate 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 such 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.

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 the second quarter of 2013, and the U.S. and Portugal in the first quarter of 2015. We are not currently generating revenues that cover our expenses or would cover our anticipated 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, 2016, we had accumulated a deficit of $377.1 million. Our ability to generate significant revenue and achieve profitability is dependent 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 any future products or product candidates and obtain necessary regulatory approvals of any future products or product candidates. Although we believe we may be cash flow positive in late 2017, 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

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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;
- timing and ordering patterns from our distributors;
- our ability to obtain regulatory approval of ILUVIEN in additional jurisdictions;
- sales, marketing and medical affairs expenses;
- manufacturing or supply issues;
- seasonality caused by insurance renewals for patients in the U.S., and by doctor and or patient absences due to holidays and vacations;
- regulatory developments affecting ILUVIEN, our future product candidates or our competitors' products;
- the emergence of products that compete with ILUVIEN;
- cost of product sales;
- variations in the level of expenses related to our products or future development programs;
- the timing and amount of royalties, milestone payments, or product purchases by our distributors;
- 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 intellectual property infringement or other lawsuit in which we 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.

ILUVIEN utilizes fluocinolone acetonide (FAc), a corticosteroid that has demonstrated undesirable side effects in the eye; therefore, the success of ILUVIEN will be dependent upon our ability to convince physicians that the benefits of its efficacy are greater than the risks of its side-effect profile.

The use of corticosteroids in the eye has been associated with undesirable side effects, including increased incidence of cataract formation and elevated IOP, which may increase the risk of glaucoma. We have 36 months of clinical data from our two completed Phase 3 pivotal clinical trials (collectively, our FAME Study), but the extent of ILUVIEN's long-term side-effect profile beyond month 36 is not yet known. 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. In the fourth quarter of 2016, we requested approval to modify our protocol to cap enrollment in the study due to our post market safety surveillance not showing any unexpected safety signals. Although we have not received formal regulatory approval, the Medicines & Healthcare products Regulatory Agency (MHRA) has agreed to allow us to suspend enrollment, pending approval of our protocol amendment. As of December 31, 2016, 548 patients were enrolled in this study. Although unlikely, data accumulated from the five-year post-authorization study, or other commercial experience, could result in the withdrawal of ILUVIEN approval in one or more jurisdictions. In addition, if we are

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not able to convince physicians that the benefits of ILUVIEN's efficacy are greater than the risks of its side-effect profile it could impact our revenues and revenue growth in our current markets where we sell ILUVIEN or in future markets where we may attempt to sell ILUVIEN.

Although we have received approval to temporarily suspend enrollment in our post authorization European registry study for ILUVIEN, we are awaiting formal and final approval from the MHRA of the change in our protocol to cap enrollment at our current level. Because final approval has not yet occurred, and if it were not approved, the cost to continue enrollment to the originally submitted protocol level of 800 patients would adversely impact our operating results, profitability and cash flow.

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. In the fourth quarter of 2016, we requested approval to modify our protocol to cap enrollment in the study due to our post market safety surveillance not showing any unexpected safety signals. Although we have not received formal regulatory approval, the MHRA has agreed to allow us to suspend enrollment, pending approval of our protocol amendment. As of December 31, 2016, 548 patients were enrolled in this study. If the MHRA were to not give formal regulatory approval to cease enrollment and we had to reach the full enrollment in the study, the additional costs of the additional patients in the study would adversely affect our cash flows and profitability in 2017 and 2018.

pSivida plans to file and obtain regulatory approval in both the EU and the U.S. for a drug to treat uveitis with FAc that uses the same insert technology as ILUVIEN, although with a different delivery device. The obtaining of regulatory approval and the subsequent commercialization of this drug either by pSivida or by another party that licenses the technology may create confusion in the marketplace and may disrupt our reimbursement agreements with governmental agencies.

Our license agreement with pSivida permits them 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 posterior segment uveitis and has announced that they plan to file a European Market Authorization in the second quarter of 2017 and a NDA in the U.S. for this drug in the second half of calendar year 2017 (Uveitis Drug). If they receive approval for the posterior segment uveitis and they or another party commercializes the Uveitis Drug in either the EU or 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 may impact the reimbursement of ILUVIEN in certain countries. This potential market place confusion or any impact to our reimbursement for ILUVIEN could have a material adverse impact on our revenues, business and operations.

Legislative or regulatory reform of the health care system in the U.S. and foreign jurisdictions may adversely impact our business, operations or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In particular, in March 2010, the Patient Protection and Affordable Care Act (the PPACA), and a related reconciliation bill were signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. The new presidential administration and Congress have indicated that they will repeal and replace the PPACA and the president in January of 2017 signed an executive order (Executive Order) that mandated that all executive agencies to the maximum extent of the law waive, defer, grant exemptions from, or delay implementation of any provision or requirement of the PPACA. Provisions affecting pharmaceutical companies in the PPACA include for pharmaceutical companies changes in the mandatory rebates required for Medicaid for drugs, certain requirements

for discounts to certain hospitals and entities, discounts for patients in Medicare Part D coverage gap and non-tax deductible fees to the federal government based on the pharmaceutical companies market share.

The PPACA has not been fully implemented and the affects if fully implemented are not known. In addition, the effect of any "repeal and replace" of this healthcare reform legislation or the Executive Order cannot be known at this time. The financial impact of the U.S. healthcare reform legislation and the current attempt to "repeal and replace" this healthcare legislation over the next few years will depend on a number of factors.

The Physician Payment Sunshine Act also imposes reporting and disclosure requirements on device and drug manufacturers for any “transfer of value” made or distributed to prescribers and other healthcare providers. In addition, device and drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in significant civil monetary penalties and potential government action. Similar laws requiring reporting of "transfer of value" have been passed in Europe, with potential penalties and government action for failure to comply.

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In addition, in September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted giving the FDA enhanced post-marketing authority including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to ensure compliance with post-approval regulatory requirements and potential restrictions on the sale and/or distribution of approved products.

Further, in some foreign countries the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval and product launch. For example, in the fourth quarter of 2016, after unsuccessfully negotiating with the French government to obtain an appropriate price, we decided to close operations in France. We expect the closing of operations to be completed in early 2017. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Our business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the U.S. to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from ILUVIEN or any future products or product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop drug candidates.

Significant developments arising from the new U.S. presidential administration and congress or the United Kingdom's vote on leaving the EU could have a material adverse effect on us.

In January of 2017, a new presidential administration and congress took power in the U.S. The new president has expressed antipathy towards existing trade agreements, such as the North American Free Trade Agreement, greater restrictions on free trade generally and significant increases on tariffs on goods imported into the U.S., particularly from China and Mexico. Changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade, manufacturing, development and investment in the territories and countries where we currently manufacture certain components of our products, such as Mexico and in countries where we sell products, and any negative sentiments towards the United States as a result of such changes, could adversely affect our business.

On June 23, 2016, the United Kingdom held a referendum and voted in favor of leaving the EU. 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.

The forthcoming withdrawal of the United Kingdom from the EU has caused and, along with events that could occur in the future as a consequence of the United Kingdom's withdrawal, 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. In addition, 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. Furthermore, 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 from the United Kingdom to another

country in the EU. 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.

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, but not limited to, 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

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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 but not limited to 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.

There are three biological anti-VEGF agents 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.

Within the corticosteroid class, Ozurdex 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 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 utilized by some physicians for the treatment of DME although it is not approved for DME.

Retinal specialists are currently using laser photocoagulation for the treatment of 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.

