

ALIMERA SCIENCES INC  
Form 10-K  
March 13, 2015  
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K  
(Mark One)

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

For the fiscal year ended December 31, 2014  
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  
(State or other jurisdiction of incorporation or organization)  
6120 Windward Parkway, Suite 290  
Alpharetta, GA  
(Address of principal executive offices)  
(678) 990-5740  
(Registrant's telephone number, including area code)

20-0028718  
(I.R.S. Employer Identification Number)  
30005  
(Zip Code)

Securities registered pursuant to Section 12(b) of the Act:  
Common Stock, \$0.01 par value per share  
(Title of each class)

The NASDAQ Stock Market LLC  
(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

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

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  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  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

Edgar Filing: ALIMERA SCIENCES INC - Form 10-K

information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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  Accelerated filer

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes

No

As of June 30, 2014, 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 \$157,828,896 based on the closing price of the registrant's Common Stock, on June 30, 2014, as reported by the NASDAQ Global Market. Shares of Common Stock held by each executive officer, director and stockholders known by the registrant to own 10% or more of the outstanding stock based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 6, 2015 there were 44,353,175 shares of the registrant's Common Stock issued and outstanding.

---

Table of Contents

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement with respect to the registrant's 2015 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, 2014, are incorporated by reference into Part III of this Form 10-K.

---

Table of Contents

Alimera Sciences, Inc.  
Form 10-K  
Table of Contents

	Page
	<u>Part I</u>
	<u>Special Note Regarding Forward-Looking Statements and Projections</u>
Item 1.	<u>4</u>
	<u>Business</u>
Item 1A.	<u>5</u>
	<u>Risk Factors</u>
Item 1B.	<u>17</u>
	<u>Unresolved Staff Comments</u>
Item 2.	<u>41</u>
	<u>Properties</u>
Item 3.	<u>41</u>
	<u>Legal Proceedings</u>
Item 4.	<u>41</u>
	<u>Mine Safety Disclosures</u>
	<u>Part II</u>
Item 5.	<u>Market for Registrant’s Common Equity, Related Shareholder Matters and Issuer</u>
	<u>Purchases of Equity Securities</u>
Item 6.	<u>42</u>
	<u>Selected Consolidated Financial Data</u>
Item 7.	<u>43</u>
	<u>Management’s Discussion and Analysis of Financial Condition and Results of</u>
	<u>Operations</u>
Item 7A.	<u>43</u>
	<u>Qualitative and Quantitative Disclosures about Market Risk</u>
Item 8.	<u>56</u>
	<u>Financial Statements and Supplementary Data</u>
Item 9.	<u>56</u>
	<u>Changes in and Disagreements with Accountants on Accounting and Financial</u>
	<u>Disclosure</u>
Item 9A.	<u>56</u>
	<u>Controls and Procedures</u>
Item 9B.	<u>59</u>
	<u>Other Information</u>
	<u>Part III</u>
Item 10.	<u>Directors, Executive Officers and Corporate Governance</u>
Item 11.	<u>60</u>
	<u>Executive Compensation</u>
Item 12.	<u>60</u>
	<u>Security Ownership of Certain Beneficial Owners and Management and Related</u>
	<u>Stockholder Matters</u>
Item 13.	<u>60</u>
	<u>Certain Relationships and Related Transactions, and Director Independence</u>
Item 14.	<u>61</u>
	<u>Principal Accountant Fees and Services</u>
	<u>Part IV</u>
Item 15.	<u>Exhibits and Financial Statements Schedules</u>
	<u>62</u>
	<u>Signatures</u>
	<u>63</u>
	<u>Index to Financial</u>
	<u>Statements</u>
	<u>64</u>
	<u>Exhibit Index</u>
	<u>96</u>

The term “ILUVIEN” is our 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.

## Explanatory Note

The registrant qualified as a smaller reporting company for the fiscal year ended December 31, 2014. Because the registrant's public float exceeded \$75.0 million at the end of the registrant’s second quarter ended June 30, 2014, the registrant will qualify and report as an accelerated filer in 2015, starting with its Quarterly Report on Form 10-Q for the quarter ending March 31, 2015. Pursuant to the rules of the Securities and Exchange Commission, the registrant is relying upon the smaller reporting company scaled disclosure rules for portions of this Annual Report on Form 10-K.



Table of Contents

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 our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties and are based on information currently available to our management. Words such as, but not limited to, “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “contemplates,” “predict,” “project,” “target,” “likely,” “potential,” “continue,” “ongoing,” “will,” “would,” “should,” or “could,” and 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 successfully commercialize ILUVIEN in the United States (U.S.) and the European Union (EU);
- our limited sales and marketing infrastructure;
- uncertainty as to the pricing and reimbursement guidelines for ILUVIEN or any future products or product candidates, including ILUVIEN;
- delay in or failure to obtain regulatory approval of ILUVIEN in additional countries or any future products or product candidates;
- our inability to successfully market and sell ILUVIEN following regulatory approval in additional markets;
- our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility;
- uncertainty as to the relationship between the benefits of ILUVIEN or any future products or product candidates and the risks of their side-effect profiles;
- the extent of government regulations;
- dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality; and
- our ability to raise sufficient 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.

Table of Contents

ITEM 1. BUSINESS

Overview

Alimera Sciences, Inc., and its subsidiaries (we, Alimera or the Company), is a pharmaceutical company that specializes in the research, development and commercialization 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 U.S., Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom and has been recommended for marketing authorization in Poland. 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 EU 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 the EU, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients treated.

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

We were able to launch in Germany without price restriction, but continue to work with the statutory health insurance funds in Germany to streamline reimbursement for ILUVIEN.

In October 2013, the United Kingdom's National Institute for Health and Care Excellence (NICE) issued a positive Final Appraisal Determination recommending ILUVIEN funding, taking into consideration a simple patient access scheme (PAS) for the treatment of pseudophakic eyes (eyes with an artificial lens) in chronic DME patients considered insufficiently responsive to available therapies. We began receiving orders for ILUVIEN from several National Health Services (NHS) facilities in January 2014 following the final technology appraisal guidance that was published in November 2013. Further, in February 2014, the Scottish Medicines Consortium, after completing its assessment and review of a similar simple PAS, announced that it has accepted ILUVIEN for restricted use within the NHS Scotland.

In July 2013, the Transparency Commission (Commission de la Transparence or CT) of the French National Health Authority (Haute Autorite de Sante) issued a favorable opinion for the reimbursement and hospital listing of ILUVIEN. We continue to negotiate with the French authorities, but have not yet reached an agreement on price. ILUVIEN is an intravitreal implant that treats patients by delivering a consistent sub-microgram daily dose of the non-proprietary corticosteroid fluocinolone acetonide (FAc) in the eye, which is sustained through 36 months. ILUVIEN is inserted in a non-surgical procedure employing a device with a 25-gauge needle which allows for a self-sealing wound. In approved European countries, the procedure is performed in a hospital or private clinic setting. In the U.S., the non-surgical procedure is performed in the retinal specialist's office. In the treatment of DME with an intraocular corticosteroid, we believe that delivering therapeutic levels and mitigating the typical corticosteroid related side effects can only be achieved by delivering drug to the back of the eye in daily sub-microgram levels where DME occurs, and minimizing exposure in the front of the eye, where the typical side effects take place. To achieve this, ILUVIEN is inserted in the back of the patient's eye to a placement site that uses the eye's natural fluid dynamics to focus drug delivery in the back of the eye. 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. Therefore, we believe ILUVIEN delivers a sustained therapeutic effect in DME, and has a side effect profile that is predictable and manageable by a retinal physician.

Our commercialization 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 including the launch and

management of Visudyne, the first pharmacological treatment indicated for patients with wet age-related macular degeneration (AMD). 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. We launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015. We also plan to commercialize ILUVIEN, directly or with a partner, in other EU and non-EU countries where it is approved or we anticipate receiving approval.



## Table of Contents

### 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 the United Kingdom and Germany in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015. We also plan to commercialize ILUVIEN, directly or with a partner, in other EU and non-EU countries where it is approved or we anticipate receiving approval.

**Pursue Approval in Additional Countries.** Under a Mutual Recognition Procedure (MRP) available in the EU, we can submit ILUVIEN for approval in any or all of the remaining 11 EU countries where we have not yet submitted for marketing approval. The International Diabetes Federation estimates there are approximately 4.3 million people suffering from diabetes in these remaining 11 countries. We are also considering pursuing approval in Switzerland, Middle Eastern and Asia Pacific markets.

**Assess the Effectiveness of ILUVIEN for Additional Retinal Diseases.** We believe that ILUVIEN has the potential to address additional retinal diseases including, among others, dry AMD, wet AMD and retinal vein occlusion (RVO).

**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 leverage our management's expertise and its broad network of relationships to continue to evaluate in-licensing and acquisition opportunities for compounds and technologies with potential treatment applications for diseases affecting the eye.

### Disease Overview and Market Opportunity

#### Diabetes and Diabetic Retinopathy

Diabetes mellitus, with its systemic and ophthalmic complications, represents a global public health threat. The estimated prevalence of diabetes worldwide in 2014 increased to 387 million people and is expected to increase to 592 million people by 2035.

According to the U.S. Centers for Disease Control and Prevention (CDC), the number of Americans diagnosed with diabetes has increased from approximately 8.1 million people in 1994 to approximately 21.0 million people in 2012. In addition to diagnosed cases, the CDC estimates that an additional 8.1 million Americans with diabetes are currently undiagnosed and are therefore not being monitored and treated to control their disease and prevent systemic and ophthalmic complications. In the EU countries in which ILUVIEN has received marketing authorizations or has been recommended for marketing authorization, according to the International Diabetes Foundation, Diabetes Atlas, Sixth Edition, 2014 Update, there are approximately 18.2 million diagnosed diabetics and 9.4 million diabetics that remain undiagnosed. With better diagnostics and improved public awareness, the number of persons diagnosed with and being treated for diabetes is expected to increase.

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 American Diabetes Association, 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, macular ischemia 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.

DME is a common ocular complication of diabetes mellitus. 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, the most common of which is diabetic retinopathy. Diabetic retinopathy is the leading cause of new-onset blindness in patients aged 20 to 70, with DME accounting for a majority of vision loss in patients with diabetic retinopathy. Vision loss from DME affects both patients and caregivers, who must assist the patient with doctor visits.

## Table of Contents

### 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.

As the diabetic patient continues to suffer from DME, the disease can undergo a transition where more inflammatory factors become present. At this stage, first line treatments may no longer reduce the macular edema or improve vision of the patient even after a significant reduction in macular edema has occurred.

### Current Treatments for DME

Anti-vascular endothelial growth factor (anti-VEGF) antibody and inhibitor intravitreal injections (anti-VEGF therapies) are the current standard of care for the treatment of DME. Lucentis and Eylea are the currently available anti-VEGF therapies marketed for the treatment of vision loss associated with DME in the EU and for the treatment of DME in the U.S. having been proven efficacious in patients suffering from 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 achieve an insufficient response from these anti-VEGF therapies. In addition, these therapies have safety profiles which include an increased risk of endophthalmitis due to frequent injections and an IOP rise in certain patients which may increase the risk of glaucoma.

Intravitreal corticosteroid therapies and laser photocoagulation are also used to treat DME. Ozurdex, a short duration corticosteroid, is marketed for the treatment of vision loss associated with DME in the EU and for the treatment of DME in the U.S. Off-label intravitreal triamcinolone injections are also used to treat DME. 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 efficacious in some but not all patients, and are limited by a need for multiple and frequent injections to maintain a therapeutic effect.

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 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 long duration corticosteroid intravitreal implant for the treatment of DME. ILUVIEN is non-bioerodable and is designed to deliver sustained sub-microgram levels of FAc at an initial rate of 0.25 ug per day and last 36 months. "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 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. In approved European countries, the procedure is performed in a hospital or private clinic setting. In the U.S., the non-surgical procedure is performed in the retinal specialist's office. Based on data from our FAME Study, we believe ILUVIEN improves vision while mitigating side effects commonly associated with the use of corticosteroids for the following reasons:

ILUVIEN delivers FAc. The active pharmaceutical ingredient in ILUVIEN is FAc, which has demonstrated efficacy in the treatment of DME in the two completed Phase 3 pivotal clinical trials, collectively referred to as our FAME Study.

ILUVIEN delivers sustained sub-microgram daily levels of a steroid to the eye. The dosage level of ILUVIEN provides lower daily and aggregate exposure to corticosteroids than other intraocular dosage forms currently

available.

ILUVIEN is designed to deliver sustained sub-microgram levels of FAc at an initial rate of 0.25 ug per day and last 36 months. In vitro release kinetics have shown that ILUVIEN provides sustained delivery of sub-microgram levels of FAc over time. Based on the results of the FAME Study, ILUVIEN provides a sustained, therapeutic effect in the treatment of DME patients for up to 36 months.

7

---

## Table of Contents

ILUVIEN's placement utilizes the eye's natural fluid dynamics. There are two natural currents of fluid within the eye; one to the front of the eye and the other to the back of the eye, or retina. We believe that ILUVIEN's delivery of sustained sub-microgram levels of FAc and insertion into the back of the eye optimizes delivery of FAc to the retina by utilizing these natural currents, maximizes efficacy and mitigates side effects.

ILUVIEN is inserted using a 25-gauge needle. Needle gauge determines the size of the wound that is created.

ILUVIEN is inserted into the eye in a non-surgical procedure using a 25-gauge needle, which results in a wound that is small enough to seal itself after the needle is removed, thus eliminating the need for additional intervention. Using a larger needle would require a more complicated procedure to create a self-sealing wound, or may require a suture to ensure closure of the wound.

### 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. These pharmacological actions have the potential to treat various ocular conditions, including DME, dry AMD, wet AMD and RVO. 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.

### ILUVIEN is Positioned to Mitigate IOP Increases

Based on our analysis of the final clinical readout from our FAME Study through month 36, it appears that ILUVIEN mitigates the incidence of steroid-induced IOP elevations associated with the intraocular use of corticosteroids, specifically Retisert®, which we believe is due to its sustained low dose and insertion in the posterior portion of the eye. Retisert is approved in the U.S. for the treatment of chronic non-infectious uveitis and contains FAc. It is surgically implanted in the posterior segment of the eye.

The side effect of increased IOP associated with corticosteroids in certain people is believed to be directly related to the interaction of corticosteroids with the cells of the trabecular meshwork, a specialized tissue that acts as a filter located in the front of the eye. In some individuals, the use of intraocular corticosteroids can result in a change in this meshwork, increasing resistance to outflow, and increasing pressure inside the eye. We believe the positioning of ILUVIEN allows it to take advantage of the posterior flow of fluid away from the trabecular meshwork of the eye. We believe ILUVIEN's sustained low dose and positioning minimizes the anterior chamber exposure to FAc, where the typical side effects associated with corticosteroids take place. We believe the FAME Study demonstrated ILUVIEN's ability to mitigate the side effects associated with Retisert in both the incidence of IOP elevations and the number of surgical interventions required to treat elevated IOP associated.

### ILUVIEN Provides Sustained Sub-Microgram Delivery

ILUVIEN 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 190µg of FAc in a polyvinyl alcohol matrix. ILUVIEN is non-bioerodable; however, 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 is designed to deliver sustained sub-microgram levels of FAc at an initial rate of 0.25 ug per day and last 36 months.

### The ILUVIEN Applicator

We developed a custom, proprietary applicator for ILUVIEN, which includes improvements over the modified syringe used during our FAME Study. These improvements include ergonomic design features, a transparent window to visually confirm ILUVIEN's presence within the applicator, a longer needle and markings to guide retinal specialists to the proper insertion point. As was the case with the modified syringe used during our FAME Study, the ILUVIEN applicator uses a 25-gauge needle, which results in a wound that is small enough to seal itself after ILUVIEN has been inserted into the back of the eye and the needle has been removed.

### ILUVIEN for Other Diseases of the Eye

We believe that ILUVIEN has the potential to address other ophthalmic diseases such as dry AMD, wet AMD and RVO. Details regarding the rationale for these other indications are as follows:

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.

8

---

## Table of Contents

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 continued 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. Anti-VEGF antibodies require persistent dosing to maintain a therapeutic effect which is a burden on both the patient and the physician. 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.

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 retinal vein occlusion. The FDA's approval of Ozurdex provides additional evidence that corticosteroids work effectively to treat RVO.

### 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, Portugal, Spain, Sweden, and the United Kingdom and has been recommended for marketing authorization in Poland. 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 EU 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 the EU, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients treated.

In September 2013, we submitted an application to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, as the Reference Member State, for ten additional EU country approvals through the MRP. In June 2014, we received a positive outcome from the Repeat-Use Procedure for ILUVIEN in these ten countries. In 2014 and 2015, we received marketing authorizations resulting from the MRP in Belgium, the Czech Republic, Denmark, Finland, Ireland, Luxembourg, the Netherlands, Norway and Sweden. The regulatory process in Poland is in the national phase in which each country grants marketing authorization.