In addition, 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 delivery device for indications for diseases outside of the eye or for the treatment of uveitis, which are retained by pSivida. Further, our agreement with pSivida permits pSivida to grant to any other party the right to use its intellectual property (i) 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, (ii) 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 (iii) 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.

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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.

Exchange rate fluctuations of foreign currencies relative to the U.S. Dollar could materially, 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 through the use of 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.

Although we currently do not have any material collaboration agreements with third-parties, other than our license with pSivida, we expect to depend on collaborations to develop and commercialize our products. If we are unable to identify or enter into an agreement with any material third-party collaborator, if our collaborations with any such third-party are not scientifically or commercially successful or if our agreement with any such third-party is terminated or allowed to expire, we could be adversely affected financially or our business reputation could be harmed.

Our business strategy includes entering into collaborations with corporate and academic collaborators for the commercialization, research and development of ILUVIEN and any future products or product candidates. Although we currently do not have any material collaboration agreements with third-parties other than our license with pSivida, we have entered into various agreements under which distributors will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in numerous countries in the Middle East, Australia, New Zealand and Canada. In addition, we have an agreement with a distributor in Italy to provide regulatory, reimbursement and sales and marketing support for future commercialization of ILUVIEN in Italy. We expect that these distributors may be able to sell ILUVIEN in the future in these territories. As of December 31, 2016 there have been sales of ILUVIEN by our distributor in the Middle East, which were not significant, and there have been no other sales in any of these remaining territories in which we have distribution agreements. These arrangements may not be commercially successful. In the future we may potentially enter into third-party collaboration arrangements including joint sales and marketing arrangements for sales and marketing of ILUVIEN in certain EEA countries and elsewhere outside of North America, and future product development arrangements. If we are unable to identify or enter into an agreement with any material third-party collaborator we could be adversely affected financially or our business reputation could be harmed. Any of these arrangements that we enter into in the future may not be scientifically or commercially successful. The termination of any of these arrangements whether currently in existence or entered into in the future might adversely affect our ability to develop, commercialize and market our products.

The success of our collaboration arrangements depends heavily on the efforts and activities of our collaborators. Our collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations. We expect that the risks which we face in connection with these future collaborations will include the following:

- our collaboration agreements are expected to be for fixed terms and subject to termination under various circumstances, including, in many cases, on short notice without cause;

- our collaborators may not promote and market our drugs in the manner we would or as well as we would if we had the resources to do so in their countries;

- our collaborators may change the focus of their development and commercialization efforts. In recent years there have been a significant number of mergers and consolidations in the pharmaceutical and biotechnology industries, some of which have resulted in the participant companies reevaluating and shifting the focus of their business following the completion of these transactions. The ability of our products to reach their potential could be limited if any of our future collaborators decreases or fails to increase spending relating to such products

- our collaboration agreements will likely require us to not conduct specified types of research and development in the field that is the subject of the collaboration. These agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in cooperation with third-parties;

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- our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with our products which are the subject of their collaboration with us.

Collaborations with pharmaceutical companies and other third-parties often are terminated or allowed to expire by the other party. With respect to our future collaborations, any such termination or expiration could adversely affect us financially as well as harm our business reputation.

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 are highly dependent upon 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 products or product candidates.

In addition, our growth will require us to hire a significant number of qualified technical, commercial and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. 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 our operations or grow.

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

As of December 31, 2016, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $104.9 million and $83.3 million, respectively, which expire at various dates beginning in 2020 through 2035. Section 382 of the Internal Revenue Code (Section 382) limits the annual utilization of NOL carry-forwards and tax credit carry-forwards following an ownership change in our company. NOL carry-forwards may be subject to annual limitations under Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of our company were to occur. In general, an ownership change occurs for purposes of Section 382 if there is a more than 50% change in ownership of a company over a 3-year testing period. We have determined that a Section 382 change in ownership occurred in late 2015. Therefore, the annual utilization of our NOLs is subject to certain limitations under Section 382 and other limitations under state tax laws. We are currently in the process of calculating these limitations. Any 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, any limitation would not have an impact on the statements of operations for the periods presented. The results of the analysis on the impact to our NOLs will be disclosed at a later date. 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 Term Loan Agreement and we raise such funds by selling additional equity, this could further limit the use of our NOLs in the future.

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

- potential products or product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

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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;
- 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.

Any failure or delay in completing clinical trials for any future products or product candidates could harm our business.

Preclinical studies and clinical trials required to demonstrate the safety and efficacy of any product or future product candidates will be time consuming and expensive and together will take several years to complete. The completion of clinical trials for any product candidates may be delayed by many factors, including:

- our inability to manufacture or obtain from third-parties materials sufficient for use in preclinical studies and clinical trials;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- unforeseen safety issues or side effects; and
- governmental or regulatory delays and changes in regulatory requirements and guidelines.

If we fail to successfully complete any future clinical trials for any products or future product candidates, we may not receive the regulatory approvals needed to market those product candidates. Therefore, any failure or delay in commencing or completing such clinical trials would harm our business materially.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

- unforeseen safety issues or any determination that a trial presents unacceptable health risks; and

- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our contract research organizations, and other third parties.

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If we are required to conduct additional clinical trials or other studies with respect to any products or future product candidates beyond those that we initially contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these trials or studies are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for those products or future product candidates, we may not be able to obtain marketing approval or we may obtain approval for indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or future product candidates. If any of this occurs, our business will be materially harmed.

If our contract research organizations (CROs), third-party vendors and investigators do not successfully carry out their duties or if we lose our relationships with them, our development efforts with respect to any future product candidates could be delayed.

We expect to be dependent on CROs, third-party vendors and investigators for preclinical testing and clinical trials related to our discovery and development efforts with respect to any products or future product candidates. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our development programs with respect to our product candidates or if their performance is substandard, it will delay the development and commercialization of our product candidates. The parties with which we contract for execution of clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our products or product candidates. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in identifying another comparable provider and contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current Good Laboratory Practices (cGLP) and similar foreign standards, and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of ILUVIEN or any future product candidates could be delayed.

We may acquire additional businesses or form strategic alliances in the future, and we may not realize the benefits of such 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. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such 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 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.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting 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 these new compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time consuming and costly. These rules and regulations may make it more difficult and more expensive for us to maintain our existing director and officer liability insurance or to obtain similar coverage from an alternative provider.

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 be dependent, 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. If there were to be negative trends in the general economy in any of the jurisdictions in which we may do business,

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these organizations may be unable to satisfy their reimbursement obligations or may 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. For example, a global economic downturn and subsequent market instability such as the one occurred in 2008 and 2009 made the business climate more volatile and costly.

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 such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected. Because we sell to only two large pharmaceutical distributors in the U.S., they accounted for 75% and 68% of our consolidated revenues for the years ended December 31, 2016 and 2015, 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 will depend in large part 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 not be able 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, 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 and, if successful, could cause us to pay substantial damages or prevent us from developing any future product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop

or delay manufacturing, sales, research or development, of the product or product candidate that is the subject of the suit.

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

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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 more effectively 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 not adequate, 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, 2016, the patent rights relating to ILUVIEN licensed to us from pSivida included six 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 patent 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 of 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 prior to 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. Some claims in pending patent applications filed or licensed by us have been rejected by patent examiners. These claims may need to be amended. 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 the license agreement. Manufacturers may also seek to obtain approval to sell a generic version of ILUVIEN prior to 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 develop, and threaten our ability to commercialize ILUVIEN and any future product candidates. Further, if we encounter delays in our clinical trials for any future product candidate, the period of time during which we could market such 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 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

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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 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.