### Commercialization

ILUVIEN is the only intraocular therapy to treat DME designed to deliver sustained sub-microgram levels of FAc lasting 36 months. 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 the United Kingdom and Germany in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015. We also plan to commercialize ILUVIEN, directly or with a partner, in other EU and non-EU 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 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 are led by an executive team with extensive commercialization expertise with ophthalmic products including the launch and management of Visudyne, the first pharmacological treatment indicated for the treatment of wet AMD. In late 2012 and early 2013 we established a core management team for our EU 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) provide certain services to us in connection with the commercialization of ILUVIEN in certain countries in Europe. Such services include marketing, brand management, sales promotion and detailing, market access, pricing and reimbursement support, regulatory, medical science liaison and communications and/or other advisory services. As of December 31, 2014, we had entered into project orders with Quintiles Commercial for the provision of sales,

marketing, management, market access and medical science personnel in Germany, the United Kingdom and France. Under these project orders Quintiles Commercial, as of December 31, 2014, employed 16 persons fully dedicated to Alimera. Quintiles Commercial also employed 3 persons partially dedicated to us in Germany, the United Kingdom and France as of December 31, 2014. In December 2013 and January 2014,

9

---



Table of Contents

respectively, we transitioned our German and United Kingdom country manager positions in-house. In the second half of 2014, we notified Quintiles Commercial that we would be terminating the project orders associated with Germany and France and transitioning the covered positions employed by Quintiles Commercial to our payroll. We expect to complete these transitions during the second quarter of 2015. In the first quarter of 2015, we notified Quintiles Commercial that we would be terminating the project orders associated with the United Kingdom and transitioning the covered positions employed by Quintiles Commercial to our payroll. We expect to complete this transition during the third quarter of 2015. As of December 31, 2014 we directly employed 9 persons in the EU.

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, 2014 our commercial organization included 21 employees, and we hired 32 additional employees in the first quarter of 2015.

Our plan includes developing our medical marketing, promotion and communication materials and ensuring that influential retinal specialists are presenting our FAME Study data and messages at key retina meetings in the U.S. and EU.

**Manufacturing**

We do not have, and do not intend to establish an in-house manufacturing capability for our products and as a result we will continue to depend heavily on third-party contract manufacturers to produce and package ILUVIEN. We rely on these manufacturers to produce active pharmaceutical ingredients, or APIs, and finished drug products in accordance with current Good Manufacturing Practices (cGMPs) and all other applicable laws and regulations. We anticipate that we will continue to rely on contract manufacturers to manufacture ILUVIEN for commercial sale. 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 finalized agreements with the manufacturer of FAc, the active pharmaceutical ingredient 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 EU (AndersonBrecon Limited trading as Packaging Coordinators, Inc.). 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 matrix consisting of FAc and polyvinyl alcohol, cutting the tubes, capping the tubes with membrane caps, curing at high temperature, loading ILUVIEN inside the ILUVIEN applicator, packaging and sterilizing the product. This process has been validated at Alliance, the third-party contract manufacturer of ILUVIEN. 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. 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 agreement, we are also responsible for supplying Alliance with the ILUVIEN applicator and the API. Pursuant to our agreement with Alliance, 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, our agreement with Alliance has an initial term of six years 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 has an initial term of three years and will automatically renew 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.

Customers

Our revenues for the fiscal year ended December 31, 2014 were generated from product sales primarily in Germany and the United Kingdom. No customers accounted for more than 10% of our total consolidated revenue for the year ended December 31, 2014. Two customers in Europe accounted for approximately 23% of our total consolidated revenues for the year ended December 31, 2013. No other customer accounted for more than 10% of revenue in 2013.

10

---

## Table of Contents

### 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 potential competition to ILUVIEN:

- Roche's products Lucentis (ranibizumab injection) and Avastin (bevacizumab) are both anti-VEGF antibodies. Lucentis is marketed in the EU by Novartis. Lucentis is currently approved for the treatment of DME, the treatment of neovascular wet AMD and the treatment of macular edema following RVO in the U.S. and the EU. Avastin, an oncology product, is used by retinal specialists in both the U.S. and in certain countries of the EU in the treatment of numerous retinal diseases but is not formulated or approved for any ophthalmic use.
  - 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 both the U.S. and the EU.
  - Regeneron/Bayer's Eylea (aflibercept), a VEGF inhibitor, is approved for the treatment of DME, neovascular wet AMD and RVO in the U.S. and in the EU.
- In addition, there are a number of other companies, including Ophthotech Corporation, Ampio Pharmaceuticals and pSivida, which are developing drug therapies or sustained delivery platforms for the treatment of ocular diseases. These companies are seeking to apply their technologies to ophthalmic indications in early stage clinical trials. We believe we will be less likely to face generic competition for ILUVIEN 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, 2014.

## Table of Contents

The agreement provides that after commercialization of ILUVIEN, pSivida will be entitled to 20% of the net profits 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, 2014 and 2013, pSivida owed us \$15.1 million and \$12.2 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 a result of the FDA approval of ILUVIEN in September 2014, we paid pSivida a milestone payment of \$25.0 million (the pSivida Milestone Payment) in October 2014. If we were to enter into any sub-license of ILUVIEN, we must share 20% of net profits and 33% of any lump sum milestone payments received from a sub-licensee, as defined in the agreement with pSivida.

### 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 our products. The drug approval process in the U.S. generally involves the following:

- completion of preclinical laboratory and animal testing and formulation studies conducted under Good Laboratory Practices (GLP) regulations;
- submission of an Investigational New Drug Application (IND) which must become effective before human clinical trials may begin;
- completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational drug for its intended use; the studies must be conducted under Good Clinical Practices (GCP) regulations;
- submission of a NDA or Biologics License Application (BLA);
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess compliance with cGMP regulations; and
- FDA review and approval of the NDA or BLA.

Preclinical tests include laboratory evaluations of the active drug's chemical and physical properties, product formulation and stability and animal studies to establish pharmacological effects and safety. The sponsor must submit the results of preclinical tests, chemistry, manufacturing and control (CMC) information and a clinical development plan including clinical protocol(s) in an IND. The sponsor cannot start clinical studies until the IND becomes effective which is 30 days after receipt by the FDA unless the FDA raises concerns or questions before expiration of the 30-day review period. In that case, the sponsor and the FDA must resolve the questions or concerns before clinical trials can proceed.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. They are typically conducted in three sequential phases but the phases may overlap or be

combined. Each trial must be reviewed and approved by an independent Institutional Review Board before it can begin.

12

---

## Table of Contents

Phase 1 trials usually involve the initial introduction of the investigational drug in a small number of human subjects to evaluate the product's safety, dosage tolerance and pharmacodynamics and if possible, to gain an early indication of its effectiveness.

Phase 2 trials are usually conducted in a limited patient population to evaluate dosage tolerance and appropriate dosage; identify possible adverse effects and safety risks; and preliminarily evaluate the efficacy of the drug for specific indications.

Phase 3 trials further evaluate clinical efficacy and test further for safety in an expanded patient population at geographically dispersed test sites. Completion of two adequate and well-controlled Phase 3 studies with results that replicate each other is the norm before an application is submitted to the FDA.

The FDA closely monitors the progress of each phase of clinical testing and may, at its discretion, reevaluate, alter, suspend or terminate testing based on data accumulated to that point and its assessment of the risk/benefit relationship to the patient. Total time required for running the clinical studies varies between two and ten years. Additional clinical testing may be required for special classes of patients, e.g., geriatric patients, pediatric patients, patients with renal impairment.

Once all the clinical studies are completed, the sponsor submits a NDA containing the results of non-clinical and clinical trials, together with detailed CMC information for the product and proposed labeling. It is also important that the sponsor provide a detailed description and justify the risk/benefit relationship of the drug to the patient. Under the Prescription Drug User Fee Act (PDUFA), the applicant has to pay a user fee, which was \$2.2 million in 2014, increasing to \$2.3 million in 2015. Once approved by the FDA, a drug requires an annual maintenance fee which is currently \$110,000.

The FDA conducts a preliminary review of the NDA and within 60 days will make a "fileability" decision. Once the submission is accepted for filing, the FDA conducts an in-depth review of the NDA. Under the PDUFA, the FDA has ten months and six months, respectively, in which to complete its review and issue an action letter for a Standard and Priority Review NDA. The review process may be extended by three months if the FDA requests additional information or the sponsor provides significant new information or clarification regarding information already provided in the submission within the last three months of the original PDUFA date. If the FDA's evaluation of the NDA and audit/inspection of clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or complete response letter (CRL). A CRL is issued if the FDA determines that it will not approve the application in its present form. The CRL will describe all of the specific deficiencies the FDA has identified and when possible, the FDA will recommend actions that the applicant can take before the application may be approved.

Upon receipt of a CRL, the applicant must take one of the following actions:

- resubmit the NDA addressing all deficiencies identified in the CRL;
- withdraw the NDA without prejudice to a subsequent submission; or
- request an opportunity for a hearing on the question of whether there are grounds for denying approval of the NDA. Within 60 days of the date of request, or within a different time period to which the applicant and the FDA agree, the FDA will either approve the NDA or refuse to approve the NDA. If the FDA refuses to approve the NDA, it will give the applicant a written notice of an opportunity for a hearing on the question of whether there are grounds for denying approval of the NDA.

Responses to the CRL can be classified as Class 1 or Class 2. Class 1 and Class 2 resubmissions have a two-month and a six-month review cycle, respectively, beginning on the date the FDA receives the resubmission. Examples of Class 1 resubmissions are: draft or final printed labeling, safety update, stability update, proposals for mandatory post-marketing commitments, assay validation data, minor re-analysis of previously submitted data and minor clarifications. A Class 2 resubmission is for any item not specified as a Class 1 item including any item that would require presentation to an Advisory Committee.

Within one year after receipt of the CRL, the applicant is required to take one of the actions cited above. If the applicant does not take one of these actions, the FDA will consider the lack of response as a request to withdraw the

NDA. The applicant can also request an extension of time to resubmit the NDA. A resubmission must fully address all the deficiencies cited. A partial response to the CRL will not be processed as a resubmission and will not start a new review cycle.

#### Other Regulatory Requirements

Risk Evaluation and Mitigation Strategy (REMS). The Food and Drug Administration Amendments Act of 2007 (FDAAA), gives the FDA authority to require a drug-specific REMS to ensure the safe use of the drug. In determining whether



## Table of Contents

a REMS is necessary, the FDA must consider the size of the population most likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events and whether or not the drug is a new chemical entity. If the FDA determines a REMS is necessary, the sponsor must propose the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health providers of the drug's risks, a limitation on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure safe use of the drug.

The FDAAA also expands the FDA's authority to require post-approval studies and clinical trials if the FDA, after drug approval, deems it appropriate. The purpose of such studies would be to assess a known serious risk or signals of a serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

**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, in 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 or surveillance 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. In the CRL received in October 2013, the FDA referenced deficiencies in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured. We do not believe that these deficiencies will affect our European commercial supply of ILUVIEN. We and our third-party manufacturer are in the process of resolving these deficiencies.

### 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 EMA, if approved, would permit marketing of the product throughout the EU (currently 27 member states). The centralized procedure is mandatory for new chemical entities, biotech and orphan drug products and products to treat AIDS, cancer, diabetes and neuro-degenerative disorder, auto-immune diseases, other immune dysfunctions and viral diseases. Products that constitute a significant therapeutic, scientific or technical innovation or which are in the interests of patients in the EU may also be submitted under this procedure. We believe ILUVIEN would have potentially qualified for this procedure as a product that constitutes a significant therapeutic, scientific or technical innovation. However, 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 central 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 once marketing authorization has been received in any EU country. Under the mutual recognition procedure, the holders of national marketing authorization in one of the countries within the EU may submit further applications to other countries within the EU, who will be requested to recognize the original authorization based on the FAR provided by the RMS. In September 2013, we submitted an application to the MHRA in the United Kingdom, as the Reference Member State, for ten additional EU country approvals through the Mutual Recognition Procedure.

Third-party reimbursement and pricing controls

## Table of Contents

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. In the U.S., it is time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payers. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us or our partners to sell our products on a competitive or profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, is expected to significantly change the way healthcare is financed by both governmental and private insurers. The provisions of the ACA became effective over various periods from 2010 through 2014. While we cannot predict what impact on federal reimbursement policies this law will have in general or specifically on any product we commercialize, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. The rebates, discounts, taxes and other costs resulting from the ACA may have a significant effect on our profitability in the future. In addition, potential reductions of the per capita rate of growth in Medicare spending under the ACA, could potentially limit access to certain treatments or mandate price controls for our products. Moreover, although the U.S. Supreme Court has upheld the constitutionality of most of the ACA, some states have indicated that they intend not to implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal the ACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us.

In many foreign markets, including the countries in the EU, 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, 2014, we owned or have 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, we only have the right to our ILUVIEN-related patent rights 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 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

## Table of Contents

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 products including Visudyne, the first pharmacological treatment indicated for patients with wet AMD. 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. 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 \$11.4 million and \$8.4 million in research and development during the years ended December 31, 2014 and 2013, respectively.

### Employees

As of March 6, 2015, we had 105 employees with 23 of these employees engaged in research, development and regulatory activities, and 82 engaged in administrative support, finance, information technology and sales and marketing activities. None of our employees is represented by a labor union and we consider our employee relations to be good.

### 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](http://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](http://www.sec.gov).

Copies of each of our filings with the SEC on Form 10-K, Form 10-Q and Form 8-K and all amendments to those reports, can be viewed and downloaded free of charge at our website, [www.alimerasciences.com](http://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](http://www.alimerasciences.com).



Table of Contents

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 heavily dependent on the commercial success of our lead product, ILUVIEN, which has received marketing authorizations in the U.S., Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom for the treatment of diabetic macular edema (DME), and on the regulatory approval of ILUVIEN in other countries, which may never occur.

We are a pharmaceutical company with only one product available for commercial sale in a limited number of markets. As a result, our future success is currently dependent upon the commercial and regulatory success of ILUVIEN. ILUVIEN has received marketing authorization in the U.S., Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom, and has been recommended for marketing authorization in Poland. 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 EU countries in which ILUVIEN has received marketing authorization, ILUVIEN is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. We launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013 and Portugal and the U.S. in the first quarter of 2015. 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 building commercial operations in the EU and the U.S. to successfully commercialize ILUVIEN for the treatment of DME.

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom, Portugal and the U.S. If we do not successfully commercialize ILUVIEN in these countries or other countries in the EU, our ability to generate revenue may be jeopardized and, consequently, our business may be seriously harmed. We 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 launch of ILUVIEN in one or more countries, including obtaining unfavorable pricing and/or reimbursement which could negatively affect our stock price.

In addition, we have incurred and expect to continue to incur significant expenses and to utilize a substantial portion of our cash resources for the commercial launch of ILUVIEN in Germany, the United Kingdom, Portugal and the U.S., 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.

We may also fail to develop future products or product candidates. If this were to occur, we will continue to be dependent on the successful commercialization of ILUVIEN, our development costs may increase and our ability to generate revenue could be impaired.

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;

17

---



Table of Contents

- perceived efficacy relative to other available therapies;
- shifts in the medical community to new treatment paradigms or standards of care;
- relative convenience and ease of administration; and
- prevalence and severity of adverse side effects associated with treatment.

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

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.

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;
- our ability to obtain regulatory approval of ILUVIEN in additional jurisdictions;
- cost of product sales;
- marketing and other expenses;
- manufacturing or supply issues;
- regulatory developments affecting ILUVIEN, our future product candidates or our competitors' products;
- the emergence of products that compete with ILUVIEN;
- variations in the level of expenses related to our products or future development programs;
- the timing and amount of royalties or milestone payments;
- 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.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial and increasing losses for the foreseeable future.

Table of Contents

We launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013, and Portugal and the U.S. in the first quarter of 2015. We are not currently generating significant revenues and we cannot estimate with precision the extent of our future losses. ILUVIEN is our only product currently approved for commercial sale. We may never achieve profitability. We expect to continue to incur substantial and increasing losses. 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, 2014, we have accumulated a deficit of \$313.3 million. Our ability to generate significant revenue and achieve profitability is dependent on our ability to successfully market and sell ILUVIEN, have ILUVIEN manufactured, to complete the development of any future products or product candidates and obtain necessary regulatory approvals of any future products or product candidates. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

We may need additional capital to support our growth, which may be difficult to obtain, restrict our operations and will result in additional dilution to our stockholders.

We do not expect to have positive cash flow from operations until 2016, if at all. At December 31, 2014, we had approximately \$76.7 million in cash and cash equivalents. We believe our cash and cash equivalents will be sufficient to fund our operations for the continued commercialization of ILUVIEN in Germany and the United Kingdom, and the launch of ILUVIEN in Portugal and the U.S. We will seek to raise additional financing to fund our working capital needs associated with the commercialization of ILUVIEN in the U.S., if necessary. If we are unable to raise additional financing, then we may 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. These factors include but are not limited to:

• the amount of our future operating losses;

• third party expenses relating to the commercialization of ILUVIEN;

• the level of success of the initial commercial launch of ILUVIEN in Germany, the United Kingdom, Portugal and the U.S.;

• the timing of approvals, if any, of ILUVIEN in additional jurisdictions;

• the need and cost of conducting additional clinical trials for ILUVIEN;

• the amount of our research and development, marketing and general and administrative expenses;

• the extent to which we enter into, maintain, and derive revenues from licensing agreements, including agreements to out-license ILUVIEN, research and other collaborations, joint ventures and other business arrangements;

• the extent to which we acquire, and our success in integrating, technologies or companies; and

• regulatory changes and technological developments in our markets.

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. 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, to cease or reduce certain research and development projects, to sell some or all of our technology or assets or business units or to merge all or a portion of our business with another entity. 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 especially in light of the current difficult financial environment. If we raise additional funds by selling shares of our capital stock, the ownership interest of our current stockholders will be diluted. In addition, our 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. 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

Table of Contents

may restrict our ability to commercialize ILUVIEN or any future products or product candidates or operate our business. For example, under our loan and security agreement (2014 Loan Agreement) with Hercules Technology Growth Capital, Inc. (Hercules), which Alimera Sciences Limited (Limited), our subsidiary, entered into in April 2014, under which Limited obtained a term loan of up to \$35.0 million (2014 Term Loan). We and certain of our subsidiaries are subject to a variety of affirmative and negative covenants, including required financial reporting, limitations on our cash balances, limitations on the disposition of assets, limitations on the incurrence of additional debt, and other requirements. Due to the limited revenue generated by ILUVIEN to date, we may not be able to maintain compliance with covenants under the 2014 Loan Agreement. In an event of default, Hercules may call the 2014 Term Loan, and we will likely need to raise additional financing. To secure the performance of our obligations under the 2014 Loan Agreement, Limited pledged all of its assets to the lender. Our or Limited's failure to comply with the covenants under the 2014 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 2014 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. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. 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.

ILUVIEN and any future products or product candidates may not be commercially viable if we fail to obtain an adequate level of reimbursement for these products from governments, private insurers, the Medicare program and 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 and any future products or product candidates we may develop in the countries in which ILUVIEN has received or been recommended for marketing authorization, or any future products or product candidates receive approval, if any, is dependent upon the pricing and reimbursement guidelines adopted in each of such countries, which levels may fall well below our current expectations.

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 EU, 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, or delay regulatory approval. 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 products, including 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. Our business could be materially adversely affected if such limitations were

imposed. 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.

In the U.S., we will need to obtain approvals for payment for ILUVIEN from private insurers, including managed care organizations, and from the Medicare program. 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. 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

Table of Contents

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.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of ILUVIEN in determining whether to approve reimbursement for ILUVIEN and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive 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.

Our business could also be adversely affected if governments, private insurers, the Medicare program or other reimbursing bodies or payers limit the indications for which ILUVIEN will be reimbursed to a smaller set than we believe it is effective in treating or establish a limitation 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.

Expansion of 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 managing this growth. We may also encounter unexpected or unforeseen delays in connection with our continued expansion of our commercial infrastructure, which may negatively impact our commercial efforts for ILUVIEN.

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom, Portugal and the U.S. We launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013, and Portugal and the U.S. in the first quarter of 2015. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources.

As of December 31, 2014, we had 70 employees, 51 of whom were located in the U.S. and 19 of whom were located in the United Kingdom, Germany and Portugal. We previously entered into a master services agreement with Quintiles Commercial to provide additional personnel for our planned launch of ILUVIEN, and subsequent operations, in Germany, the United Kingdom and France. As of December 31, 2014, Quintiles Commercial employed 16 persons fully dedicated to Alimera and employed three persons partially dedicated to Alimera in Germany, the United Kingdom and France. We have determined that Quintiles Commercial is not as effective in filling certain positions in certain geographies as we believe that we can be in hiring directly. In December 2013 and January 2014, respectively, we transitioned our German and United Kingdom country manager positions in-house. In the second half of 2014, we notified Quintiles Commercial that we would be terminating the project orders associated with Germany and France and transitioning the covered positions employed by Quintiles Commercial to our payroll. We expect to complete these transitions during the second quarter of 2015. In the first quarter of 2015, we notified Quintiles Commercial that we would be terminating the project orders associated with the United Kingdom and transitioning the

covered positions employed by Quintiles Commercial to our payroll. We expect to complete this transition during the third quarter of 2015. As our development and commercialization plans and strategies evolve beyond our initial planned EU launches, we will need to further expand the size of our organization by recruiting additional managerial, operational, sales, marketing, financial and other personnel.

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, 2014, our commercial U.S. organization included 21 employees, and we hired 32 additional employees in the first quarter of 2015.

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:

21

---



Table of Contents

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 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 expanding 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 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.

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

We have limited international commercialization experience and 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;

## Table of Contents

political instability, including war and terrorism or the threat of war and terrorism; and

adverse economic conditions, including the stability and solvency of business financial markets, financial institutions and sovereign nations.

In addition, compliance with foreign and U.S. laws and regulations that are applicable to our international operations is complex and may increase our cost of doing business in international jurisdictions, and our international operations could expose us to fines and penalties if we fail to comply with these regulations. These laws and regulations include import and export requirements, U.S. laws such as the Foreign Corrupt Practices Act, and local laws prohibiting corrupt payments to governmental officials. Although we have implemented policies and procedures designed to help ensure compliance with these laws, there can be no assurance that our employees, partners and other persons with whom we do business will not take actions in violation of our policies or these laws. Any violations of these laws could subject us to civil or criminal penalties, including substantial fines or prohibitions on our ability to offer our products in one or more countries, and could also materially and adversely harm our business and financial condition.

The regulatory approval of ILUVIEN in additional countries or any future products or product candidates in any country is uncertain. Failure to obtain regulatory approval in additional foreign jurisdictions would prevent us from marketing 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., Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom, and has been recommended for marketing authorization in Poland. 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 U.S. Food and Drug Administration (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 EU countries in which ILUVIEN has received or been recommended for 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 current Good Manufacturing Practice (cGMP) regulations.

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, including those in the U.S., Canada, the EU and other countries where drugs are regulated, can delay, limit or deny approval of a drug candidate for many reasons, including that:

a drug candidate may not be safe or effective;

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;

• 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 of certain of our methods for analyzing our trial data, including how we evaluate the relationship between risk and benefit. Further, we may pursue approval of and market other future products or product candidates, in additional countries in the EU and Canada. Regulatory agencies within these countries will require that we obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedures within these countries can involve additional testing, and the time

## Table of Contents

required to obtain approval may differ from that required to obtain FDA approval. 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 and may not receive necessary approvals to commercialize ILUVIEN in any additional market. The failure to obtain these approvals 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 EU 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, Portugal, Spain, Sweden and the United Kingdom and been recommended for marketing authorization in Poland for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. 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. 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 EU 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.

The terms of our 2014 Loan Agreement require us to meet certain operating covenants and place restrictions on our operating and financial flexibility.

Due to the limited revenue generated by ILUVIEN to date, we may not be able to maintain compliance with covenants under our 2014 Loan Agreement with Hercules. The 2014 Term Loan is secured by a lien covering all of our assets, other than our intellectual property. The 2014 Loan Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to satisfy certain financial covenants, maintain our legal existence and governmental approvals, deliver 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 an event of default under our 2014 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 2014 Loan Agreement on terms less favorable to us or to immediately cease operations. Any declaration by Hercules of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Further, if we are liquidated, Hercules' right to repayment would be senior to the rights of the holders of our common stock.

ILUVIEN utilizes FAc, a corticosteroid that has demonstrated undesirable side effects in the eye; therefore, the success of ILUVIEN will be dependent upon the achievement of an appropriate relationship between the benefits of its efficacy and 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

## Table of Contents

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. We have agreed with EU regulatory authorities to conduct a five-year post-authorization, open label registry study of the safety of ILUVIEN in 800 patients treated per the labeled indication. 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. Further, delay in the commercial launch of ILUVIEN could result in the withdrawal of our marketing or regulatory authorization for ILUVIEN in certain jurisdictions, including certain EU member states where ILUVIEN has already received marketing authorization.

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. 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 FDA 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 FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. 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 FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, 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.

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

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. We are also subject to the provisions of the Federal Anti-Kickback Statute 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



Table of Contents

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 or related to environmental matters and claims under state laws, including state anti-kickback and fraud laws.

While 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.

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, or 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. Provisions affecting pharmaceutical companies include the following:

• Mandatory rebates for drugs sold into the Medicaid program have been increased, and the rebate requirement has been extended to drugs used in risk-based Medicaid managed care plans.

• The 340B Drug Pricing Program under the Public Health Services Act has been extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities.

• Pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the “Donut Hole.”

Pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company’s market share of prior year total sales of branded products to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense. The aggregate industry-wide fee is expected to total \$28 billion through 2019, of which \$3.0 billion will be payable in 2014. Since we expect our branded pharmaceutical sales to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

The law provides that biologic products may receive 12 years of market exclusivity, with a possible six-month extension for pediatric products. After this exclusivity ends, generic manufacturers will be permitted to enter the market, which is likely to reduce the pricing for such products and could affect the company’s profitability. In addition, generic manufacturers will be permitted to challenge one or more of the patents for a branded drug after a product is marketed for four years.

The full effects of the U.S. healthcare reform legislation cannot be known until the new law is implemented through regulations or guidance issued by the Centers for Medicare & Medicaid Services and other federal and state healthcare

agencies. The financial impact of the U.S. healthcare reform legislation over the next few years will depend on a number of factors including but not limited to the policies reflected in implementing regulations and guidance and changes in sales volumes for products affected by the new system of rebates, discounts and fees.

The Physician Payment Sunshine Act also imposes new 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

Table of Contents

family members during the preceding calendar year. Failure to submit required information may result in significant civil monetary penalties.

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, including the EU and Canada, 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. 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.

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 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;
- have fewer or less severe adverse side effects;
- are better tolerated;
- receive better reimbursement terms;
- are more accepted by physicians;
- 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. There are three biological products, Lucentis, Eylea and Avastin, we believe provides competition for ILUVIEN. Lucentis is currently approved for the treatment of 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. and the EU. Lucentis is marketed in the U.S. by Genentech and in the EU by Novartis. Eylea is currently approved for the treatment of DME, the treatment of neovascular wet

27

---

Table of Contents

AMD and the treatment of macular edema following RVO in the U.S. and the EU. Eylea is marketed in the U.S. by Regeneron and in the EU by Bayer. Avastin, an oncology product marketed by the Roche Group, is used by retinal specialists in both the U.S. and in certain countries of the EU in the treatment of numerous retinal diseases but is not formulated or approved for any ophthalmic use.

Within the corticosteroid class, Ozurdex is expected to provide competition for ILUVIEN. Ozurdex has recently been approved in the U.S. and the EU for the treatment of DME. Ozurdex is also indicated for macular edema resulting from RVO and for uveitis in the U.S. and the EU.

Retinal specialists are currently using laser photocoagulation and off-label therapies 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.

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 could cause a decline in our financial condition and results of operations.

As a result of our European operations, we are subject to increased risk because we incur a significant portion of our operating expenses and receive revenues in multiple currencies other than the U.S. dollar. For example, in Europe where we have operating costs in a foreign currency, we are subject to risk if the foreign currency in which our costs are paid appreciates against the currency in which we generate revenue because the appreciation effectively increases our cost in that country.

The financial condition and results of operations of some of our operating entities are reported in foreign currencies and then translated into U.S. dollars at the applicable exchange rate for inclusion in our consolidated financial statements. As a result, appreciation of the U.S. dollar against these foreign currencies generally will have a negative impact on our reported operating losses while depreciation of the U.S. dollar against these foreign currencies will generally have a positive effect on reported operating losses. We do not seek to mitigate this translation 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.

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 EU (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 EU (with PCI), if any of the third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with

Table of Contents

them or get them approved by the applicable regulatory authorities, such as the FDA in the U.S., in a timely manner. Further, all of our manufacturers rely on additional third-parties for the manufacture of component parts. Any inability to acquire sufficient quantities of ILUVIEN implants, the ILUVIEN applicator or the active pharmaceutical ingredient in a timely manner from these third-parties could delay commercial production of, and impact our ability to fulfill demand for, ILUVIEN, if any.

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, the commercial launch of ILUVIEN would be delayed 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 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 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 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. For example, during routine manufacturing inspection, we identified a quality issue related to one of our suppliers that affected certain batches of work in process, which resulted in a write-off of \$1.4 million during the year ended December 31, 2013. Any significant delays in the manufacture of ILUVIEN or the quality of the product could materially harm our business and prospects.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, 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. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the 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, 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. For example, in the CRL we received in October 2013, the FDA referenced deficiencies in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured.

Other than the master services agreement entered into with Quintiles Commercial in November 2012, we currently do not have any material collaboration agreements with third-parties. 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



Table of Contents

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 research, development and commercialization of ILUVIEN and any future products or product candidates. Other than the master services agreement entered into with Quintiles Commercial in November 2012, we currently do not have any collaboration agreements with third-parties. Areas in which we may potentially enter into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing of ILUVIEN in certain EU 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 arrangements we do enter into may not be scientifically or commercially successful. The termination of any of these arrangements might adversely affect our ability to develop, commercialize and market our products.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our collaborators will 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;

- we expect to be required in our collaboration agreements not to 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;

- 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; and

- 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.

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 President and Chief Executive Officer, Richard Eiswirth, our Chief Operating Officer and Chief Financial Officer, Philip Ashman, Ph.D., our EU Senior Vice President and EU 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.

At December 31, 2014, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately \$87.4 million and \$70.8 million, respectively, which expire at various dates beginning in 2021 through 2034. Section 382 of the Internal Revenue Code limits the annual utilization of NOL carry-forwards and tax credit carry-forwards following an ownership change

30

---

Table of Contents

in our company. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code 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. The issuance of shares of our Series A Convertible Preferred Stock in October 2012 constituted such a change in ownership. As a result of this change in ownership, we performed a formal analysis in connection with IRC Section 382 and determined that approximately \$13.7 million of our NOL carry-forwards generated prior to the change in ownership could not be utilized 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 drugs and drug targets 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.

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 product candidates could severely harm our business.

Preclinical studies and clinical trials required to demonstrate the safety and efficacy of any 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;

Table of Contents

• 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 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.

If we are required to conduct additional clinical trials or other studies with respect to any 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 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 potential products. 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 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 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.

## Table of Contents

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.

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. In addition, as of December 31, 2014 and thereafter we are required to obtain an opinion on our internal controls over financial reporting from our independent registered public accounting firm which reports on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, 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 or our independent registered public accounting firm identifies 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 SEC or other regulatory authorities, which would require additional financial and management resources.

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.

The global economic downturn and market instability has made the business climate more volatile and more costly. These 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 Germany, the United Kingdom, Portugal and the U.S. As a result of negative trends in the general economy in the jurisdictions in which we may do business, 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.

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. There were no customers that accounted for more than 10% of our total consolidated revenues for the year ended December 31, 2014. For the year ended December 31, 2013, two pharmacy customers in Europe accounted for approximately 23% of our total consolidated revenues.

#### 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



## Table of Contents

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 development, regulatory approval or commercialization of our products.

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 research, development, manufacturing or sales 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, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations 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 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.

## Table of Contents

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 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, 2014, the patent rights relating to ILUVIEN licensed to us from pSivida include 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 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.

Table of Contents

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. 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. 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

## Table of Contents

of ILUVIEN or one or more of our future products. 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 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 both the U.S. and Canada 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 IPO in April 2010 at a price of \$11.00 per share. Subsequently, our common stock has traded as low as \$1.09 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, including our ability to build our own commercial infrastructure for the sale of ILUVIEN in Germany, the United Kingdom, Portugal and the U.S.;

- the ability of ILUVIEN to be approved in any additional jurisdiction;

- the ability of ILUVIEN or any future products or product candidates, if approved in additional jurisdictions, to achieve 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;

additions or departures of key personnel;

commencement of, or our involvement in, litigation;

our ability to meet our repayment and other obligations under our loan agreements;

37

---



Table of Contents

- 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 scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, the notification of the results of regulatory filings and the anticipated commercial launch of ILUVIEN or any future products or product candidates. 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.

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

In addition to our outstanding common stock, as of December 31, 2014, there were a total of 7,681,256 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

38

---

Table of Contents

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. 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, 2015, an additional 1,772,814 shares became available for future issuance under our 2010 Equity Incentive Plan in accordance with the annual increase. In addition, we have reserved 494,422 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, 2015, an additional 34,915 shares became available for future issuance under our 2010 Employee Stock Purchase Plan.

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

For so long as at least 37.5% of the shares of Series A Convertible Preferred Stock originally issued to the investors at the closing of our Series A Convertible Preferred Stock financing in October 2012 are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock: (i) increase or decrease the authorized number of shares of Series A Convertible Preferred Stock; (ii) 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; (iii) 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; (iv) 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; (v) 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; (vi) 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; (vii) issue stock or other equity securities of any subsidiary (other than to us or another of our wholly-

Table of Contents

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;

- 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.



Table of Contents

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 EU 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 space located in Berlin, Germany, and in Lisbon, Portugal, both consisting of less than 1,000 square feet of office space. Our lease for these facilities in Germany and Portugal expire in March 2015 and July 2015, respectively. Management believes that the leased facilities are suitable and adequate to meet the Company's anticipated near-term needs. We anticipate that following the expiration of the leases, additional or alternative space will be available at commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

The Company is not a party to any material pending legal proceedings, and management is not aware of any contemplated proceedings by any governmental authority against the Company.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

## 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, 2014	High	Low
First quarter 2014	\$8.44	\$4.29
Second quarter 2014	\$8.36	\$5.00
Third quarter 2014	\$6.54	\$4.58
Fourth quarter 2014	\$6.48	\$4.64
Year Ended December 31, 2013	High	Low
First quarter 2013	\$3.36	\$1.55
Second quarter 2013	\$5.69	\$2.59
Third quarter 2013	\$5.17	\$3.08
Fourth quarter 2013	\$5.14	\$1.65

## Holders

As of March 6, 2015 there were 46 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

## Sales of Unregistered Securities

## 2014 Series B Preferred Stock Private Placement

On December 12, we sold an aggregate of 8,291,873 shares of our Series B Convertible Preferred Stock in a private placement to certain accredited institutional investors for \$6,030.00 per share. We also issued an additional 124,378 shares of Series B Preferred Stock to such accredited institutional investors as a subscription premium. The sale of the shares resulted in gross proceeds to us of \$50.0 million prior to the payment of expenses related to the offering. No underwriters were involved in the foregoing sale of securities. The issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act under the Securities Act. The recipients of securities in such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates issued in such transaction.