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

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 harms people, 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.

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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 $10.0 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 product revenue is generated in new countries, we intend to obtain compulsory coverage in those countries that require it. However, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our product development and commercialization efforts.

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.

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

Our research and development activities may involve the controlled use of potentially hazardous substances, including chemical and biological materials. In addition, our operations may produce hazardous waste products. Federal, state and local laws and regulations in the U.S. govern the use, manufacture, storage, handling and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance 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. In the event of an accident, 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.

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.

We completed our Initial Public Offering (IPO) in April 2010 at a price of $11.00 per share. Subsequently, our common stock has traded as low as $1.01 per share. 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, Portugal and the United Kingdom;
- the ability of ILUVIEN to be approved in any additional jurisdiction;

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- the ability of ILUVIEN or any future products or product candidates, if approved in additional jurisdictions, to achieve and maintain 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;
- 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;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board of directors or management;
- results from our clinical trial programs;
- our ability to develop and market new and enhanced products or product candidates on a timely basis;
- general economic conditions and slow or negative growth of our markets; and
- political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various regulatory, scientific, clinical and other product development goals or milestones. These milestones may include the submission of regulatory filings, the notification of the results of regulatory filings and the anticipated commercial launch of ILUVIEN in various new jurisdictions or for new or expanded indications, or 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.

Certain of our stockholders 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, certain 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

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concentration of voting power may have the effect of delaying or impeding actions that could be beneficial to you, including actions that may be supported by our Board of Directors.

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, Series A Convertible Preferred Stock Warrants and Series B Convertible Preferred Stock. Sales by these stockholders of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock. Additionally, a small number of investors have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

We also have the right to sell shares of our common stock through an at-the-market offering. For example, in 2016, we sold a total of 662,779 shares of common stock at a weighted average price of $1.83 per share pursuant to our at-the-market offering through Cowen and Company, LLC (Cowen). Pursuant to our sales agreement with Cowen, 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, 2016, there were a total of 10,804,412 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options granted under our equity incentive plans. Upon the exercise of these options, in accordance with their respective terms, these shares 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 of time, 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. 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. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be diluted by subsequent sales. Such 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 stock options 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, 2017, 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, 2016 we have reserved 411,662 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, 2017, an additional 82,760 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.

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

- increase or decrease the authorized number of shares of Series A Convertible Preferred Stock;

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

- amend our certificate of incorporation or the certificate of designation of the Series A Convertible Preferred Stock, in each case in a manner that adversely affects the rights, preference or privileges of the Series A Convertible Preferred Stock;

- redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of common stock or preferred stock; provided, however, that this restriction shall not apply to (A) the redemption of rights issued pursuant to any “poison pill” rights plan or similar plan adopted by us after the closing of the Series A Convertible Preferred Stock financing 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 the implementation of a “poison pill” rights plan or similar plan by us;

- 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 on the date of the closing of the Series A Convertible Preferred Stock financing shall not be subject to this restriction and shall not be included for purposes of determining whether such 20% increase has occurred; or

- issue stock or other equity securities of any subsidiary (other than to us or another of our wholly-owned subsidiaries or declare or pay any dividend or other distribution of cash, shares or other assets or redemption or repurchase of shares of any subsidiary; or (viii) 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 might be considered favorable and could entrench current management.

We are a Delaware corporation and 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;

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- do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of our outstanding common stock to elect some directors;

- establish a classified Board of Directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election;

- require that directors only be removed from office for cause;

- provide that vacancies on the Board of Directors, including newly created directorships, may be filled only by a majority vote of directors then in office;

- contain certain protective provisions in favor of the holders of Series A Convertible Preferred Stock;

- limit who may call special meetings of stockholders;

- prohibit common stockholder action by written consent, requiring all actions of the holders of common stock to be taken at a meeting of the stockholders; and

- establish advance notice requirements for nominating candidates for election to the Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

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

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

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ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

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. 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, however is cancelable without penalty in December 2019. We also lease office space located in Berlin, Germany, and Lisbon, Portugal, each consisting of less than 1,000 square feet of office space. Our leases for these facilities in Germany and Portugal expire in June 2018 and March 2020, respectively. We anticipate that following the expiration of the leases, additional or alternative space will be available at commercially reasonable terms. We also lease office space in France, consisting of less than 1,000 square feet. As part of our decision in 2016 to close operations in France, which will not be completed until early 2017, we gave notice to the leasing company that we would not be renewing the lease after April 2017.

ITEM 3. LEGAL PROCEEDINGS

On December 22, 2016, Cantor Fitzgerald & Co. (Cantor Fitzgerald) filed a complaint in the Supreme Court of the State of New York, County of New York against us. 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 denied liability. This lawsuit is in its earliest stages, no date has been set for trial and we are not able to predict the outcome.

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. Prior to that time, 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, 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

Year Ended December 31, 2015	High	Low
First quarter 2015	$5.92	$4.12
Second quarter 2015	$5.18	$3.98
Third quarter 2015	$5.03	$1.94
Fourth quarter 2015	$3.45	$2.00

Holders

As of March 1, 2017 there were 31 holders of record of our common stock.

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

None.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

As a smaller reporting company, we are not required to provide this information.

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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, Alimera or the Company) is a pharmaceutical company that specializes in the commercialization, research and development of prescription ophthalmic pharmaceuticals. We are presently focused 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 been 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. In the fourth quarter of 2016, we requested approval to modify our protocol to cap enrollment in the study due to our post market safety surveillance not showing any unexpected safety signals. Although we have not received formal regulatory approval, the Medicines & Healthcare products Regulatory Agency (MHRA) has agreed to allow us to suspend enrollment, pending approval of our protocol amendment. As of December 31, 2016, 548 patients were enrolled in this study.

We launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015.

In addition, we have entered into various agreements under which distributors will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in numerous countries in the Middle East, Italy, Australia, New Zealand and Canada.

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of December 31, 2016, we had accumulated a deficit of $377.1 million. We expect to incur substantial losses through the continued commercialization of ILUVIEN as we:

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

As of December 31, 2016, we had approximately $31.0 million in cash and cash equivalents.

We launched ILUVIEN in Germany and the United Kingdom, in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015. Our distributor in the Middle East launched ILUVIEN in the United Arab Emirates in the fourth quarter of 2016. In Italy, our distributor plans to launch ILUVIEN in 2017. We do not expect to have positive cash flow from operations until 2017, if at all. 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 or there may be substantial doubt about our ability to continue as a going concern.

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In October 2016, we entered into the Fourth Loan Amendment (as defined below) with Hercules Capital, Inc. (Hercules) in order to modify certain terms of the Term Loan Agreement (as defined below) and obtained additional loan amounts. If there is an event of default, all amounts may become due under the Term Loan Agreement and there would continue to be substantial doubt about our ability to continue as a going concern.

Our Agreement with pSivida US, Inc.

We entered into an agreement with pSivida US, Inc. (pSivida) for the use of fluocinolone acetonide (FAc) in pSivida's proprietary delivery device in February 2005, which was subsequently amended and restated in 2008. pSivida is a global drug delivery company committed to the biomedical sector and the development of drug delivery products. Our agreement with pSivida provides us with a worldwide exclusive license to develop and sell ILUVIEN, which consists of a tiny polyimide tube with a permeable membrane cap on one end and an impermeable silicone cap on the other end that is filled with FAc in a polyvinyl alcohol matrix for delivery to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis). This agreement also provides us with a worldwide non-exclusive license to develop and sell pSivida's proprietary delivery device to deliver other corticosteroids to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis) 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 delivery device in connection with indications for diseases outside of the eye or for the treatment of uveitis. Further, our agreement with pSivida permits pSivida to grant to any other party the right to use its intellectual property (i) 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, (ii) 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 (iii) 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. We were not in breach of our agreement with pSivida as of December 31, 2016.