## 2014 Common Stock Private Placement

On January 31, 2014, we issued an aggregate of 6,250,000 shares of our common stock for aggregate gross proceeds of approximately \$37.5 million (Private Placement). The Private Placement was issued and sold pursuant to a Securities Purchase Agreement, dated January 27, 2014, between us and certain purchasers. The per share purchase price of a share of common stock was \$6.00. Cowen and Company, LLC served as sole placement agent in the Private Placement.



The issuance was made in reliance on Rule 506 promulgated under the Securities Act of 1933, as amended (the Securities Act) and was made without general solicitation or advertising. Each purchaser represented that it was an accredited investor with access to information about us sufficient to evaluate the investment and that the common stock was being acquired

Table of Contents

without a view to distribution or resale in violation of the Securities Act. A Form D filing was made in accordance with the requirements of Regulation D. In connection with the Private Placement, we agreed to file one or more registration statements registering for resale the shares of common stock sold in the Private Placement. The recipients of securities in the Private Placement represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates issued in such transaction.

2012 Series A Preferred Stock Private Placement

On October 2, 2012, we sold units consisting of an aggregate of 1,000,000 shares of our Series A Convertible Preferred Stock and warrants to purchase an additional 300,000 shares of Series A Convertible Preferred Stock (or such number of shares of our common stock then issuable upon conversion of such shares of Series A Convertible Preferred Stock) in a private placement to certain accredited institutional investors for \$40.00 per unit. The sale of the units resulted in gross proceeds to us of \$40.0 million prior to the payment of related expenses. No underwriters were involved in the foregoing sale of securities. The issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act under the Securities Act. The recipients of securities in such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates issued in such transaction.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Not applicable.

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 research, development and commercialization 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, Portugal, Spain, Sweden, and the United Kingdom and has been recommended for marketing authorization in Poland. 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 Union (EU) 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 the EU, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients treated. We launched ILUVIEN in the United Kingdom and Germany, in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015.

We were able to launch in Germany without price restriction, but continue to work with the statutory health insurance funds in Germany to streamline reimbursement for ILUVIEN.

In October 2013, the United Kingdom's National Institute for Health and Care Excellence (NICE) issued a positive Final Appraisal Determination recommending ILUVIEN funding, taking into consideration a simple patient access scheme (PAS) for the treatment of pseudophakic eyes (eyes with an artificial lens) in chronic DME patients considered insufficiently responsive to available therapies. We began receiving orders for ILUVIEN from several National Health Services (NHS) facilities in

43

---

Table of Contents

January 2014 following the final technology appraisal guidance that was published in November 2013. Further, in February 2014, the Scottish Medicines Consortium, after completing its assessment and review of a similar simple PAS, announced that it has accepted ILUVIEN for restricted use within the NHS Scotland.

In July 2013, the Transparency Commission (Commission de la Transparence or CT) of the French National Health Authority (Haute Autorite de Sante) issued a favorable opinion for the reimbursement and hospital listing of ILUVIEN for the treatment of DME considered insufficiently responsive to available therapies. We continue to negotiate with the French authorities, but have not yet reached an agreement on price.

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of December 31, 2014, we have accumulated a deficit of \$313.3 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

- continue the commercialization of ILUVIEN in the EU;
- commercialize ILUVIEN in the U.S.;
- 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, 2014, we had approximately \$76.7 million in cash and cash equivalents.

We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and in Portugal and the U.S. in the first quarter of 2015. We do not expect to have positive cash flow from operations until 2016, if at all. Due to the limited revenue generated by ILUVIEN to date, we may not be able to maintain compliance with covenants under our loan and security agreement (2014 Loan Agreement) with Hercules Technology Growth Capital, Inc. (Hercules) which provides for a term loan of up to \$35,000,000 (2014 Term Loan). In an event of default under our 2014 Loan Agreement, Hercules may call the 2014 Term Loan, and we would need to raise additional financing. If we are unable to obtain 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.

**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 membrane caps 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.

The agreement provides that after commercialization of ILUVIEN, pSivida will be entitled to 20% of the net profits, 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, 2014 and 2013, pSivida owed us \$15.1 million and \$12.2 million, respectively, in commercialization costs. Due to the uncertainty of future profits from ILUVIEN, we have fully reserved these amounts in the accompanying consolidated financial statements.

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

Our Credit Facility

44

---

## Table of Contents

### 2010 Term Loan

We entered into a loan and security agreement with Silicon Valley Bank (SVB) and MidCap Financial LLP (MidCap and together with SVB, the Lenders) in October 2010, which was subsequently amended in May 2011 (as amended, the 2010 Term Loan Agreement). Pursuant to the 2010 Term Loan Agreement, in October 2010 we borrowed an aggregate of \$6.25 million from the Lenders (the 2010 Term Loan). The 2010 Term Loan Agreement also provided for the ability to drawdown an additional \$11.0 million subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained.

In August 2011, we began repaying the outstanding principal under the 2010 Term Loan in 33 equal monthly installments plus interest at a rate of 11.5%. At maturity, we were also required to make an additional interest payment equal to 4% of the total amount borrowed. We paid to the Lenders an upfront fee of \$62,500 upon execution of the 2010 Term Loan Agreement and an additional fee of \$50,000 in connection with the May 2011 amendment. In accordance with the Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) 470-50-40-17, Debt - Modifications and Extinguishments (ASC 470-50-40-17), we were amortizing the deferred financing costs on the 2010 Term Loan and the \$50,000 modification fee over the remaining term of the 2010 Term Loan, as modified.

In October 2010, in connection with entering into the 2010 Term Loan, we issued SVB a warrant to purchase up to 15,909 shares of our common stock and MidCap a warrant to purchase up to 23,864 shares of our common stock. Each of the warrants were exercisable upon issuance, had a per-share exercise price of \$11.00 and a term of 10 years. We estimated the fair value of warrants granted using the Black-Scholes option pricing model to be \$389,000. We allocated a portion of the proceeds from the 2010 Term Loan to the warrants in accordance with ASC 470-20-25-2, Debt Instruments with Detachable Warrants. As a result, we recorded a discount of \$366,000 which was amortized to interest expense using the effective interest method. The Lenders were also issued warrants to purchase up to an aggregate of 69,999 additional shares of our common stock, which were exercisable only upon the drawdown of the additional \$11.0 million subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained. In May 2013, we repaid all amounts owed to the Lenders under the 2010 Term Loan, including the final interest payment equal to 4% of the total amount borrowed, and a 1.0% prepayment penalty on the then outstanding principal owed to MidCap. In connection with the repayment of the 2010 Term Loan, we recognized a loss on early extinguishment of debt of \$153,000 associated with the remaining unamortized deferred financing costs, unamortized discount associated with the Lenders' warrants, the final interest payment, the prepayment penalty and a lender fee and warrants associated with a new term loan.

### 2010 Revolving Loan Agreement

In October 2010, we entered into a loan and security agreement with SVB, which was subsequently amended in May 2011 (as amended, the 2010 Revolving Loan Agreement), pursuant to which we obtained a secured revolving line of credit from SVB against eligible U.S. domestic accounts receivable with borrowing availability up to \$20.0 million. Upon entering into the 2010 Revolving Loan Agreement, we paid to SVB an upfront fee of \$100,000. As of December 31, 2012, no amounts under the 2010 Revolving Loan Agreement were outstanding or available to us. In May 2013, we terminated the 2010 Revolving Loan Agreement.

### 2013 Loan Agreement

In May 2013, Alimera Sciences Limited (Limited), our subsidiary, entered into a loan and security agreement (2013 Loan Agreement) with Silicon Valley Bank (SVB) to provide Limited with additional working capital for general corporate purposes. Under the 2013 Loan Agreement, SVB has made a term loan (2013 Term Loan) in the principal amount of \$5.0 million to Limited and agreed to provide up to an additional \$15.0 million to Limited under a working capital line of credit (2013 Line of Credit). In connection with the 2013 Loan Agreement, a previous term loan was repaid in full and terminated. In accordance with ASC 470-50-40-17, we recognized a loss on early extinguishment of debt of \$153,000 during the nine months ended September 30, 2013, associated with the remaining unamortized deferred financing costs, unamortized discount associated with the warrants issued to the lenders, a final interest payment, a prepayment penalty and a lender fee and warrants associated with the 2013 Loan Agreement. No advances were made at closing under the 2013 Line of Credit and no amounts were outstanding as of December 31, 2013, respectively. In April 2014, the 2013 Term Loan was repaid and the 2013 Line of Credit was terminated in connection

with the 2014 Loan Agreement described below.

The 2013 Term Loan provided for interest only payments for six months followed by 36 monthly payments of interest, plus principal. We made our first amortization payment on the 2013 Term Loan in December 2013. Interest on outstanding borrowings under the 2013 Term Loan were payable at the rate of 7.50%. Borrowings under the 2013 Line of Credit would have been advanced at 80% of eligible accounts receivable as defined in the 2013 Loan Agreement. Interest was payable on the balance of eligible accounts financed at the rate of 2.75% above SVB's most recently announced "prime rate." Limited was also required to pay SVB on a monthly basis an unused line fee equal to 0.25% per annum of the average unused portion of the

Table of Contents

2013 Line of Credit during the preceding month. The maturity dates were June 30, 2015 with respect to the 2013 Line of Credit and October 31, 2016 with respect to the 2013 Term Loan.

In connection with entering into the 2013 Loan Agreement, Limited paid SVB a facility fee of \$25,000. Additionally, we re-priced warrants to purchase an aggregate of up to 31,818 shares of our common stock previously issued to SVB in connection with an earlier term loan. Upon re-pricing, each of the warrants was exercisable immediately at a per-share exercise price of \$2.86 and had a remaining term of 7.4 years. We estimated the incremental fair value received by SVB using the Black-Scholes option pricing model to be \$46,000. In accordance with ASC 470-50-40-17, we expensed the facility fee and incremental value of the warrants associated with the 2013 Term Loan as part of a loss on early extinguishment of the earlier term loan.

In connection with the 2013 Line of Credit, Limited paid a commitment fee of \$100,000. In accordance with ASC 470-50-40-17, we capitalized the commitment fee and \$49,000 of deferred financing costs remaining on an earlier line of credit as deferred financing costs, which were being amortized over the remaining term of the 2013 Line of Credit. Upon repayment of the 2013 Term Loan in April 2014, Limited paid SVB an outstanding loan balance prepayment penalty of \$133,000, and an early termination fee of \$113,000 in connection with the termination of the 2013 Line of Credit in April 2014.

**2014 Loan Agreement**

In April 2014, Limited entered into the 2014 Loan Agreement with Hercules. Under the 2014 Loan Agreement, Hercules made a term loan 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 the 2013 Term Loan. Hercules made an additional advance of \$25.0 million to Limited in September 2014 as a result of the approval of ILUVIEN by the FDA in September 2014 to fund the pSivida Milestone Payment. The 2014 Term Loan provides for interest only payments through November 2015. The interest only period may be extended until June 1, 2017 if we realize certain revenue thresholds and no event of default has occurred under the 2014 Loan Agreement. Interest on the 2014 Term Loan accrues 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 term loan will be due and payable to Hercules in equal monthly payments of principal and interest through May 1, 2018.

In connection with the initial advance, Limited paid to Hercules a facility charge of \$262,500 and incurred legal and other fees of approximately \$383,000. Limited incurred \$375,000 in additional fees in connection with the second advance which were included in accounts payable at September 30, 2014 and paid in October 2014. If Limited repays the 2014 Term Loan prior to maturity, it will pay Hercules a prepayment penalty of 1.25% of the total principal amount repaid.

We also 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 2014 Loan Agreement and an increase to the applicable interest rate, and would permit Hercules to exercise remedies with respect to the collateral under the 2014 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. We and certain of our subsidiaries are guarantors of the obligations of Limited to Hercules under the 2014 Loan Agreement pursuant to separate guaranty agreements between Hercules and each of Limited and such subsidiaries (Guaranties). Pursuant to the Guaranties, we and these subsidiaries granted Hercules a first priority security interest in substantially all of their respective assets excluding intellectual property.

In connection with Limited entering into the 2014 Loan Agreement, we entered into a warrant agreement with Hercules to purchase up to 285,016 shares of our common stock at an exercise price of \$6.14 per share. Sixty percent of the warrants were exercisable at the closing in April 2014 and the remaining 40% became exercisable upon the funding of the additional \$25.0 million to Limited in September 2014.

The weighted average interest rates of our notes payable approximate the rate at which we could obtain alternative financing; therefore, the carrying amount of the notes approximated their fair value at December 31, 2014 and December 31, 2013.



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 2016, 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

## Table of Contents

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 and Development Expenses

Substantially all of our research and development 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 and development 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 and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel, including medical sales liaisons;
- 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 the provision of medical affairs support, including symposia development for physician education;
- costs related to compliance with FDA, EU or other regulatory requirements;
- 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 and development 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. The costs of clinical trials may vary significantly over the life of a project owing to but not limited to the following:

- the number of sites included in the trials;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the duration of patient follow-up;
- the phase of development the product candidate is in; and
- the efficacy and safety profile of the product candidate.

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts

applied to the level of patient enrollment

47

---

## Table of Contents

and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

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, Portugal, Spain, Sweden and the United Kingdom, and has been recommended for marketing authorization in Poland. 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 EU countries in which ILUVIEN has received marketing authorization, it is indicated for the treatment of vision impairment 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.

Within the Operating expenses section of the Consolidated Statements of Operations for the year ended December 31, 2013, we reclassified depreciation expense of \$138,000 from General and administrative expenses to Depreciation and amortization to conform to the current year presentation.

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

In November 2012, we entered into an agreement with Quintiles Commercial Europe Limited. Under the Agreement, Quintiles Commercial Europe Limited and its affiliates (collectively, Quintiles Commercial) will provide certain services to us in relation to the commercialization of ILUVIEN, in certain countries in Europe under subsequent project orders. Such services may include marketing, brand management, sales promotion and detailing, market access, pricing and reimbursement support, regulatory, medical science liaison and communications and/or other advisory services. As of December 31, 2014, we had entered into eight project orders with Quintiles Commercial for the provision of sales, marketing, management, market access and medical science personnel in Germany, the United

Kingdom and France. Under these project orders, Quintiles Commercial, as of December 31, 2014, employed 16 persons fully dedicated to Alimera. Quintiles Commercial also employed three persons partially dedicated to Alimera in Germany, the United Kingdom and France, as of December 31, 2014. In December 2013 and January 2014, respectively, we transitioned our German and United Kingdom country manager positions in-house. In the second half of 2014, we notified Quintiles Commercial that we would be terminating the project orders associated with Germany and France and transitioning the covered positions employed by Quintiles Commercial to our payroll. We expect to complete these transitions during the second quarter of 2015. In the first quarter of 2015, we notified Quintiles Commercial that we would be terminating the project orders associated with the United Kingdom and transitioning the covered positions

## Table of Contents

employed by Quintiles Commercial to our payroll. We expect to complete this transition during the third quarter of 2015. As of December 31, 2014 we directly employed 9 persons in the EU.

In accordance with the terms of these project orders and the July 2014 amendments, as of December 31, 2014, we expect to incur approximately \$4.4 million in costs with Quintiles Commercial for the year ending December 31, 2015. For the years ended December 31, 2014 and 2013, respectively, we incurred \$5.8 million and \$7.5 million of expense associated with this agreement. At December 31, 2014, \$1.4 million is included in outsourced services payable and \$700,000 is included in prepaid expenses and other current assets in our accompanying consolidated financial statements in association with these project orders.

We have a European management team and local management teams in Germany and the United Kingdom totaling 16 persons at December 31, 2014 providing strategic oversight and operational management to the personnel provided by Quintiles Commercial. In Portugal, we launched ILUVIEN with our own team, comprised of four persons, in the first quarter of 2015. As of December 31, 2014, we had hired four persons in Portugal.

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, medical science liaisons and payor relations directors. We will continue to hire additional sales and marketing personnel through the first quarter of 2015 and anticipate launching ILUVIEN with a field force of approximately 50 people, including sales personnel, reimbursement specialists, medical sciences liaisons and payor relations directors.

### Interest Expense, Net and Other

Interest expense consists primarily of interest and amortization of deferred financing costs and debt discounts associated with an earlier term loan entered into in 2010, our 2013 Term Loan and our 2014 Loan Agreement. Interest income consists primarily of interest earned on our cash, cash equivalents and investments.

### 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 Accounting Standards Codification (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 29,994,312, and 27,225,082 for the years ended December 31, 2014 and 2013, 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, 2014 and 2013, 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.  
Clinical Trial Prepaid and Accrued Expenses

49

---

## Table of Contents

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.

### 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.

### 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 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 deferred tax assets due to our history of operating losses, a valuation allowance has been established against our 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 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

Table of Contents

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. At December 31, 2014 we had federal NOL carry-forwards of approximately \$87.4 million and state NOL carry-forwards of approximately \$70.8 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 2024 and 2034 and the state NOL carry-forwards will expire at various dates between 2021 and 2034. 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 may be subject to annual limitations on the use of these NOLs under Internal Revenue Code (IRC) Section 382 (or comparable provisions of state law). The issuance of the Series A Convertible Preferred Stock on October 2, 2012 constituted such a change in ownership. As a result of this change in ownership, we performed a formal analysis in connection with IRC Section 382 and determined that approximately \$13.7 million of our NOLs generated prior to the change in ownership could not be utilized in the future. Our remaining NOLs remain subject to future limitation under IRC Section 382.

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. We believe our income tax filing positions and deductions are more likely than not of being sustained on audit and do not anticipate any adjustments that will result in a material change to our financial position; therefore, we have not recorded ASC 740 liabilities. We recognize accrued interest and penalties related to unrecognized tax benefits as interest expense and income tax expense, respectively, in our statements of operations. Our tax years since 2003 remain subject to examination in Georgia, Tennessee, and on the federal level. We do not anticipate any material changes to our uncertain tax positions within the next 12 months.

Foreign Currency Translation

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

Our foreign currency assets and liabilities are remeasured into U.S. dollars at end-of-period exchange rates, except for nonmonetary balance sheet accounts, which are remeasured at historical exchange rates. Revenue and expenses are remeasured at average exchange rates in effect during each period, except for those expenses related to the non-monetary balance sheet amounts, which are remeasured at historical exchange rates. Gains or losses from foreign currency remeasurement are included in income.

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

Table of Contents

## Results of Operations

The following selected consolidated financial and operating data are derived from our 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,	
	2014	2013
	(In thousands)	
NET REVENUE	\$8,423	\$1,872
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(1,442 )	(1,863 )
GROSS MARGIN	6,981	9
RESEARCH AND DEVELOPMENT EXPENSES	11,363	8,429
GENERAL AND ADMINISTRATIVE EXPENSES	12,371	9,475
SALES AND MARKETING EXPENSES	15,535	16,371
DEPRECIATION AND AMORTIZATION	659	138
OPERATING EXPENSES	39,928	34,413
NET LOSS FROM OPERATIONS	(32,947 )	(34,404 )
INTEREST EXPENSE AND OTHER	(2,090 )	(533 )
UNREALIZED FOREIGN CURRENCY (LOSS) GAIN, NET	(542 )	825
LOSS ON EARLY EXTINGUISHMENT OF DEBT	(440 )	(153 )
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	283	(11,964 )
NET LOSS BEFORE TAXES	(35,736 )	(46,229 )
PROVISION FOR TAXES	(174 )	—
NET LOSS	\$(35,910 )	\$(46,229 )

Year ended December 31, 2014 compared to the year ended December 31, 2013

**Net Revenue.** Net revenue increased by approximately \$6.5 million, or 342%, to approximately \$8.4 million for the year ended December 31, 2014, compared to approximately \$1.9 million for the year ended December 31, 2013. We initiated the commercial launch of ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and began recognizing revenue at that time. The increase was due to revenue growth in Germany and the implementation of NICE guidance for the reimbursement of ILUVIEN in the United Kingdom in early 2014. No customer accounted for more than 10% of revenue during the year ended December 31, 2014. For the year ended December 31, 2013 two pharmacy customers in Europe accounted for approximately 23% of our total consolidated revenues.

**Cost of goods sold.** Cost of goods sold decreased by approximately \$500,000, or 26%, to approximately \$1.4 million for the year ended December 31, 2014, compared to approximately \$1.9 million for the year ended December 31, 2013. We initiated the commercial launch of ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and began recognizing cost of goods sold at that time. Cost of goods sold was impacted by two inventory issues during the year ended December 31, 2013. During a routine manufacturing inspection, we identified a quality issue related to one of our suppliers that affected certain batches of work in process which we had to write off. This write-off amounted to \$1.4 million. Additionally, we reserved approximately \$400,000 for potential United Kingdom inventory expiration. For the year ended December 31, 2014, we reserved approximately \$430,000 for potential German inventory expiration, as a result of lower than expected sales in Germany.

**Research and development expenses.** Research and development expenses increased by approximately \$3.0 million, or 36%, to approximately \$11.4 million for the year ended December 31, 2014, compared to approximately \$8.4 million for the year ended December 31, 2013. The increase was primarily attributable to increases of \$980,000 in additional payroll and related costs associated with additional medical and clinical personnel hired during 2013 to support the commercialization of ILUVIEN in the EU being employed for the full year ended 2014, \$780,000 related

to a consultant that was engaged to assist with the pursuit of approval of ILUVIEN in the U.S., \$480,000 in stock based compensation incurred in connection with the additional hires and stock option grants made in late 2013, \$450,000 in payroll and related costs for medical science liaisons

Table of Contents

hired in the fourth quarter of 2014 to support the U.S. launch of ILUVIEN in the first quarter of 2015 and \$410,000 related to scientific communications in preparation for the commercial launch in the U.S.

General and administrative expenses. General and administrative expenses increased by approximately \$2.9 million, or 31%, to approximately \$12.4 million for the year ended December 31, 2014, compared to approximately \$9.5 million for the year ended December 31, 2013. The increase was primarily attributable to an increase of approximately \$1.0 million in European payroll and related costs primarily attributable to transitioning our British and German country managers from Quintiles Commercial to Alimera in early 2014 and hired a Portuguese country manager in mid-2014, \$360,000 in payroll and related costs for additional administrative personnel to support our global organization, \$700,000 in stock based compensation incurred in connection with the additional hires, stock option grants made in late 2013 and contingent options that vested as a result of the FDA approval of ILUVIEN in 2014 and \$310,000 in professional fees associated with internal controls compliance and attestation, as our independent auditors were required to opine on our internal controls for the first time for the year ended December 31, 2014.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately \$900,000, or 6%, to approximately \$15.5 million for the year ended December 31, 2014, compared to approximately \$16.4 million for the year ended December 31, 2013. The decrease was primarily attributable to a decreases of approximately \$1.9 million in costs incurred with Quintiles Commercial for market access assistance in the United Kingdom in 2013 in preparation for the implementation of the NICE guidance for reimbursement, \$1.4 million in savings associated with one time launch costs incurred in the EU in 2013 for the launch of ILUVIEN in Germany and the United Kingdom and \$480,000 associated with Quintiles Commercial as certain positions were transitioned to Alimera over the course of 2014. These decreases were offset by an increases of approximately \$2.4 million in U.S. marketing cost incurred, \$440,000 in payroll and related costs for additional sales and marketing personnel hired in 2014 in preparation for the U.S. launch of ILUVIEN in the first quarter of 2015 and \$190,000 in stock based compensation incurred in connection with the additional hires and stock option grants made in late 2013.

Depreciation and amortization. Depreciation and amortization increased by approximately \$520,000, or 371%, to approximately \$660,000 for the year ended December 31, 2014, compared to approximately \$140,000 for the year ended December 31, 2013. The increase was primarily attributable to amortization of \$510,000 associated with an intangible asset which was capitalized in connection with the pSvida Milestone Payment upon FDA approval of ILUVIEN in September 2014.

Interest expense and other. Interest expense and other increased by approximately \$1.6 million, or 302%, to approximately \$2.1 million for the year ended December 31, 2014, compared to approximately \$530,000 for the year ended December 31, 2013. Interest expense for the year ended December 31, 2014 was primarily interest expense incurred in connection with our 2013 Term Loan and 2014 Loan Agreement. Interest expense for the year ended December 31, 2013 was primarily interest expense incurred in connection with our 2010 Term Loan and our 2013 Term Loan. The increase was primarily attributable to higher principal balances for the year ended December 31, 2014 as a result of the 2014 Loan Agreement.

Unrealized foreign currency (loss) gain, net. Unrealized foreign currency (loss) gain, net was a loss of approximately \$540,000 for the year ended December 31, 2014, compared to a gain of approximately \$830,000 for the year ended December 31, 2013. The 2014 unrealized foreign currency loss was primarily attributable to the weakening of the Euro during 2014 and the revaluation of Alimera Sciences Limited's U.S. dollar denominated liabilities. The 2013 unrealized foreign currency gain was primarily attributable to the strengthening of the Euro during 2013 and the revaluation of Alimera Sciences Limited's U.S. dollar denominated liabilities.

Change in fair value of derivative warrant liability. During the year ended December 31, 2014, we recognized a gain of approximately \$280,000 related to the decrease in the fair value of our derivative warrant liability. The change in fair value was primarily due to an decrease in the fair market value of our underlying common stock during the year ended December 31, 2014. During the year ended December 31, 2013, we recognized a loss of approximately \$12.0 million related to the increase in the fair value of our derivative warrant liability. The change in fair value was primarily due to an increase in the fair market value of our underlying common stock during the year ended December 31, 2013.

### Liquidity and Capital Resources

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of \$313.3 million from our inception through December 31, 2014. 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.

53

---

Table of Contents

On January 31, 2014, we sold 6,250,000 shares of our common stock for aggregate gross proceeds of approximately \$37.5 million, prior to the payment of approximately \$2.3 million of related issuance costs and placement agent fees. On December 12, 2014, we closed a preferred stock financing in which we sold 8,416,251 shares of Series B Convertible Preferred Stock for gross proceeds of \$50.0 million, prior to the payment of approximately \$430,000 of related issuance costs.

As of December 31, 2014, we had approximately \$76.7 million in cash and cash equivalents. We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and in Portugal and the U.S. in the first quarter of 2015. Based on our current plans, we believe our cash and cash equivalents will be sufficient to fund our operations beyond the projected commercialization of ILUVIEN in the United Kingdom, Germany, Portugal and the U.S. and the expected generation of positive cash flow from operations in 2016, at the earliest, if at all. However, 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. If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

In the event additional financing is needed or desired, we may seek to fund our operations through the sale of equity securities, strategic collaboration agreements and debt financing. 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 especially in light of the current difficult financial environment. If we 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 attempt to raise additional funds through strategic collaboration agreements and debt financing, 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 the twelve months ended December 31, 2014, cash used in our operations of \$24.3 million was primarily due to our net loss of \$35.9 million, increased by \$280,000 for a non-cash gain for the change in our derivative warrant liability and offset by non-cash charges of approximately \$3.9 million for stock compensation expense, \$660,000 of depreciation and amortization expense, \$540,000 for unrealized foreign currency transactions, \$460,000 amortization of deferred financing costs and debt discount and \$440,000 for the loss from early extinguishment of debt. Further impacting cash from operations was an increase in accrued expenses and other current liabilities of \$6.1 million and increase in accounts receivable of \$440,000. The increase in accrued expenses and other current liabilities of \$6.1 million was primarily due to increases of \$2.6 million of amounts payable to Quintiles Commercial and \$2.0 million for a milestone payment payable to a consultant that was engaged to assist with the pursuit of approval of ILUVIEN in the U.S.

For the twelve months ended December 31, 2013, cash used in our operations of \$37.8 million was primarily due to our net loss of \$46.2 million, offset by a non-cash loss of \$12.0 million for a change in derivative warrant liability and by non-cash charges of \$2.5 million for stock compensation expense, and increased by a non-cash gain of \$830,000 for unrealized foreign currency transactions. Further decreasing cash was a decrease in accrued expenses and other current liabilities of \$2.6 million and increases in prepaid expenses and other current assets of \$1.4 million, inventory of \$1.4 million and accounts receivable of \$480,000. The decrease in accrued expenses and other current liabilities of \$2.6 million was primarily due to decreases of \$2.0 million in amounts paid to Quintiles Commercial. The increase in prepaid expense and other current assets of \$1.4 million was primarily due to increases of \$1.3 million in advances to Quintiles Commercial during the fourth quarter of 2013.

For the year ended December 31, 2014, net cash used in our investing activities was approximately \$25.8 million, which was primarily due to the payment of a \$25.0 million milestone payment to pSivida which was payable upon the FDA's approval of ILUVIEN in September 2014.

For the year ended December 31, 2013, net cash used in our investing activities was approximately \$970,000, which was primarily due to the purchase of back-up manufacturing equipment for ILUVIEN.

For the year ended December 31, 2014, net cash provided by our financing activities was approximately \$114.7 million. In January 2014, we entered into a securities purchase agreement with investors pursuant to which we sold an aggregate of 6,250,000 shares of our common stock at a purchase price of \$6.00 per share. Gross proceeds from the offering were \$37.5 million prior to the payment of approximately \$2.4 million of related issuance costs. In April 2014, we entered into a term loan agreement with Hercules, which resulted in proceeds of \$10.0 million in April of 2014 and \$25.0 million in September of 2014 prior to the payment of approximately \$1.0 million in related costs, and \$4.9 million used to prepay and terminate our 2013 Term Loan. Further increasing cash from our financing activities was \$770,000 from the proceeds from exercises of stock options. In December 2014, we closed a preferred stock financing in which we sold 8,416.251 shares of Series B Convertible Preferred Stock for gross proceeds of \$50.0 million, prior to the payment of approximately \$430,000 of related issuance costs.



Table of Contents

For the year ended December 31, 2013, net cash provided by our financing activities was approximately \$1.7 million, which was primarily due to proceeds from the 2013 Term Loan of \$5.0 million offset by the use of approximately \$3.2 million to repay the 2010 Term Loan.

**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, or 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.

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, 2016 for public entities, with no early adoption permitted. Our management is still evaluating the potential impact of adopting this guidance on our financial statements.

In June 2014, the FASB issued 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. Our management is still evaluating the potential impact of adopting this guidance on our financial statements.

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. Our management is still evaluating the potential impact of adopting this guidance on our financial statements.

Table of Contents

ITEM 7A. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

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 64 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, 2014. 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, 2014, 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.

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, 2014, based on criteria for effective internal control over financial reporting established in the 1992 Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Our change in filer status required for the first time, as of December 31, 2014, an audit of internal control over financial reporting (ICFR) under Section 404(b) of the Sarbanes Oxley Act of 2002. Due to the time constraints, we have elected to delay the adoption of 2013 COSO Framework until 2015.

Based on this assessment, our management concluded that we maintained effective internal control over financial reporting as of December 31, 2014 based on the specified criteria.



Table of Contents

The independent registered public accounting firm of Grant Thornton LLP, as auditor of the consolidated balance sheets of Alimera Sciences Inc. and its subsidiaries as of December 31, 2014 and the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity (deficit), and cash flows for the year ended December 31, 2014, has issued an attestation report on the Company's internal control over financial reporting, which is included on page 58.

**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 2014 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.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Alimera Sciences, Inc.,

We have audited the internal control over financial reporting of Alimera Sciences, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2014, based on criteria established in the 1992 Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in the 1992 Internal Control-Integrated Framework issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of the Company as of and for the year ended December 31, 2014, and our report dated March 13, 2015 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

Atlanta, Georgia  
March 13, 2015

Table of Contents

ITEM 9B. OTHER INFORMATION

None.

59

---

Table of Contents

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information required under this item will be contained in the Company's Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2014, under the captions "Election of Directors," "Executive Officers," "Corporate Governance," and "Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

**ITEM 11. EXECUTIVE COMPENSATION**

Information required under this item will be contained in the Company's Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2014, under the captions "Corporate Governance" and "Executive Compensation," and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K, 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 of 1933 or the Securities Exchange Act of 1934, 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**

Information required under this item will be contained in the Company's Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2014, under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

Table of Contents

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**  
Information required under this item will be contained in the Company's Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2014, under the captions "Corporate Governance" and "Certain Relationships and Related Persons Transactions" and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Information required under this item will be contained in the Company's Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2014, under the caption "Ratification of Selection of Independent Registered Public Accounting Firm" and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.



Table of Contents

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS SCHEDULES

The consolidated financial statements filed as part of this annual report on Form 10-K are listed and indexed at page 64. Certain schedules are omitted because they are not applicable, or not required, or because the required information is included in the consolidated financial statements or notes thereto.

The Exhibits listed in the Exhibit Index immediately preceding the Exhibits are filed as part of this annual report on Form 10-K.

Table of Contents

## Signatures

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, 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 13, 2015.

ALIMERA SCIENCES, INC.

By: /s/ C. Daniel Myers  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1934, this annual report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ C. Daniel Myers C. Daniel Myers	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2015
/s/ Richard S. Eiswirth, Jr. Richard S. Eiswirth, Jr.	Chief Operating Officer and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 13, 2015
/s/ Philip R. Tracy Philip R. Tracy	Chairman of the Board of Directors	March 13, 2015
/s/ Mark J. Brooks Mark J. Brooks	Director	March 13, 2015
/s/ Brian K. Halak, Ph.D. Brian K. Halak, Ph.D.	Director	March 13, 2015
/s/ James R. Largent. James R. Largent	Director	March 13, 2015
/s/ Peter J. Pizzo, III Peter J. Pizzo, III	Director	March 13, 2015
/s/ Calvin W. Roberts, M.D. Calvin W. Roberts, M.D.	Director	March 13, 2015
/s/ Glen Bradley, Ph.D. Glen Bradley, Ph.D.	Director	March 13, 2015
/s/ Garheng Kong, M.D., Ph.D. Garheng Kong, M.D., Ph.D.	Director	March 13, 2015

Table of Contents

ALIMERA SCIENCES, INC.  
INDEX TO FINANCIAL STATEMENTS

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	<u>65</u>
Consolidated Financial Statements as of December 31, 2014 and 2013 and for the years ended December 31, 2014 and 2013:	
Consolidated <u>Balance Sheets</u>	<u>66</u>
Consolidated <u>Statements of Operations</u>	<u>67</u>
<u>Consolidated Statements of Comprehensive Loss</u>	<u>68</u>
Consolidated <u>Statements of Changes in Stockholders' (Deficit) Equity</u>	<u>69</u>
Consolidated <u>Statements of Cash Flows</u>	<u>70</u>
<u>Notes to Consolidated Financial Statements</u>	<u>71</u>

64

---

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the 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, 2014 and 2013, and the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2014. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, 2014 and 2013, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2014 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 \$313 million as of December 31, 2014. 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2014, based on criteria established in the 1992 Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 13, 2015 expressed an unqualified opinion.