The agreement provides that after commercialization of ILUVIEN, pSivida will be entitled to 20% of the net profits and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined in the amended and restated agreement. In connection with this arrangement we are entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits. As of December 31, 2016 and 2015, we could offset future royalty payments to pSivida in the amounts of $25.8 million and $21.6 million, respectively, due to the accumulation of commercialization costs. Due to the uncertainty of future profits from ILUVIEN, we have fully reserved these amounts in the accompanying consolidated financial statements. As of December 31, 2016 we owed pSivida approximately $240,000 for their portion of net profits on a cash basis, as defined in the amended and restated agreement, from the fourth quarter of 2016.

As a result of the Food and Drug Administration's (FDA) approval of ILUVIEN in September 2014, we paid pSivida a milestone payment of $25.0 million (the pSivida Milestone Payment) in October 2014.

In the second quarter of 2016, pSivida disputed portions of our claimed commercialization costs for the year ended December 31, 2014. As part of this dispute, pSivida notified us that it disagreed with $1.3 million of the $13.0 million in commercialization costs receivable that we had reported as of December 31, 2014 and claimed incremental profit sharing payments of $136,000 for the year ended December 31, 2014. We are disputing pSivida's assertions using the alternative dispute resolution mechanism under the pSivida Agreement. If pSivida's assertions were to prevail in the alternative dispute resolution mechanism and their assertions were then applied to the commercialization cost calculations for the years ended December 31, 2016 and 2015, then we believe the commercialization costs receivable from pSivida would be reduced from $25.8 million to $21.2 million as of December 31, 2016 and from $21.6 million to $18.5 million as of December 31, 2015. If pSivida's assertions were to prevail in the alternative dispute resolution mechanism, the impact on the statements of operations for the years ended December 31, 2016 and 2015 would be immaterial.

Our Credit Facility

Hercules Loan Agreement

2014 Loan Agreement

In April 2014, Alimera Sciences Limited (Limited), a subsidiary of ours, entered into a loan and security agreement (2014 Loan Agreement) with Hercules Capital, Inc. (Hercules) providing for a term loan of up to $35.0 million (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) and October 2016 (the Fourth Loan Amendment and, collectively with the 2014 Loan Agreement, the First Loan Amendment, the Second Loan Amendment and the Third Loan Amendment, the Term Loan Agreement). Under the 2014 Loan Agreement, Hercules made an advance in the initial principal amount of $10.0 million 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 $25.0 million to Limited in September 2014,

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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. The interest rate on the Term Loan Agreement was 11.25% as of December 31, 2016.

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 on May 1, 2018 (End of Term Payment).

We and Limited, on a consolidated basis with our 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 Term Loan Agreement and an increase to the applicable interest rate and would permit Hercules to exercise remedies with respect to the collateral under the 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 payable on the date that the 2014 Term Loan was to be paid in full.

We 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 Accounting Standard Codification (ASC) 470-50, Debt. As a result, we 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 $2.0 million 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 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 our public offering in August 2016 (see Note 12 Common Stock), 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 Term Loan Agreement. Pursuant to the terms of the Fourth Loan Amendment, Hercules agreed to provide up to an additional $10.0 million to Limited with (i) the first $5.0 million available at Limited's option through June 30, 2017 subject to (A) the Consolidated Group's achievement of $12.0 million 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 $5.0 million available at Limited's option through December 31, 2017 subject to (A) the Consolidated Group's achievement of $15.0 million in trailing three month net product revenue, (B) no event of default having occurred since the Effective Date and (C) the prior $5.0 million having been advanced to Limited (the Additional Advances and, together with the 2014 Term Loan, the Term Loan). The

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Fourth Loan Amendment provides for interest only payments through November 30, 2018 (the Interest-Only Period). Pursuant to the Fourth Loan Amendment, interest on the Term Loan accrues at a floating per annum rate equal to 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 will bear "payment-in kind" interest at the rate of 1.0% (PIK Interest), which PIK Interest will 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 and which amount will be payable when the aggregate outstanding principal amount of the Term Loan is payable. The Term Loan will 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 matures in full on November 1, 2020.

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. If Limited prepays the Term Loan, it will pay Hercules a prepayment penalty (i) if such amounts are 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 are 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 are 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 result in the acceleration of Limited's obligations under the 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 Term Loan Agreement, as amended by the Fourth Loan Amendment. In the event that we maintain $35.0 million in liquidity, including cash and eligible accounts receivable, at the end of the month and have not been and are not in breach of the amended debt facility, the six-month trailing revenue covenant is effectively waived for such month. As of December 31, 2016, our liquidity as defined under the Term Loan Agreement was $40.9 million, which consisted of $31.0 million in cash and cash equivalents and 80% of our $12.4 million in eligible U.S. accounts receivable.

General Discussion of the Term Loan Agreement

Pursuant to the Term Loan Agreement, Limited's obligations to Hercules are secured by a first-priority security interest in substantially all of Limited's assets, excluding intellectual property. Hercules does, however, maintain 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 are guarantors of the obligations of Limited to Hercules under the 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 Term Loan Agreement also places limitations on our 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, we issued a warrant to Hercules to purchase up to 285,016 shares of our 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 $25.0 million to Limited in September 2014.

We 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, we 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, we 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, we agreed to issue a new warrant to Hercules (the 2016 Warrant) to purchase up to 458,716 shares of our 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 our 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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Fair Value of Debt

The weighted average interest rates of our notes payable approximate the rate at which we could obtain alternative financing and the fair value of the warrants that were issued in connection with our notes payable are immaterial. Therefore, the carrying amount of the notes approximated their fair value at December 31, 2016 and 2015.

Financial Operations Overview

We began generating revenue from ILUVIEN in the second quarter of 2013, but do not expect positive cash flow from operations until late 2017, 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. We expect any revenue we generate will fluctuate from quarter to quarter as a result of the nature, timing and amount of any milestone payments we may receive from potential collaborative and strategic relationships, as well as revenue we may receive upon the sale of our products to the extent any are successfully commercialized.

Research, Development and Medical Affairs Expenses

Substantially all of our research, development and medical affairs expenses incurred to date related to our continuing operations have been related to the development of ILUVIEN. We anticipate that we will incur additional research, development and medical affairs expenses in the future as we evaluate and possibly pursue the regulatory approval of ILUVIEN in additional jurisdictions, the development of ILUVIEN for additional indications, or develop additional products or product candidates. We recognize research, development and medical affairs expenses as they are incurred. Our research, development and medical affairs expenses consist primarily of:

- salaries and related expenses for personnel, including medical sales liaisons;
- costs related to the provision of medical affairs support, including symposia development for physician education;
- costs related to compliance with FDA, EEA or other regulatory requirements;
- fees paid to consultants and contract research organizations (CRO) in conjunction with independently monitoring clinical trials and acquiring and evaluating data in conjunction with clinical trials, including all related fees such as investigator grants, patient screening, lab work and data compilation and statistical analysis;
- costs incurred with third parties related to the establishment of a commercially viable manufacturing process for products or product candidates;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- costs related to post marketing authorization studies;
- consulting fees paid to third-parties involved in research and development activities; and
- costs related to stock options or other stock-based compensation granted to personnel in development functions.

We expense both internal and external development costs as they are incurred.

We expect that a large percentage of our research, development and medical affairs expenses in the future will be incurred 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 total cost to completion. We expect to continue to develop stable formulations of ILUVIEN or any future products or product candidates, test such formulations in preclinical studies for toxicology, safety and efficacy and to conduct clinical trials for each future product candidate. We anticipate funding clinical trials ourselves, but we may engage collaboration partners at certain stages of clinical development. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials 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 clinical trials by us or our future collaborators may take several years or more, the length of time generally varying with the type, complexity, novelty and intended use of a product candidate.

Our only commercial product is ILUVIEN, which has received marketing authorization in the U.S., Austria, Belgium, the Czech Republic, Denmark, Finland, Germany, France, 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

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associated with chronic DME considered insufficiently responsive to available therapies. ILUVIEN has not been approved in any jurisdiction other than as set forth above. In order to grant marketing approval, a health authority such as the FDA or foreign regulatory agencies must conclude that clinical and preclinical data establish the safety and efficacy of ILUVIEN or any future products or product candidates with an appropriate benefit to risk profile relevant to a particular indication and that the product can be manufactured under current Good Manufacturing Practice (cGMP) in a reproducible manner to deliver the product's intended performance in terms of its stability, quality, purity and potency. Until our submissions are reviewed by health authorities, there is no way to predict the outcome of their review. Even if the clinical studies meet their predetermined primary endpoints and a registration dossier is accepted for filing, a health authority could still determine that an appropriate benefit to risk relationship does not exist for the indication that we are seeking. We cannot forecast with any degree of certainty whether ILUVIEN or any future products or product candidates will be subject to future collaborations or how such arrangements would affect our development plan or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will receive cash inflows from the commercialization and sale of an approved product candidate.

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.

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 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.

We launched ILUVIEN in Germany and the United Kingdom, in the second quarter of 2013 and the U.S. and Portugal in the first quarter of 2015. We expect significant increases in our sales and marketing expenses as we continue the commercialization of ILUVIEN in these countries.

In November 2012, we entered into a master services agreement with Quintiles Commercial Europe Limited. Under the agreement, Quintiles Commercial Europe Limited and its affiliates (collectively, Quintiles Commercial) provided certain services to us in relation to the commercialization of ILUVIEN, in France, Germany and the United Kingdom. In December 2013 and January 2014, respectively, we transitioned our German and United Kingdom country manager positions in-house. In April 2015, we terminated the project orders associated with France and Germany and transitioned the persons employed by Quintiles Commercial to our payroll. In July 2015, we terminated the remaining project orders associated with the United Kingdom and transitioned the covered positions employed by Quintiles Commercial to our payroll. As of December 31, 2015 the master services agreement with Quintiles Commercial had been terminated.

As of December 31, 2016, we had a European management team, local management teams and commercial personnel in France, Germany, Portugal and the United Kingdom totaling 31 persons, of which three are consultants.

In the fourth quarter of 2016, after unsuccessfully negotiating with the French government to obtain an appropriate price, we decided to close operations in France. We expect the closing of operations to be completed in early 2017. We are continuing to evaluate our options to enter the French market, including potential distributor relationships.

In the fourth quarter of 2014, following the FDA approval of ILUVIEN in the U.S., we began establishing the infrastructure to support the anticipated commercial launch of ILUVIEN in the U.S. in the first quarter of 2015 with the addition of regional sales directors, reimbursement specialists and payor relations directors. We hired additional sales and marketing personnel through the first quarter of 2015 for the launch of ILUVIEN and as of December 31, 2016, had a field force of approximately 45 people, including sales personnel, reimbursement specialists and payor

relations directors.

Interest Expense and Other

Interest expense consists primarily of interest and amortization of deferred financing costs and debt discounts associated with our Term Loan Agreement. Interest income consists primarily of interest earned on our cash, cash equivalents and investments.

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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.

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, Earning Per Share. We had a net loss for all 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 34,550,161 and 32,164,307 for the years ended December 31, 2016 and 2015, 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, 2016 and 2015, the weighted average shares used to calculate both basic and diluted loss per share are the same.

Critical Accounting Policies and Estimates

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

Revenue Recognition - U.S. Product Sales

Product sales consist of U.S. sales of ILUVIEN. In the U.S., we sell ILUVIEN to a limited number of pharmaceutical distributors who in turn sell the product downstream to pharmacies and physician practices. Revenue from product sales is recognized 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, collection from the customer is reasonably assured, we have no further performance obligations and returns can be reasonably estimated. We record revenue from product sales upon delivery to our pharmaceutical distributors.

Revenue from U.S. product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, such as Medicaid and Veterans' Administration (VA), distribution-related fees and other sales-related deductions. We estimate reductions to product sales based upon contracts with customers and government agencies, statutorily-defined discounts applicable to government-funded programs, estimated payer mix, inventory levels, shelf life of the product and other relevant factors. 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.

We estimate reductions to product sales for Medicaid and VA programs and for certain other qualifying federal and state government programs. Based upon our contracts with government agencies, statutorily-defined discounts applicable to government-funded programs, historical experience and estimated payer mix, we estimate and record an allowance for rebates and chargebacks. Our liability for Medicaid rebates consists of estimates for claims that a state will make for a current quarter, claims for prior quarters that have been estimated for which an invoice has not been received and invoices received for claims from prior quarters that have not been paid. Our reserves related to discounted pricing to VA, Public Health Services and other institutions (collectively qualified healthcare providers)

represent our estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices we charge to our customers (i.e., pharmaceutical distributors). Our customers charge us for the difference between what they pay for the products and the ultimate selling price to the qualified healthcare providers. Our reserve for this discounted pricing is based on expected sales to qualified healthcare providers and the chargebacks that customers have already claimed.

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We have written contracts with our customers that include terms for distribution-related fees. We estimate and record distribution and related fees due to its customers based on gross sales.

Consistent with industry practice, we offer our customers a limited right to return product purchased directly from us, which is principally based upon the product's expiration date. We will accept returns for three months prior to and up to nine months after the product expiration date. Depending on the circumstances, we may provide replacement products or cash credit for returns. Product returned is generally not resalable given the nature of our products and method of administration. We develop estimates for product returns based upon historical experience, inventory levels, shelf life of the product and other relevant factors. We monitor product supply levels in the distribution channel, as well as sales by its customers to healthcare providers using product-specific data provided by its customers. If necessary, our estimates of product returns may be adjusted in the future based on actual returns experience, known or expected changes in the marketplace, or other factors.

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 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.

Stock-Based Compensation

We have stock option plans which provide for grants of stock options to employees, directors and consultants or other service providers to purchase shares of our common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. Compensation cost is recognized 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 utilize 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 utilize the “simplified” method for “plain vanilla” options as discussed within the Securities and Exchange Commission’s (SEC) 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 utilize the simplified method for the foreseeable future until more detailed information about exercise behavior will be more widely

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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, a valuation allowance has been established 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, 2016 we had federal NOL carry-forwards of approximately $104.9 million and state NOL carry-forwards of approximately $83.3 million, respectively, that are available to reduce future income otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2029 and 2035 and the state NOL carry-forwards will expire at various dates between 2020 and 2035. 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 these NOLs were generated, we would be subject to annual limitations on the use of these NOLs under Section 382 (or comparable provisions of state law). We have determined that a Section 382 change in ownership occurred in late 2015. Therefore, the annual utilization of our NOLs is subject to certain limitations under Section 382 and other limitations under state tax laws. We are currently in the process of calculating these limitations. Any 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, any limitation would not have an impact on the statements of operations for the periods presented. The results of the analysis on the impact to our NOLs will be disclosed at a later date.