/s/ GRANT THORNTON LLP

Atlanta, Georgia  
March 13, 2015

Table of Contents

ALIMERA SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS  
AS OF DECEMBER 31, 2014 AND 2013

	December 31,	
	2014	2013
	(In thousands, except share and per share data)	
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 76,697	\$ 12,628
Accounts receivable, net	850	500
Prepaid expenses and other current assets	3,234	3,474
Inventory, net (Note 4)	1,734	1,786
Deferred financing costs	754	250
Total current assets	83,269	18,638
PROPERTY AND EQUIPMENT — at cost less accumulated depreciation	1,653	982
INTANGIBLE ASSET, net	24,490	—
<b>TOTAL ASSETS</b>	<b>\$ 109,412</b>	<b>\$ 19,620</b>
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 5,021	\$ 1,735
Accrued expenses (Note 7)	954	934
Accrued milestone payments	2,000	—
Outsourced services payable	1,466	603
Note payable (Note 9)	1,023	1,667
Capital lease obligations	11	10
Total current liabilities	10,475	4,949
<b>NON-CURRENT LIABILITIES:</b>		
Derivative warrant liability	16,098	16,381
Note payable — less current portion (Note 9)	33,065	3,194
Other non-current liabilities	255	21
<b>COMMITMENTS AND CONTINGENCIES (Note 10)</b>		
<b>STOCKHOLDERS' (DEFICIT) EQUITY:</b>		
Preferred stock, \$.01 par value — 10,000,000 shares authorized at December 31, 2014 and 2013:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 600,000 issued and outstanding at December 31, 2014 and 1,000,000 issued and outstanding at December 31, 2013; liquidation preference of \$24,000 at December 31, 2014 and \$40,000 at December 31, 2013	19,227	32,045
Series B Convertible Preferred Stock, 8,417 authorized and 8,416.251 issued and outstanding at December 31, 2014 and none issued and outstanding at December 31, 2013; liquidation preference of \$50,750 at December 31, 2014 and \$0 at December 31, 2013	49,568	—
Common stock, \$.01 par value — 100,000,000 shares authorized, 44,320,342 shares issued and outstanding at December 31, 2014 and 31,610,991 shares issued and outstanding at December 31, 2013	443	316
Additional paid-in capital	292,851	240,135
Common stock warrants	1,497	412
Accumulated deficit	(313,255)	(277,345)
Accumulated other comprehensive loss	(812)	(488)

Edgar Filing: ALIMERA SCIENCES INC - Form 10-K

TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	49,519	(4,925	)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 109,412	\$ 19,620	

See Notes to Consolidated Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE YEARS ENDED DECEMBER 31, 2014 AND 2013

	Years Ended December 31,	
	2014	2013
	(In thousands, except share and per share data)	
NET REVENUE	\$8,423	\$1,872
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(1,442)	(1,863)
GROSS MARGIN	6,981	9
RESEARCH AND DEVELOPMENT EXPENSES	11,363	8,429
GENERAL AND ADMINISTRATIVE EXPENSES	12,371	9,475
SALES AND MARKETING EXPENSES	15,535	16,371
DEPRECIATION AND AMORTIZATION	659	138
OPERATING EXPENSES	39,928	34,413
NET LOSS FROM OPERATIONS	(32,947)	(34,404)
INTEREST EXPENSE AND OTHER	(2,090)	(533)
UNREALIZED FOREIGN CURRENCY (LOSS) GAIN, NET	(542)	825
LOSS ON EARLY EXTINGUISHMENT OF DEBT	(440)	(153)
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	283	(11,964)
NET LOSS BEFORE TAXES	(35,736)	(46,229)
PROVISION FOR TAXES	(174)	—
NET LOSS	(35,910)	(46,229)
BENEFICIAL CONVERSION FEATURE OF PREFERRED STOCK (Note 11)	(750)	(4,950)
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	\$(36,660)	\$(51,179)
NET LOSS PER SHARE APPLICABLE TO COMMON STOCKHOLDERS — Basic and diluted	\$(0.91)	\$(1.62)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	40,397,224	31,579,553

See Notes to Consolidated Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS  
FOR THE YEARS ENDED DECEMBER 31, 2014 AND 2013

	Years Ended December 31,	
	2014	2013
NET LOSS	\$ (35,910	) \$ (46,229
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	(324	) (488
TOTAL OTHER COMPREHENSIVE LOSS	(324	) (488
COMPREHENSIVE LOSS	\$ (36,234	) \$ (46,717

See Notes to Consolidated Financial Statements.



Table of Contents

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIT) EQUITY  
FOR THE YEARS ENDED DECEMBER 31, 2014 AND 2013

	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	
	Shares	Amount	Shares	Amount	Shares	Amount				Loss	Total
(In thousands, except share data)											
BALANCE —											
December 31, 2012	31,541,286	\$315	1,000,000	\$32,045	—	\$—	\$237,485	\$415	\$(231,116)	\$—	\$39,144
Issuance of common stock	26,123	—	—	—	—	—	53	—	—	—	53
Exercise of stock options	43,582	1	—	—	—	—	71	—	—	—	72
Modification of common stock warrants	—	—	—	—	—	—	—	46	—	—	46
Forfeiture of common stock warrants	—	—	—	—	—	—	49	(49)	—	—	—
Intrinsic value of beneficial conversion feature	—	—	—	(4,950)	—	—	4,950	—	—	—	—
Accretion of beneficial conversion feature	—	—	—	4,950	—	—	(4,950)	—	—	—	—
Issuance of preferred stock, net of issuance costs	—	—	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	2,477	—	—	—	2,477
Net loss	—	—	—	—	—	—	—	—	(46,229)	—	(46,229)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	(488)	(488)
BALANCE —											
December 31, 2013	31,610,991	316	1,000,000	32,045	—	—	240,135	412	(277,345)	\$(488)	(4,925)
Issuance of common stock, net of issuance costs	6,284,915	63	—	—	—	—	35,146	—	—	—	35,209
	391,307	4	—	—	—	—	770	—	—	—	774

Edgar Filing: ALIMERA SCIENCES INC - Form 10-K

Exercise of stock options											
Issuance of preferred stock, net of issuance costs	—	—	—	—	8,416	49,568	—	—	—	—	49,568
Conversion of preferred stock	6,015,037	60	(400,000 )	(12,818 )	—	—	12,758	—	—	—	—
Issuance of common stock warrants	—	—	—	—	—	—	—	1,277	—	—	1,277
Exercise of common stock warrants	18,092	—	—	—	—	—	192	(192 )	—	—	—
Intrinsic value of beneficial conversion feature	—	—	—	—	—	(750 )	750	—	—	—	—
Accretion of beneficial conversion feature	—	—	—	—	—	750	(750 )	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	3,850	—	—	—	3,850
Net loss	—	—	—	—	—	—	—	—	(35,910 )	—	(35,910 )
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	(324 )	(324 )
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

See Notes to Consolidated Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE YEARS ENDED DECEMBER 31, 2014 AND 2013

	Years Ended December 31,	
	2014	2013
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(35,910	) \$(46,229
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	659	138
Inventory reserve	—	410
Unrealized foreign currency transaction gain	542	(825
Amortization of deferred financing costs and debt discount	466	159
Loss on early extinguishment of debt	440	153
Stock option expense	3,850	2,477
Change in fair value of derivative warrant liability	(283	) 11,964
Changes in assets and liabilities:		
Accounts receivable	(444	) (483
Prepaid expenses and other current assets	206	(1,355
Inventory	(135	) (1,416
Accounts payable	2,987	(259
Accrued expenses and other current liabilities	3,077	(2,347
Other long-term liabilities	244	(208
Net cash used in operating activities	(24,301	) (37,821
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Payment of license intangible (Note 6)	(25,000	) —
Purchases of property and equipment	(842	) (973
Net cash used in investing activities	(25,842	) (973
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	774	72
Proceeds from sale of common stock	37,598	53
Payment of issuance cost of common stock	(2,389	) —
Proceeds from issuance of Series B convertible preferred stock	50,000	—
Payment of Series B convertible preferred stock offering costs	(105	) —
Proceeds from issuance of notes payable (Note 9)	35,000	5,000
Payment of debt issuance costs (Note 9)	(1,016	) (291
Payment of principal on notes payable	(4,861	) (3,169
Payment of debt extinguishment costs	(246	) —
Payments on capital lease obligations	(10	) (11
Net cash provided by financing activities	114,745	1,654
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS	(533	) 204
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	64,069	(36,936
CASH AND CASH EQUIVALENTS — Beginning of year	12,628	49,564
CASH AND CASH EQUIVALENTS — End of year	\$76,697	\$12,628
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for interest	\$1,247	\$607

Edgar Filing: ALIMERA SCIENCES INC - Form 10-K

Supplemental schedule of noncash investing and financing activities:

Conversion of Series A Convertible Preferred Stock to common stock	\$12,818	\$—
Series B Convertible Preferred Stock offering costs accrued but unpaid	\$327	\$—
Property and equipment acquired under capital leases	\$—	\$33

There were no income tax or dividend payments made for the years ended December 31, 2014 and 2013.

See Notes to Consolidated Financial Statements.

70

---

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS

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

The Company is presently focused on diseases affecting the back of the eye, or retina, because the Company's management believes these diseases are not well treated with current therapies and represent a significant market opportunity. The Company's only commercial product is ILUVIEN®, which has received marketing authorization in the United States (U.S.), Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom and has been recommended for marketing authorization in Poland. In the U.S., ILUVIEN is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP). In the European Union (EU) 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 these countries, the Company has committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients treated per the labeled indication.

The Company launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015. To date, the majority of the Company's sales have been in Germany and the United Kingdom. The Company was able to launch in Germany without price restrictions, but continues to work with the statutory health insurance funds in Germany to streamline reimbursement for ILUVIEN.

In October 2013, the United Kingdom's National Institute for Health and Care Excellence (NICE) issued a positive Final Appraisal Determination recommending ILUVIEN funding, taking into consideration a simple patient access scheme (PAS) for the treatment of pseudophakic eyes (eyes with an artificial lens) in chronic DME patients considered insufficiently responsive to available therapies. The Company began receiving orders for ILUVIEN from several National Health Service (NHS) facilities in January 2014 following the final technology appraisal guidance that was published in November 2013. Further, in February 2014, the Scottish Medicines Consortium, after completing its assessment and review of a similar simple PAS, announced that it has accepted ILUVIEN for restricted use within the NHS Scotland.

In July 2013, the Transparency Commission (Commission de la Transparence or CT) of the French National Health Authority (Haute Autorite de Sante) issued a favorable opinion for the reimbursement and hospital listing of ILUVIEN by the French National Health Insurance for the treatment of chronic DME considered insufficiently responsive to available therapies. The Company continues to negotiate with the French authorities, but has not yet reached an agreement on price.

In July 2014, the Company reached agreement with INFARMED, the marketing authorization body of the Portuguese Ministry of Health, for the pricing and reimbursement of ILUVIEN for the public sector in Portugal.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following accounting policies relate primarily to the continuing operations of the Company:

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

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

Reclassifications — Within the operating expenses section of the Consolidated Statements of Operations for the year ended December 31, 2013, the Company reclassified depreciation expense of \$138,000 from general and administrative expenses to depreciation and amortization to conform to the current year presentation.

Cash and Cash Equivalents — Cash and cash equivalents include cash and highly liquid investments that are readily convertible into cash and have a maturity of 90 days or less when purchased. Generally, cash and cash equivalents held at financial institutions are in excess of federally insured limits. The Company limits its exposure to credit loss by placing its cash and cash equivalents in highly liquid investments with high quality financial institutions. Cash and cash equivalents were \$76,697,000 and \$12,628,000 at December 31, 2014 and 2013, respectively, with approximately 96.0% and 100.0% of these balances, respectively held in U.S. based financial institutions.

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

Accounts Receivable and Allowance for Doubtful Accounts — Accounts receivable are generated through sales primarily to pharmacies, hospitals and wholesalers which began in 2013. The Company does not require collateral from its customers for accounts receivable. The carrying amount of accounts receivable is reduced by an allowance for doubtful accounts that reflects management's best estimate of the amounts that will not be collected. In addition to reviewing delinquent accounts receivable, management considers many factors in estimating its general allowance, including historical data, experience, customer types, credit worthiness, and economic trends. From time to time, management may adjust its assumptions for anticipated changes in any of those or other factors expected to affect collectability. Provisions for doubtful accounts are charged to operations at the time management determines these accounts may become uncollectable. The Company writes off accounts receivable when management determines they are uncollectable and credits payments subsequently received on such receivables to bad debt expense in the period received. There were accounts receivable write-offs of \$21,000 for the year ended December 31, 2014 and no allowance for doubtful accounts at December 31, 2014. There were no accounts receivable write-offs for the year ended December 31, 2013 and no allowance for doubtful accounts at December 31, 2013.

Inventory — Inventories are stated at the lower of cost or market with cost determined under the first in, first out (FIFO) method. Included in inventory costs are component parts, work-in-progress and finished goods. The Company relies on third party manufacturers for the production of all inventory and does not capitalize any internal costs. The Company periodically reviews inventories for excess, obsolete or expiring inventory and writes down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than that estimated, or if there are any further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-downs will be required.

Intangible Assets — The cost of intangible assets with determinable useful lives is amortized to reflect the pattern of economic benefits consumed, which approximates a straight-line basis, over the estimated periods benefited. The estimated useful life of the intangible asset is approximately thirteen years.

Property and Equipment — Property and equipment are stated at cost. Additions and improvements are capitalized while repairs and maintenance are expensed. Depreciation is provided on the straight-line method over the useful life of the related assets beginning when the asset is placed in service. The estimated useful lives of the individual assets are as follows: furniture and fixtures and manufacturing equipment, five years; office equipment and leasehold improvements, 29 months to five years; and software, three years.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

**Income Taxes** — In accordance with the Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) 740, Income Taxes, the Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of its assets and liabilities. The Company records a valuation allowance against its net deferred tax asset to reduce the net carrying value to an amount that is more likely than not to be realized.

Income tax positions are considered for uncertainty in accordance with ASC 740-10. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position; therefore, no ASC 740-10 liabilities have been recorded. The Company will recognize accrued interest and penalties related to unrecognized tax benefits, if any, as interest expense and income tax expense, respectively, in the consolidated statements of operations.

Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of deferred tax assets as a result of the Company's history of operating losses, a valuation allowance has been established against the net deferred tax asset balance. The valuation allowance is based on management's estimates of taxable income in the jurisdictions in which the Company operates and the period over which deferred tax assets will be recoverable. In the event that actual results differ from these estimates or the Company adjusts these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact the Company's financial position and results of operations.

**Research and Development Costs** — Research and development costs are expensed as incurred.

**Stock-Based Compensation** — The Company has stock option plans which provide for grants of stock options to employees and directors to purchase shares of the Company's common stock at exercise prices generally equal to the fair market values of such stock at the dates of grant. Compensation cost is recognized for all share-based awards based on the grant date fair value in accordance with the provisions of ASC 718, Compensation — Stock Compensation. The fair values for the options are estimated at the dates of grant using a Black-Scholes option-pricing model.

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

**Derivative Financial Instruments** — The Company generally does not use derivative instruments to hedge exposures to cash flow or market risks. However, certain warrants to purchase Series A convertible Preferred Stock or common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the ASC, are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. These warrants were considered derivative instruments at issuance because the agreements provide for settlement in Series A Convertible Preferred Shares or common shares at the option of the holder, an adjustment to the warrant exercise price for common shares at some point in the future, and contain anti-dilution provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants are subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The warrant exercise price



no longer can be adjusted at some point in the future. The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying common stock. Such financial instruments are initially recorded at fair value with subsequent changes in fair value recorded as a component of change in fair value of derivative warrant liability in the consolidated statements of operations in each reporting period. If these instruments subsequently meet the requirements for equity classification, the Company reclassifies the fair value to equity. At December 31, 2014 and 2013, these warrants represented the only outstanding derivative instruments issued or held by the Company.

**Fair Value of Financial Instruments** — The carrying amounts of the Company's financial instruments, including cash and cash equivalents and current assets and liabilities approximate their fair value because of their short maturities. The weighted average interest rate of the Company's notes payable approximates the rate at which the Company could obtain alternative financing; therefore, the carrying amount of the note approximates the fair value. The Company uses the Black-Scholes option

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

pricing model and assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments.

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

For Alimera Sciences, Inc., foreign currency assets and liabilities are remeasured into U.S. dollars at end-of-period exchange rates, except for non-monetary 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 the statement of operations.

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

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

	Years Ended December 31,	
	2014	2013
Series A convertible preferred stock	9,022,556	15,037,594
Series B convertible preferred stock	8,416,251	—
Series A convertible preferred stock warrants	4,511,279	4,511,279
Common stock warrants	362,970	109,772
Stock options	7,681,256	7,566,437
Total	29,994,312	27,225,082

Reporting Segments — The Company's chief decision maker is the Chief Executive Officer (CEO). While the CEO is apprised of a variety of financial metrics and information, the business is principally managed on an aggregate basis as of December 31, 2014. For the year ended December 31, 2014, the Company's revenues were generated in the European Union (EU). Additionally, the majority of the Company's expenditures and personnel either directly supported its efforts in the EU, or cannot be specifically attributed to a geography. Therefore, the Company has only one reportable operating segment.

Promotional and Advertising Costs — Promotional and advertising costs are expensed as incurred.