In the event that 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 such determination was made. We believe that the most significant uncertainty that will impact 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, 2016 and December 31, 2015 are approximately $59,000 and $46,000, 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 2012 to 2015 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 2003. 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.

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

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historical rates and the resulting cumulative translation adjustments are included as a component of accumulated other comprehensive income.

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Results of Operations - Segment Review

The following selected unaudited financial and operating data are derived from our consolidated financial statements and should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements. The results and discussions that follow are reflective of how executive management monitors the performance of our reporting segments.

Certain operating expenses are allocated between our reporting segments based on activity-based costing methods. These activity-based costing methods require us to make estimates that impact the amount of each expense category that is attributed to each segment. Changes in these estimates will directly impact 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 2016 or 2015. However, in 2015, as a result of the FDA approval of ILUVIEN in the U.S. in late 2014, there was a shift in allocation of research, development and medical affairs costs between segments to more accurately reflect the benefit of those costs on future revenue streams. In addition, there was a shift in sales and marketing and general and administrative activity between segments in late 2014 and 2015 in anticipation and as a result of the commercial launch of ILUVIEN in the U.S.

U.S. Segment

	Years Ended December 31,	
	2016	2015
	(In thousands)	
NET REVENUE	$25,765	$15,170
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(1,694)	(792)
GROSS PROFIT	24,071	14,378
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	7,875	9,712
GENERAL AND ADMINISTRATIVE EXPENSES	9,316	8,244
SALES AND MARKETING EXPENSES	22,134	19,777
DEPRECIATION AND AMORTIZATION	2,678	2,491
OPERATING EXPENSES	42,003	40,224
NET LOSS FROM OPERATIONS	$(17,932)	$(25,846)

Year ended December 31, 2016 compared to the year ended December 31, 2015

Net Revenue. Net revenue increased by approximately $10.6 million, or 70%, to approximately $25.8 million for the year ended December 31, 2016, compared to approximately $15.2 million for the year ended December 31, 2015. The growth was primarily attributable to increases in both the number of end user accounts and the order frequency from our existing accounts, as well as we continued to recognize gains in market acceptance. We also benefited from ILUVIEN being available for sale for the full year ending December 31, 2016. During the year ended December 31, 2015 ILUVIEN was only available following our launch in March of 2015.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $910,000, or 115%, to approximately $1.7 million for the year ended December 31, 2016 compared to approximately $790,000 for the year ended December 31, 2015. The increase was primarily attributable to our increase in sales volume.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately $1.8 million, or 19%, to approximately $7.9 million for the year ended December 31, 2016, compared to approximately $9.7 million for the year ended December 31, 2015. The decrease was primarily attributable to decreases of approximately $1.1 million in costs with third parties related to potential product enhancements incurred during 2015, $480,000 in medical affairs and scientific communication costs associated with the U.S. launch in 2015 and $220,000 in U.S. compliance reporting costs. These costs were offset by increases of approximately $310,000 in costs associated with maintaining the registration of ILUVIEN in the U.S., and $210,000 in pharmacovigilance costs.

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General and administrative expenses. General and administrative expenses increased by approximately $1.1 million, or 13%, to approximately $9.3 million for the year ended December 31, 2016, compared to approximately $8.2 million for the year ended December 31, 2015. The increase was primarily attributable to increases of $960,000 for certain one-time costs associated with pursuing alternative debt options, including contingent advisory fees, and $270,000 in costs incurred with our third party manufactures of ILUVIEN.

Sales and marketing expenses. Sales and marketing expenses increased by approximately $2.3 million, or 12%, to approximately $22.1 million for the year ended December 31, 2016, compared to approximately $19.8 million for the year ended December 31, 2015. The increase was primarily attributable to increases of approximately $880,000 in additional costs incurred in 2016 for the commercial team hired for the launch of ILUVIEN in the U.S., $750,000 for additional commissions paid to our U.S. sales force due to increased sales in 2016 and $480,000 in additional marketing costs including professional fees for the promotion of ILUVIEN incurred during 2016, medical marketing and an increased presence at certain regional and national meetings.

Depreciation and amortization. Depreciation and amortization increased by approximately $200,000, or 8%, to approximately $2.7 million for the year ended December 31, 2016, compared to approximately $2.5 million for the year ended December 31, 2015. The increase was primarily attributable to depreciation expense associated with capital leases entered into in March 2015 for automobiles for the U.S. commercial team.

International Segment

	Years Ended December 31,	
	2016	2015
	(In thousands)	
NET REVENUE	$8,568	$7,268
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(650)	(970)
GROSS PROFIT	7,918	6,298
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	4,500	5,128
GENERAL AND ADMINISTRATIVE EXPENSES	5,947	5,946
SALES AND MARKETING EXPENSES	7,297	8,313
DEPRECIATION AND AMORTIZATION	89	64
OPERATING EXPENSES	17,833	19,451
NET LOSS FROM OPERATIONS	$(9,915)	$(13,153)

Year ended December 31, 2016 compared to the year ended December 31, 2015

Net Revenue. Net revenue increased by approximately $1.3 million, or 18%, to approximately $8.6 million for the year ended December 31, 2016, compared to approximately $7.3 million for the year ended December 31, 2015. The increase was primarily attributable to higher sales volumes in Portugal and Germany offset by decreases in sales volume in the United Kingdom. Revenue was further reduced by the change in the value of the British pound sterling and the Euro which impacted reported revenue by $210,000 for the year ended December 31, 2016 compared to the year ended December 31, 2015.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization decreased by approximately $320,000, or 33%, to approximately $650,000 for the year ended December 31, 2016, compared to approximately $970,000 for the year ended December 31, 2015. The decrease was primarily attributable to a decrease of $450,000 in charges for expiring inventory, offset by increased sales volume and increases in our supplier costs.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately $600,000, or 12%, to approximately $4.5 million for the year ended December 31, 2016, compared to approximately $5.1 million for the year ended December 31, 2015. The decrease was primarily attributable to decreases of approximately $320,000 in ongoing medical affairs costs and $320,000 scientific communication costs.

General and administrative expenses. General and administrative expenses were approximately $5.9 million for both the years ended December 31, 2016 and 2015.

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Sales and marketing expenses. Sales and marketing expenses decreased by approximately $1.0 million, or 12%, to approximately $7.3 million for the year ended December 31, 2016, compared to approximately $8.3 million for the year ended December 31, 2015. The decrease was primarily attributable to a decrease of approximately $1.5 million in marketing costs including reductions of $820,000 in trade show costs, $470,000 in medical communication costs and $180,000 in market research costs. These decreases were offset by an increase of approximately $530,000 in market access costs as we pursue expanded reimbursement in the United Kingdom and other European countries.

Consolidated other income and expense

The following selected unaudited financial and operating data are derived from our consolidated financial statements and should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements.

	Years Ended December 31,	
	2016	2015
	(In thousands)	
NET LOSS FROM OPERATIONS	$(27,847)	$(38,999)
INTEREST EXPENSE AND OTHER	(5,178)	(4,693)
UNREALIZED FOREIGN CURRENCY LOSS, NET	(40)	(106)
LOSS ON EARLY EXTINGUISHMENT OF DEBT	(2,564)	—
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	2,627	13,283
NET LOSS BEFORE TAXES	(33,002)	(30,515)
PROVISION FOR TAXES	(172)	(130)
NET LOSS	$(33,174)	$(30,645)

Year ended December 31, 2016 compared to the year ended December 31, 2015

Interest expense and other. Interest expense and other increased by approximately $500,000, or 11%, to approximately $5.2 million for the year ended December 31, 2016, compared to approximately $4.7 million for the year ended December 31, 2015. The increase was primarily attributable to costs associated with the amendments to our Term Loan Agreement.

Unrealized foreign currency loss, net. Unrealized foreign currency (loss) gain, net was a loss of approximately $40,000 for the year ended December 31, 2016, compared to a loss of approximately $106,000 for the year ended December 31, 2015. The 2016 and 2015 unrealized foreign currency losses were primarily attributable to the weakening of the Euro during the period and the revaluation of Limited’s U.S. dollar denominated net liabilities.

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 Term Loan Agreement.

Change in fair value of derivative warrant liability. During the years ended December 31, 2016 and 2015, we recognized gains of approximately $2.6 million and $13.3 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, 2016 and 2015 and the time remaining to exercise the warrants.

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Liquidity and Capital Resources

Since inception, we have incurred recurring losses, negative cash flow from operations and have accumulated a deficit of $377.1 million from our inception through December 31, 2016. 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, $0.01 par value per share, 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. We intended to use the net proceeds from this offering for general corporate purposes, including capital expenditures, debt repayments 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 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, further reduced by approximately $100,000 of related commissions, issuance costs and placement agent fees.

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.

In October 2016, Limited entered into the Fourth Loan Amendment. Under the Fourth Loan Amendment, Hercules agreed to provide up to an additional $10.0 million to Limited with (i) the first $5.0 million available at Limited’s option through June 30, 2017 subject to (A) the achievement of $12.0 million in trailing three month net product revenue and (B) no event of default having occurred since the Effective Date and (ii) the second $5.0 million available at Limited’s option through December 31, 2017 subject to (A) the achievement of $15.0 million in trailing three month net product revenue, (B) no event of default having occurred since the Effective Date and (C) the prior $5.0 million having been advanced to Limited. If there is an event of default, all amounts may become due under the Term Loan Agreement and there would be substantial doubt about our ability to continue as a going concern.

As of December 31, 2016, we had approximately $31.0 million in cash and cash equivalents. We launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015. 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 be determined by many factors, some of which are beyond our control and we may need funds sooner than currently anticipated.

We cannot be sure that additional financing would 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 twelve months 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 an increase in accounts payable,

accrued expenses and other current liabilities of $2.1 million and a decrease in inventory of $1.0 million. 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 earned, but not paid, in the three months ended December 31, 2016 to our sales force.

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For the twelve months ended December 31, 2015, cash used in our operations of $45.4 million was primarily due to our net loss of $30.6 million, which is subject to further adjustment for non-cash items. These items included approximately $13.3 million for a non-cash gain for the change in the value of our derivative warrant liability, charges of approximately $5.0 million for stock compensation expense, $2.6 million of depreciation and amortization expense, $840,000 of amortization of our debt discount, $450,000 in inventory reserves and $110,000 for unrealized foreign currency transactions losses. Further impacting cash from operations was an increase in accounts receivable of $8.9 million, decrease in accounts payable, accrued expenses and other current liabilities of $1.9 million and increase in inventory of $390,000. Accounts receivable increased primarily due to the U.S. launch of ILUVIEN during the first quarter of 2015. Accounts payable, accrued expenses and other current liabilities decreased primarily due to the milestone payment of $2.0 million paid to a consultant that was engaged to assist with the pursuit of approval of ILUVIEN in the U.S. and a decrease of $1.2 million in amounts payable to Quintiles Commercial, offset by increases of $460,000 in accruals associated with accrued rebate, chargeback and other revenue reserves, $450,000 in clinical studies accruals and $300,000 in commissions payable to our U.S. sales force.

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, 2015, net cash used in our investing activities was approximately $450,000, which was primarily due to the purchase of drug safety management software.

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 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. 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 Term Loan Agreement and $230,000 in payments on capital leases.

For the year ended December 31, 2015, net cash provided by our financing activities was approximately $630,000. During the fourth quarter of 2015 we sold 268,978 shares of common stock at a weighted average price of $3.07 per share for proceeds of approximately $800,000 excluding approximately $79,000 of related issuance costs and placement agent fees. Further increasing cash from our financing activities was $570,000 from the proceeds from exercises of stock options. These increases were offset by decreases due to the payment of issuance costs of approximately $330,000 in January 2015 associated with the sale of our Series B Convertible Preferred Stock in December 2014, $290,000 in payments on capital leases and $260,000 in fees to modify our Term Loan Agreement.

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 for the purpose of facilitating off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of 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, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB), or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of 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 June 2014, the FASB issued Accounting Standards Update (ASU) 2014-12, Compensation Stock - Compensation (Topic 718). ASU 2014-12 applies to all reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. It requires that a performance target that affects vesting and that could be achieved after the requisite

service period be treated as a performance condition and follows existing accounting guidance for the treatment of performance conditions. The standard will be effective for annual periods and interim periods within those annual periods beginning after December 15, 2015, with early adoption permitted. The adoption of this guidance did not have a material impact on our financial statements.

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 April 2015, the FASB issued ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. ASU 2015-03 is intended to simplify the presentation of debt issuance costs. These amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted and the standard is to be retrospectively applied to all periods presented upon adoption. We elected to early adopt ASU 2015-03 effective December 31, 2015, and as a result reclassified $629,000 from deferred financing costs to note payable, net of discount in our Consolidated Balance Sheet as of December 31, 2015.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes, which simplifies the presentation of deferred income taxes. This ASU requires that deferred tax assets and liabilities be classified as non-current in a statement of financial position. We elected to early adopt ASU 2015-17 effective December 31, 2015 on a prospective basis. Adoption of this ASU resulted in a reclassification of our net current deferred tax asset to the net non-current deferred tax asset in our Consolidated Balance Sheet as of December 31, 2015.

Accounting Standards Issued but Not Yet Effective

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 provides a single, comprehensive revenue recognition model for all contracts with customers. The revenue guidance contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2017 for public entities, with early adoption permitted in the annual reporting period beginning after December 15, 2016. We have begun our evaluation of the new guidance on our business and, at this time, do not believe there will be a material impact on our current direct product sales in international markets. For the U.S. business, we continue to evaluate the variable consideration provisions of the new guidance and the impact it will have specifically on our gross to net revenue adjustments, including chargebacks and rebates. We anticipate adopting the new revenue standard using the modified retrospective transition method.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern. ASU 2014-15 provides guidance around management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company’s ability to continue as a going concern within one year from the date the financial statements are issued. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. We do not expect there to be a material impact upon adopting this guidance in 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. We do not expect the impact of the adoption to have a material effect on its financial statements.

In February 2016, the FASB issued ASU No. 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. We are currently in the process of evaluating the impact of the adoption on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718). This standard makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation and the financial statement presentation of excess tax benefits or deficiencies. ASU 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, although early adoption is permitted. We do not expect the impact of the adoption to have a material effect on its financial statements.

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ITEM 7A. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Liquidity

See the “Liquidity and Capital Resources” section of this annual report on Form 10-K for additional discussion of liquidity and related risks.

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our loan agreement with Hercules. We do not believe we are materially exposed to changes in interest rates. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a 100 basis point, or 1%, unfavorable change in interest rates would have resulted in approximately a $356,000 increase in interest expense for the year ended December 31, 2016.