Recent Accounting Pronouncements — In May 2014, the FASB issued Accounting Standards Update (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, 2016 for public entities, with no early adoption permitted. The Company is still evaluating the potential impact of adopting this guidance on its financial statements. In June 2014, the FASB issued 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

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

periods and interim periods within those annual periods beginning after December 15, 2015, with early adoption permitted. The Company is still evaluating the potential impact of adopting this guidance on its financial statements. 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. The Company is still evaluating the potential impact of adopting this guidance on its financial statements.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 3. FACTORS AFFECTING OPERATIONS

To date the Company has incurred recurring losses, negative cash flow from operations, and has accumulated a deficit of \$313,255,000 from the Company's inception through December 31, 2014. As of December 31, 2014, the Company had approximately \$76,697,000 in cash and cash equivalents.

The Company believes that it has sufficient funds available to fund its operations for the continued commercialization of ILUVIEN in Germany and the United Kingdom, and the launch of ILUVIEN in Portugal and the U.S. The Company does not expect the generation of positive cash flow from operations until 2016, at the earliest, if at all. The Company may seek to raise additional financing to fund its working capital needs associated with the commercialization of ILUVIEN in the U.S. If the Company is unable to raise additional financing, then it may adjust its commercial plans so that it can continue to operate with its existing cash resources.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company's recurring net losses, negative cash flow from operations and accumulated deficit raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## 4. INVENTORY

Inventory consisted of the following:

	December 31,	
	2014	2013
	(In thousands)	
Component parts (1)	\$76	\$266
Work-in-process (2)	219	587
Finished goods	1,972	1,343
Total inventory	2,267	2,196
Inventory reserve	(533	) (410
Inventory — net	\$1,734	\$1,786

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

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

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31,	
	2014	2013
	(In thousands)	
Furniture and fixtures	\$367	\$308
Office equipment	652	425
Software	601	439
Leasehold improvements	417	82
Manufacturing equipment	974	937
Total property and equipment	3,011	2,191
Less accumulated depreciation and amortization	(1,358	) (1,209
Property and equipment — net	\$1,653	\$982

Depreciation and amortization expense associated with property and equipment totaled \$149,000 and \$138,000 for the years ended December 31, 2014 and 2013, respectively.

## 6. INTANGIBLE ASSETS

The Company had no intangible assets as of December 31, 2013. As a result of the FDA's approval of ILUVIEN in September 2014, the Company was required to pay pSivida US, Inc. (pSivida) a milestone payment of \$25,000,000 (the pSivida Milestone Payment) in October 2014 (see Note 8).

The gross carrying amount of the intangible asset is \$25,000,000, which is being amortized over approximately 13 years from the acquisition date. The net book value of the intangible asset was \$24,490,000 as of December 31, 2014, and amortization expense was \$510,000 for the year ended December 31, 2014.

The estimated remaining amortization as of December 31, 2014 is as follows (in thousands):

Years Ending December 31	
2015	\$1,940
2016	1,940
2017	1,940
2018	1,940
2019	1,940
Thereafter	14,790
Total	\$24,490

## 7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2014	2013
	(In thousands)	
Accrued clinical investigator expenses	\$309	\$562
Accrued other compensation expenses	226	106
Other accrued expenses	419	266
Total accrued expenses	\$954	\$934

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

8. LICENSE AGREEMENTS

The Company 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, and a subsequent amendment in 2008. pSivida is a global drug delivery company committed to the biomedical sector and the development of drug delivery products. The agreement with pSivida provides the Company with a worldwide exclusive license to develop and sell ILUVIEN. The Company's license rights to pSivida's proprietary delivery device could revert to pSivida if the Company were to (i) fail twice to cure its breach of an obligation to make certain payments to pSivida following receipt of written notice thereof; (ii) fail to cure other breaches of material terms of its 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 its property, file a petition under any bankruptcy or insolvency act or have any such petition filed against it and such proceeding remains undismissed or unstayed for a period of more than 60 days; or (iv) notify pSivida in writing of its decision to abandon its license with respect to a certain product using pSivida's proprietary delivery device.

Upon commercialization of ILUVIEN, the Company must share 20% of net profits, determined on a cash basis, and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined by the agreement, with pSivida. In connection with this arrangement the Company is 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, which is recovered as a reduction of future royalty payments. As of December 31, 2014 and 2013, the Company was owed \$15,144,000 and \$12,219,000, respectively, in commercialization costs. Due to the uncertainty of future net profits, the Company has fully reserved these amounts in the accompanying consolidated financial statements. As a result of the FDA's approval of the NDA for ILUVIEN in September 2014, the Company paid pSivida an additional milestone payment of \$25,000,000 in October 2014.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 9. LOAN AGREEMENTS

## 2010 Term Loan

The Company entered into a loan and security agreement with Silicon Valley Bank (SVB) and MidCap Financial LLP (MidCap and together with SVB, the Lenders) in October 2010, which was subsequently amended in May 2011 (as amended, the 2010 Term Loan Agreement). Pursuant to the 2010 Term Loan Agreement, in October 2010 the Company borrowed an aggregate of \$6,250,000 from the Lenders (the 2010 Term Loan). The 2010 Term Loan Agreement also provided for the ability to drawdown an additional \$11,000,000 subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained.

In August 2011, the Company began repaying the outstanding principal under the 2010 Term Loan in 33 equal monthly installments plus interest at a rate of 11.5%. At maturity, the Company was also required to make an additional interest payment equal to 4% of the total amount borrowed. The Company paid to the Lenders an upfront fee of \$62,500 upon execution of the 2010 Term Loan Agreement and an additional fee of \$50,000 in connection with the May 2011 amendment. In accordance with ASC 470-50-40-17, Debt - Modifications and Extinguishments (ASC 470-50-40-17), the Company was amortizing the deferred financing costs on the 2010 Term Loan and the \$50,000 modification fee over the remaining term of the 2010 Term Loan, as modified.

In October 2010, in connection with entering into the 2010 Term Loan, the Company issued SVB a warrant to purchase up to 15,909 shares of the Company's common stock and MidCap a warrant to purchase up to 23,864 shares of the Company's common stock. Each of the warrants were exercisable upon issuance, had a per-share exercise price of \$11.00 and a term of 10 years. The Company estimated the fair value of warrants granted using the Black-Scholes option pricing model to be \$389,000. The Company allocated a portion of the proceeds from the 2010 Term Loan to the warrants in accordance with ASC 470-20-25-2, Debt Instruments with Detachable Warrants. As a result, the Company recorded a discount of \$366,000 which was amortized to interest expense using the effective interest method. The Lenders were also issued warrants to purchase up to an aggregate of 69,999 additional shares of the Company's common stock, which were exercisable only upon the drawdown of the additional \$11,000,000 subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained.

In May 2013, the Company repaid all amounts owed to the Lenders under the 2010 Term Loan, including the final interest payment equal to 4% of the total amount borrowed, and a 1.0% prepayment penalty on the then outstanding principal owed to MidCap. In connection with the repayment of the 2010 Term Loan, and in accordance with ASC 470-50-40-17, the Company recognized a loss on early extinguishment of debt of \$153,000 associated with the remaining unamortized deferred financing costs, unamortized discount associated with the Lenders' warrants, the final interest payment, the prepayment penalty and a lender fee and warrants associated with a new term loan.

## 2010 Revolving Loan Agreement

In October 2010, the Company and SVB entered into a loan and security agreement, which was subsequently amended in May 2011 (as amended, the 2010 Revolving Loan Agreement), pursuant to which the Company obtained a secured revolving line of credit from SVB against eligible U.S. domestic accounts receivable with borrowing availability up to \$20,000,000. Upon entering into the 2010 Revolving Loan Agreement, the Company paid to SVB an upfront fee of \$100,000. In May 2013, the Company and SVB terminated the 2010 Revolving Loan Agreement.

## 2013 Loan Agreement

In May 2013, Alimera Sciences Limited (Limited), a subsidiary of the Company, entered into a loan and security agreement (2013 Loan Agreement) with SVB to provide Limited with additional working capital for general corporate purposes. Under the 2013 Loan Agreement, SVB has made a term loan (2013 Term Loan) in the principal amount of \$5,000,000 to Limited and has agreed to provide up to an additional \$15,000,000 to Limited under a working capital line of credit (2013 Line of Credit). No advances were made at closing under the 2013 Line of Credit and no amounts were outstanding as of December 31, 2013. At December 31, 2013, the Company's ability to borrow under the 2013 Line of Credit was limited based on the Company's accounts receivable at the date as described below.



The 2013 Term Loan provides for interest only payments for six months followed by 36 monthly payments of interest, plus principal. The Company made its first amortization payment on the 2013 Term Loan in December 2013. Interest on outstanding borrowings under the 2013 Term Loan is payable at the rate of 7.50%. Borrowings under the 2013 Line of Credit will be advanced at 80% of eligible accounts receivable as defined in the 2013 Loan Agreement. Interest is payable on the balance of eligible accounts financed at the rate of 2.75% above SVB's most recently announced "prime rate." Limited is also required to pay SVB on a monthly basis an unused line fee equal to 0.25% per annum of the average unused portion of the 2013

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Line of Credit during the preceding month. The maturity dates are June 30, 2015 with respect to the 2013 Line of Credit and October 31, 2016 with respect to the 2013 Term Loan.

In connection with entering into the 2013 Loan Agreement, Limited paid SVB a facility fee of \$25,000. Additionally, the Company re-priced warrants to purchase an aggregate of up to 31,818 shares of the Company's common stock previously issued to SVB in connection with the 2010 Term Loan; 15,909 of which were previously exercisable only upon the drawdown of the additional \$11,000,000 of the 2010 Term Loan subject to FDA approval of the NDA for ILUVIEN by December 31, 2011. Upon re-pricing, each of the warrants was exercisable immediately at a per-share exercise price of \$2.86 and had a remaining term of 7.4 years. The Company estimated the incremental fair value received by SVB using the Black-Scholes option pricing model to be \$46,000. In accordance with ASC 470-50-40-17, the Company expensed the facility fee and incremental value of the warrants associated with the 2013 Term Loan as part of the loss on early extinguishment of the 2010 Term Loan. Warrants to purchase up to an aggregate of 54,090 additional shares of the Company's common stock, which were exercisable only upon the drawdown of the additional \$11,000,000 of the 2010 Term Loan subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained, remain outstanding.

In connection with the 2013 Line of Credit, Limited paid a commitment fee of \$100,000. In accordance with ASC 470-50-40-17, the Company capitalized the commitment fee and \$49,000 of deferred financing costs remaining on the 2010 Revolving Loan Agreement as deferred financing costs, which are being amortized over the remaining term of the 2013 Line of Credit.

Upon repayment of the 2013 Term Loan in April 2014, Limited paid SVB an outstanding loan balance prepayment penalty of \$133,000, and an early termination fee of \$113,000 in connection with the termination of the 2013 Line of Credit in April 2014.

2014 Loan Agreement

In April 2014, Limited entered into a loan and security agreement (2014 Loan Agreement) with Hercules Technology Growth Capital, Inc. (Hercules) providing for a term loan of up to \$35,000,000 (2014 Term Loan). Under the 2014 Loan Agreement, Hercules made an advance in the initial principal amount of \$10,000,000 to Limited at closing to provide Limited with additional working capital for general corporate purposes and to repay the 2013 Term Loan. Hercules made an additional advance of \$25,000,000 to Limited in September 2014 following the approval of ILUVIEN by the FDA in September 2014 to fund the pSivida Milestone Payment. The 2014 Term Loan provides for interest only payments through November 2015. The interest only period may be extended until June 1, 2017 if the Company realizes certain revenue thresholds and no event of default has occurred under the 2014 Loan Agreement. As of December 31, 2014, the interest only period has not been extended. Interest on the 2014 Term Loan accrues 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 term loan will be due and payable to Hercules in equal monthly payments of principal and interest through May 1, 2018.

In connection with the initial advance, Limited paid to Hercules a facility charge of \$262,500 and incurred legal and other fees of approximately \$383,000. Limited incurred \$375,000 in additional fees in connection with the second advance. If Limited repays the 2014 Term Loan prior to maturity, it will pay Hercules a prepayment penalty of 1.25% of the total principal amount repaid.

Limited and the Company, on a consolidated basis with its other subsidiaries, also 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 2014 Loan Agreement and an increase to the applicable interest rate, and would permit Hercules to exercise remedies with respect to the collateral under the 2014 Loan Agreement. As of December 31, 2014, the Company, on a consolidated basis with its subsidiaries, was in compliance with the covenants of the 2014 Term Loan.

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 2014 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.

In connection with Limited entering into the 2014 Loan Agreement, the Company entered into a warrant agreement with Hercules to purchase up to 285,016 shares of the Company's common stock at an exercise price of \$6.14 per share. The

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Company estimated the fair value of warrants granted using the Black-Scholes option pricing model to be \$1,349,000. The Company allocated a portion of the proceeds from the 2014 Term Loan to the warrants in accordance with ASC 470-20-25-2, Debt Instruments with Detachable Warrants. As a result, the Company recorded a discount of \$1,277,000 which is amortized to interest expense using the effective interest method. Sixty percent of the warrants were exercisable at the closing in April 2014 and the remaining forty percent became exercisable upon the funding of the additional \$25,000,000 to Limited in September 2014.

The weighted average interest rates of the Company's notes payable approximate the rate at which the Company could obtain alternative financing; therefore, the carrying amount of the notes approximated their fair value at December 31, 2014 and 2013.

81

---

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 10. COMMITMENTS AND CONTINGENCIES

Term Note Payable — In April 2014, the Company entered into the 2014 Term Loan (Note 9). As of December 31, 2014 a schedule of future minimum principal payments under the Note Payable is as follows (in thousands):

Years Ending December 31	(In thousands)
2015	\$ 1,023
2016	12,968
2017	14,487
2018	6,522
Total	\$35,000

As of December 31, 2014, the Company had \$324,000 accrued and unpaid interest payable on the Notes Payable. As of December 31, 2013, the Company had no accrued and unpaid interest payable on its Notes Payable under the 2013 Loan Agreement.

Operating Leases — The Company leases office space and equipment under non-cancelable agreements accounted for as operating leases. The leases generally require that the Company pay taxes, maintenance, and insurance. Management expects that in the normal course of business, leases that expire will be renewed or replaced by other leases. In August 2014, the Company signed a lease for office space in the U.S. through September 2021. In December 2014, Limited signed a lease for office space in the United Kingdom from December 17, 2014 to December 24, 2024, however the lease is cancellable after five years. The lease has a contingent escalation clause based on inflation beginning in 2020.

The Company also leases office space in Germany and Portugal that can be renewed on an annual basis. At

December 31, 2014, a schedule by year of future minimum payments under operating leases is as follows:

Years Ending December 31	(In thousands)
2015	\$376
2016	509
2017	516
2018	525
2019	485
Thereafter	618
Total	\$3,029

Rent expense under all operating leases totaled approximately \$521,000 and \$576,000 for the years ended December 31, 2014 and 2013, respectively.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Capital Leases — The Company leases equipment under capital leases. The property and equipment is capitalized at the lesser of fair market value or the present value of the minimum lease payments at the inception of the leases using the Company's incremental borrowing rate.

At December 31, 2014, a schedule by year of future minimum payments under capital leases, together with the present value of minimum lease payments, is as follows (in thousands):

Years Ending December 31	(In thousands)
2015	12
2016	9
Total	21
Less amount representing interest	(2 )
Present value of minimum lease payments	19
Less current portion	(11 )
Non-current portion	\$8

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

	December 31,	
	2014	2013
	(In thousands)	
Office equipment	\$33	\$33
Less accumulated amortization	(16 )	(5 )
Total	\$17	\$28

Depreciation expense associated with office equipment under capital leases was \$11,000 for each of the years ended December 31, 2014 and 2013.

Significant Agreements — In February 2010, the Company entered into an agreement with a third party manufacturer for the manufacture of the ILUVIEN implant, the assembly of the ILUVIEN applicator and packaging of the completed ILUVIEN commercial product. The Company is responsible for supplying the ILUVIEN applicator and the active pharmaceutical ingredient. In accordance with the terms of the agreement, the Company must order at least 80% of the ILUVIEN units required in the U.S., Canada and the EU from the third party manufacturer for an initial term of six years. The agreement has an initial six year term and will automatically renew for successive one year periods 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 March 2011, the Company entered into an agreement with a contract research organization (CRO) for clinical and data management services to be performed in connection with a physician utilization study which was being conducted to assess the safety and utility of the commercial version of the ILUVIEN applicator. For the years ended December 31, 2014 and 2013, the Company incurred \$16,000 and \$690,000, respectively, of expense associated with this agreement. At December 31, 2014 no amounts are recorded in outsourced services payable. At December 31, 2013 \$30,000 is included in outsourced services payable.

In February 2012, the Company engaged a consultant in connection with the Company's efforts to obtain the approval of ILUVIEN from the FDA. For the years ended December 31, 2014 and 2013, the Company recorded approximately \$425,000 and \$1,700,000, respectively, in costs pertaining to consulting fees related to the Company's agreement with this consultant. In addition, the Company expensed a \$2,000,000 success fee payable to this consultant which was payable upon the approval of our NDA by the FDA and paid in January 2015. At December 31, 2014, the \$2,000,000 was included in accrued milestone payments.