Credit Quality Risk

We are subject to credit risk in connection with accounts receivable from our product sales of ILUVIEN. We have contractual payment terms with each of our customers, and we monitor our customers’ financial performance and credit worthiness so that we can properly assess and respond to any changes in their credit profile. During the years ended December 31, 2016 and 2015 we did not recognize any charges for write-offs of accounts receivable. As of December 31, 2016 and 2015, our only two U.S. customers, which are large pharmaceutical distributors, accounted for 90% and 88%, respectively, of our accounts receivable balances.

Foreign Exchange Risk

As discussed further above, we market ILUVIEN outside the U.S. Therefore, significant changes in foreign exchange rates of the countries outside the U.S. where our product is sold can impact our operating results and financial condition. As sales outside the U.S. continue to grow, and as we expand our international operations, we will continue to assess potential steps, including foreign currency hedging and other strategies, to mitigate our foreign exchange risk.

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 67 and are incorporated herein.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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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, 2016, 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, 2016 based on the specified criteria.

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 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

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

ITEM 9B. OTHER INFORMATION

None.

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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, and executive officers 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 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of fiscal year ended December 31, 2016 (2017 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 2017 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 2017 Proxy Statement and is incorporated herein by reference.

Equity Compensation Plan Information

The following table provides information as of December 31, 2016, 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	10,804,412 (1)	$ 3.22	1,080,492	(2)
Equity compensation plans not approved by security holders	—	—	—	
Total	10,804,412	$ 3.22	1,080,492	

(1) Of these shares, 9,736,130 were subject to options then outstanding under the 2010 Plan, 65,072 were subject to options then outstanding under the 2005 Plan and 1,003,210 were subject to options then outstanding under the 2004 Plan.

(2) Represents 668,830 shares of common stock available for issuance under our 2010 Plan and 411,662 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, 2017, 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, 2017, an additional 82,760 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 2017 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 2017 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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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 3, 2017.

ALIMERA SCIENCES, INC.

By: /s/ C. Daniel Myers
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 3, 2017
/s/ Richard S. Eiswirth, Jr. Richard S. Eiswirth, Jr.	President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 3, 2017
/s/ James R. Largent James R. Largent	Chairman of the Board of Directors	March 3, 2017
/s/ Glen Bradley, Ph.D. Glen Bradley, Ph.D.	Director	March 3, 2017
/s/ Mark J. Brooks Mark J. Brooks	Director	March 3, 2017
/s/ Brian K. Halak, Ph.D. Brian K. Halak, Ph.D.	Director	March 3, 2017
/s/ Garheng Kong, M.D., Ph.D. Garheng Kong, M.D., Ph.D.	Director	March 3, 2017
/s/ Peter J. Pizzo, III Peter J. Pizzo, III	Director	March 3, 2017
	Director	

/s/ Calvin W. Roberts, M.D.
Calvin W. Roberts, M.D.

March 3, 2017

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ALIMERA SCIENCES, INC.
INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Alimera Sciences, Inc.

We have audited the accompanying consolidated balance sheets of Alimera Sciences, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Alimera Sciences, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

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 flow from operations, and has an accumulated deficit of $377 million as of December 31, 2016. These conditions, along with the other matters as set forth in Note 3, raise substantial doubt about its ability to continue as a going concern. Management's plans in regards to these matters are also discussed in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ GRANT THORNTON LLP

Atlanta, Georgia
March 3, 2017

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ALIMERA SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS
AS OF DECEMBER 31, 2016 AND 2015

	December 31,	
	2016	2015
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 30,979	$ 31,075
Restricted cash	31	37
Accounts receivable, net	13,839	9,799
Prepaid expenses and other current assets	2,107	2,696
Inventory, net (Note 4)	446	1,552
Total current assets	47,402	45,159
NON-CURRENT ASSETS:		
Property and equipment — at cost less accumulated depreciation	1,787	2,553
Intangible asset, net	20,604	22,549
Deferred tax asset	436	223
TOTAL ASSETS	$ 70,229	$ 70,484
CURRENT LIABILITIES:		
Accounts payable	$ 4,986	$ 4,002
Accrued expenses (Note 7)	3,758	3,911
Derivative warrant liability	188	—
Note payable (Note 9)	—	31,786
Capital lease obligations	191	234
Total current liabilities	9,123	39,933
NON-CURRENT LIABILITIES:		
Derivative warrant liability	—	2,815
Note payable — less current portion (Note 9)	33,084	—
Capital lease obligations — less current portion	274	582
Other non-current liabilities	2,162	834
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $.01 par value — 10,000,000 shares authorized at December 31, 2016 and 2015:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 600,000 issued and outstanding at December 31, 2016 and 2015; liquidation preference of $24,000 at December 31, 2016 and 2015	19,227	19,227
Series B Convertible Preferred Stock, 8,417 authorized and 8,416.251 issued and outstanding at December 31, 2016 and 2015; liquidation preference of $50,750 at December 31, 2016 and 2015	49,568	49,568
Common stock, $.01 par value — 150,000,000 shares authorized, 64,862,904 shares issued and outstanding at December 31, 2016 and 100,000,000 shares authorized 45,005,833 shares issued and outstanding at December 31, 2015	649	450
Additional paid-in capital	330,781	299,376
Common stock warrants	3,707	2,747
Accumulated deficit	(377,074)	(343,900)
Accumulated other comprehensive loss	(1,272)	(1,148)

TOTAL STOCKHOLDERS' EQUITY	25,586	26,320
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 70,229	$ 70,484

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

	Years Ended December 31,	
	2016	2015
	(In thousands, except share and per share data)	
NET REVENUE	$34,333	$22,438
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(2,344)	(1,762)
GROSS PROFIT	31,989	20,676
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	12,375	14,840
GENERAL AND ADMINISTRATIVE EXPENSES	15,263	14,190
SALES AND MARKETING EXPENSES	29,431	28,090
DEPRECIATION AND AMORTIZATION	2,767	2,555
OPERATING EXPENSES	59,836	59,675
NET LOSS FROM OPERATIONS	(27,847)	(38,999)
INTEREST EXPENSE AND OTHER	(5,178)	(4,693)
UNREALIZED FOREIGN CURRENCY LOSS, NET	(40)	(106)
LOSS ON EARLY EXTINGUISHMENT OF DEBT	(2,564)	—
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	2,627	13,283
NET LOSS BEFORE TAXES	(33,002)	(30,515)
PROVISION FOR TAXES	(172)	(130)
NET LOSS	$(33,174)	$(30,645)
NET LOSS PER SHARE — Basic and diluted	$(0.63)	$(0.69)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	52,801,603	44,450,216

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

	Years Ended December 31,	
	2016	2015
	(In thousands)	
NET LOSS	$(33,174)	$(30,645)
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	(124)	(336)
TOTAL OTHER COMPREHENSIVE LOSS	(124)	(336)
COMPREHENSIVE LOSS	$(33,298)	$(30,981)

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, 2016 AND 2015

	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, 2014	44,320,342	$443	600,000	$19,227	8,416	$49,568	$292,851	$1,497	$(313,255)	$(812)	$49,519
Issuance of common stock, net of issuance costs	341,239	4	—	—	—	—	920	—	—	—	924
Exercise of stock options	344,252	3	—	—	—	—	568	—	—	—	571
Modification of common stock warrants	—	—	—	—	—	—	—	1,250	—	—	1,250
Stock-based compensation	—	—	—	—	—	—	5,037	—	—	—	5,037
Net loss	—	—	—	—	—	—	—	—	(30,645)	—	(30,645)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	(336)	(336)
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			