In November 2012, the Company entered into an agreement with Quintiles Commercial Europe Limited. Under the agreement, Quintiles Commercial Europe Limited and its affiliates (collectively, Quintiles Commercial) will provide certain services to the Company in connection with the commercialization of ILUVIEN in certain countries in Europe

under subsequent project orders. Such services may include marketing, brand management, sales promotion and detailing, market access, pricing and reimbursement support, regulatory, medical science liaison and communications and/or other advisory services. As of December 31, 2014, the Company had entered into project orders with Quintiles Commercial for the provision of services in Germany, the United Kingdom and France. Under these project orders Quintiles Commercial, as of December 31,

83

---

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

2014, employed 16 persons fully dedicated to the Company. Quintiles Commercial also employed three persons partially dedicated to Alimera in Germany, the United Kingdom and France as of December 31, 2014. In the second half of 2014, the Company notified Quintiles Commercial that it would be terminating the project orders associated with Germany and France and transitioning the covered positions employed by Quintiles Commercial to its payroll. The Company expects to complete these transitions during the second quarter of 2015. In the first quarter of 2015, the Company notified Quintiles Commercial that it would be terminating the project orders associated with the United Kingdom and transitioning the covered positions employed by Quintiles Commercial to its payroll. The Company expects to complete this transition during the third quarter of 2015. As of December 31, 2014, under the existing project orders, the Company expects to incur approximately \$4,400,000 in costs with Quintiles Commercial during 2015. For the year ended December 31, 2014, the Company incurred \$5,800,000 of expense associated with this agreement. At December 31, 2014, \$1,443,000 is included in outsourced services payable and \$703,000 is included in prepaid expenses and other current assets.

Employment Agreements — The Company is party to employment agreements with five executives. The agreements generally provide for annual salaries, bonuses, and benefits and for the “at-will” employment of such executives. Effective January 1, 2015, the Company was party to five agreements with salaries ranging from \$309,000 to \$504,000. If any of the agreements are terminated by the Company without cause, or by the employee for good reason, as defined in the agreements, the Company will be liable for one year of salary and benefits. Certain other employees have general employment contracts which include stipulations regarding confidentiality, Company property, and miscellaneous items.



Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 11. PREFERRED STOCK

## Series A Convertible Preferred Stock

On October 2, 2012, the Company closed its preferred stock financing in which it sold units consisting of 1,000,000 shares of Series A Convertible Preferred Stock and warrants to purchase 300,000 shares of Series A Convertible Preferred Stock for gross proceeds of \$40,000,000, prior to the payment of approximately \$560,000 of related issuance costs. The powers, preferences and rights of the Series A Convertible Preferred Stock are set forth in the certificate of designation filed by the Company with the Secretary of State of the State of Delaware on October 1, 2012. Each share of Series A Convertible Preferred Stock, including any shares of Series A Convertible Preferred Stock issued upon exercise of the warrants, is convertible into shares of the Company's common stock at any time at the option of the holder at the rate equal to \$40.00 divided by the then current conversion price (Conversion Price). The initial Conversion Price of \$2.91 of the Series A Convertible Preferred Stock was subject to adjustment to \$3.16 or \$2.66 based on the occurrence or non-occurrence of certain events relating to guidance from NICE regarding ILUVIEN, in addition to certain customary price based anti-dilution adjustments. A voluntary conversion by the holder prior to the determination of this adjustment is subject to a Conversion Price of \$3.16 per share. Each share of Series A Convertible Preferred Stock shall automatically be converted into shares of common stock at the then-effective Conversion Price upon the occurrence of the later to occur of both (i) the Company receives and publicly announces the approval by the FDA of the Company's NDA for ILUVIEN and (ii) the date on which the Company consummates an equity financing transaction pursuant to which the Company sells to one or more third party investors either (a) shares of common stock or (b) other equity securities that are convertible into shares of common stock and that have rights, preference or privileges, senior to or on a parity with, the Series A Convertible Preferred Stock, in each case having an as-converted per share of common stock price of not less than \$10.00 and that results in total gross proceeds to the Company of at least \$30,000,000. The rights and preferences of Series A Convertible Preferred Stock also place limitations on the Company's ability to declare or pay any dividend or distribution on any shares of capital stock.

On June 30, 2013, the Conversion Price was automatically adjusted to \$2.66. As a result of the adjustment to the Conversion Price, the value of the common stock underlying the Series A Convertible Preferred Stock at issuance exceeded the amount of the net proceeds allocated to the Series A Convertible Preferred Stock at issuance. Therefore, the Company recorded the contingent beneficial conversion feature of \$4,950,000 as an increase in additional paid in capital. Because the Series A Convertible Preferred Stock was immediately convertible into common stock at the option of the holder on June 30, 2013, the Company immediately accreted the full value of the beneficial conversion feature to the carrying value of the Series A Convertible Preferred Stock on that date.

Each unit sold in the preferred stock financing included a warrant to purchase 0.30 shares of Series A Convertible Preferred Stock at an exercise price equal to \$44.00 per share. At the election of the holder of a warrant, the warrant may be exercised for the number of shares of common stock then issuable upon conversion of the Series A Convertible Preferred Stock that would otherwise be issued upon such exercise at the then-effective Conversion Price. These warrants are considered derivative instruments because the agreements provide for settlement in Series A Convertible Preferred Stock shares or common stock shares at the option of the holder, an adjustment to the warrant exercise price for common shares at some point in the future, and contain anti-dilution provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants are subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. Therefore the warrants were recorded as a liability at issuance. At December 31, 2014 and 2013 the fair market value of the warrants was estimated to be \$16,098,000 and \$16,381,000, respectively. The Company recorded a gain of \$283,000 as a result of the change in fair value of the warrants during the year ended December 31, 2014.

In April 2014, 2,255,639 shares of common stock were issued pursuant to the conversion of 150,000 shares of Series A Convertible Preferred Stock held by an investor. In September 2014, 3,759,398 shares of common stock were issued pursuant to the conversion of 250,000 shares of Series A Convertible Preferred Stock held by another investor.



Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Series B Convertible Preferred Stock

On December 12, 2014, the Company closed a preferred stock financing in which it sold 8,291.873 shares of Series B Convertible Preferred Stock for a purchase price of \$6,030.00 per share, or an aggregate purchase price of \$50,000,000, prior to the payment of approximately \$432,000 of related issuance costs. The Company has also agreed to issue the purchasers an additional 124.378 shares of Series B Convertible Preferred Stock as a subscription premium. The powers, preferences and rights of the Series B Convertible Preferred Stock are set forth in the certificate of designation filed by the Company with the Secretary of State of the State of Delaware. Each share of Series B Convertible Preferred Stock is convertible into 1,000 shares of the Company's common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series B Convertible Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of the Company's common stock then issued and outstanding. The Series B Convertible Preferred Stock ranks junior to the Company's existing Series A Convertible Preferred Stock, and senior to the Company's common stock, with respect to rights upon liquidation. The Series B Convertible Preferred Stock ranks junior to all existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions), the Series B Convertible Preferred Stock will not have voting rights. The Series B Preferred Stock is not redeemable at the option of the holder. The Series B Convertible Preferred Stock is not subject to any price-based or other anti-dilution protections and does not provide for any accruing dividends. The Company determined that the conversion option of the Preferred Shares represented a beneficial conversion feature, as the conversion feature had intrinsic value to the holder on the commitment date as a result of the subscription premium. Therefore, the Company recorded a beneficial conversion feature of \$750,000 as an increase in additional paid in capital. Because the Series B Convertible Preferred Stock was immediately convertible into common stock at the option of the holder at issuance, the Company immediately accreted the full value of the beneficial conversion feature to the carrying value of the Series B Convertible Preferred Stock on that date.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 12. STOCK INCENTIVE PLANS

The Company has stock option and stock incentive plans which provide for grants of shares to employees and grants of options to employees and directors to purchase shares of the Company's common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. Options granted to employees typically become exercisable over a four-year vesting period and have a ten-year contractual term. Initial options granted to directors typically vest over a four-year period and have a ten-year contractual term. Annual option grants to directors typically vest immediately and have a ten-year contractual term. Upon the exercise of stock options, the Company may issue the required shares out of authorized but unissued common stock or out of treasury stock at management's discretion.

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

	Years Ended December 31,			
	2014	2013	Options	Weighted Average Exercise Price
Options outstanding at beginning of period	7,566,438	\$2.74	5,493,079	\$2.67
Grants	716,500	5.56	2,630,000	2.71
Forfeitures	(210,375 )	3.10	(513,059 )	1.96
Exercises	(391,307 )	1.97	(43,582 )	1.64
Options outstanding at year end	7,681,256	3.03	7,566,438	2.74
Options exercisable at year end	4,452,274	3.17	3,304,981	3.09
Weighted average per share fair value of options granted during the year	\$4.43		\$2.14	

The following table provides additional information related to outstanding stock options, fully vested stock options, and stock options expected to vest as of December 31, 2014:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
Outstanding	7,681,256	\$3.03	7.05 years	\$21,710
Exercisable	4,452,274	3.17	5.87 years	12,887
Outstanding, vested and expected to vest	7,258,603	3.04	6.95 years	20,574

(In thousands)

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

	Years Ended December 31,
	2014
	2013

Edgar Filing: ALIMERA SCIENCES INC - Form 10-K

Risk-free interest rate	1.79	%	1.73	%
Volatility factor	102.54	%	100.76	%
Grant date fair value of common stock	\$4.43		\$2.14	
Weighted-average expected life	5.89 years		5.92 years	
Assumed forfeiture rate	10.00	%	10.00	%

87

---

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	Years Ended December 31,	
	2014	2013
	(In thousands)	
Marketing	\$548	\$366
Research and development	981	504
General and administrative	2,274	1,586
Total employee stock-based compensation expense	\$3,803	\$2,456

As of December 31, 2014, there was approximately \$6,101,000 of total unrecognized compensation cost related to outstanding stock option awards that will be recognized over a weighted average period of 2.7 years. The total fair value of shares vested during the year ended December 31, 2014 was approximately \$3,833,000.

The total estimated fair value of options granted during the years ended December 31, 2014 and 2013 was \$3,177,000 and \$5,618,000, respectively. The total estimated intrinsic value of options exercised during the years ended December 31, 2014 and 2013 was \$1,710,000 and \$79,000, respectively.

As of December 31, 2014, the Company was authorized to grant options to purchase up to an additional 774,723 shares under the 2010 Equity Incentive Plan. The Company's 2010 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year equal to the 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, 2015, an additional 1,772,814 shares became available for future issuance under the 2010 Plan. These additional shares from the annual increase under the 2010 Plan are not included in the foregoing discussion.

The following table summarizes outstanding and exercisable options at December 31, 2014:

Exercise Prices	Options Outstanding		Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable	Weighted Average Remaining Contractual Life
\$1.33 - \$1.99	3,408,452	6.32	2,309,473	5.61
\$2.00 - \$2.99	2,442,796	7.70	1,020,648	5.98
\$3.00 - \$4.99	449,564	6.26	345,813	5.43
\$5.00 - \$10.99	1,019,794	8.71	415,690	7.46
\$11.00 - \$11.91	360,650	5.78	360,650	5.78
	7,681,256		4,452,274	

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

13. COMMON STOCK WARRANTS

The Company has issued warrants to purchase common stock to various members of the board of directors, third-parties for services, and lenders. Total warrants to purchase common stock issued and exercisable were 362,970 and 109,772 at December 31, 2014 and 2013, respectively. At December 31, 2014, the exercise prices ranged from \$6.14 to \$11.00 per share. The warrants are exercisable for a period between 5 and 10 years from the issuance date. Warrants to purchase 39,773 of the Company's common stock were granted to the Lenders during the year ended December 31, 2010 in connection the issuance of the 2010 Term Loan (Note 9). The Lenders also held warrants to purchase an aggregate of up to 69,999 shares of the Company's common stock, which were exercisable only upon the drawdown of the additional \$11,000,000 subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained. In May 2013, in connection with the 2013 Loan Agreement, the Company re-priced warrants to purchase an aggregate of up to 31,818 shares of the Company's common stock previously issued to SVB in connection with the 2010 Term Loan; 15,909 of which were previously exercisable only upon the drawdown of the additional \$11,000,000 of the 2010 Term Loan subject to FDA approval of the NDA for ILUVIEN by December 31, 2011. Upon re-pricing, each of the warrants was exercisable immediately at a per-share exercise price of \$2.86 and had a remaining term of 7.4 years. SVB exercised 31,818 of their warrants in the first quarter of 2014 in which the Company issued 18,092 shares of common stock as part of a cashless exercise.

In connection with Limited entering into the 2014 Loan Agreement (Note 9), the Company entered into a warrant agreement with Hercules to purchase up to 285,016 shares of the Company's common stock at an exercise price of \$6.14 per share. Sixty percent of the warrants were exercisable at the closing in April 2014 and the remaining forty percent became exercisable upon the funding of the additional \$25,000,000 to Limited in September 2014.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

14. CONCENTRATIONS AND CREDIT RISK

There were no customers that accounted for more than 10% of revenue for the year ended December 31, 2014 or accounts receivable at December 31, 2014. There were two pharmacy customers that comprised \$314,000 of the Company's accounts receivable at December 31, 2013. These same two customers accounted for approximately 23% of the Company's total consolidated revenues for the year ended December 31, 2013.

For the years ended December 31, 2014 and 2013, one vendor comprised of approximately 14% and two vendors comprised approximately 42% of the Company's total purchases, respectively.

90

---



Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 15. INCOME TAXES

The components of net loss before taxes are as follows:

	Years Ended December 31,	
	2014	2013
	(In thousands)	
United States	\$ (12,102	) \$ (29,303
Foreign	(23,458	) (16,926
Loss before provision for income taxes	\$ (35,560	) \$ (46,229

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

The provision for income taxes consists of the following components:

	Years Ended December 31,	
	2014	2013
	(In thousands)	
Current benefit (expense):		
Federal	\$—	\$—
State	—	—
Foreign	174	—
Current income tax expense	\$ 174	\$—

	Years Ended December 31,	
	2014	2013
	(In thousands)	
Deferred benefit (expense):		
Federal	\$ 3,050	\$ (18,565
State	355	(2,162
Foreign	(3,161	) 3,160
Valuation allowance	244	(17,567
Deferred income tax (benefit) expense	(244	) 17,567
	\$—	\$—

Worldwide net deferred tax assets and liabilities are as follows:

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	December 31,	
	2014	2013
Deferred tax assets (current and non-current)	(In thousands)	
Depreciation and amortization	\$8	\$34
Other deferred tax assets	3,305	1,906
NOL carry-forwards	32,191	33,454
Research and development costs	5,167	6,142
Collaboration agreement receivable reserves	5,749	4,638
Valuation allowance	(46,400)	(46,156)
Total deferred tax assets	\$20	\$18
Deferred tax liabilities (current and non-current)		
Unrealized foreign currency gains	\$(20)	\$(18)
Other deferred tax liabilities	—	—
Total deferred tax liabilities	(20)	(18)
Net deferred tax assets and deferred tax liabilities (current and non-current)	\$—	\$—

In Accordance with ASC 740-10-45-4, the Company presents below the current and non-current components of the Company's deferred tax assets and deferred tax liabilities. The Company has applied the jurisdictional netting requirements of ASC 740-10-45-5 to allocate the valuation allowance between current and non-current deferred tax assets on a jurisdictional basis. The current deferred tax liability and the non-current deferred tax asset disclosed below are attributable to the United States. Deferred tax positions in each foreign jurisdiction net to zero on both a current and non-current basis.

	Years Ended December 31,	
	2014	2013
	(In thousands)	
Current deferred tax liability	\$(20)	\$(18)
Non-current deferred tax asset	20	18

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

	Years Ended December 31,					
	2014		2013			
	Amount	Percent	Amount	Percent		
Federal tax benefit at statutory rate	\$(12,150)	34.0%	\$(15,718)	34.0%		
State tax — net of federal benefit	(479)	1.3	(1,160)	2.5		
Permanent items and other	331	(0.9)	31,851	(68.9)		
Prior period transfer pricing adjustments	3,502	(9.8)	—	—		
Foreign rate differential	8,190	(22.9)	2,594	(5.6)		
Other	536	(1.5)	—	—		
Change in valuation allowance	244	(0.7)	(17,567)	38.0		
Total tax benefit (expense)	\$174	(0.5)%	\$—	—		

The significant increase for the current year in the effect of permanent differences is caused by intercompany transactions between Alimera Sciences, Inc. and its subsidiaries in the prior year. For financial statement purposes, the transaction eliminates in consolidation. For income tax purposes, the transaction resulted in taxable income in the United States which was offset by net operating losses.

Income tax positions are considered for uncertainty in accordance with ASC 740-10. The Company believes that its income tax filing positions and deductions are more likely than not of being sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position; therefore, no ASC 740-10 liabilities and no related penalties and interest have been recorded. The Company does not anticipate any material changes to its uncertain tax positions within the next 12 months. Tax years since from 2011 to 2014 remain subject to examination in Georgia, Tennessee, and on the federal level, with the exception of the assessment of NOL carry-forwards available for utilization which can be examined for

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of deferred tax assets due to the history of operating losses, a valuation allowance has been established against the entire net deferred tax asset balance. The valuation allowance is based on management's estimates of taxable income in the jurisdictions in which the Company operates and the period over which deferred tax assets will be recoverable. In the event that actual results differ from these estimates or the Company adjusts these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact the Company's financial position and results of operations.

At December 31, 2014 and 2013, the Company had federal net operating loss (NOL) carry-forwards of approximately \$87,380,000 and \$82,380,000 and state NOL carry-forwards of approximately \$70,840,000, and \$65,840,000 respectively, that are available to reduce future income unless otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2029 and 2034 and the state NOL carry-forwards will expire at various dates between 2020 and 2034.

NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of the Company were to occur. The Company periodically evaluates its NOL carry-forwards and whether certain changes in ownership, including its IPO, have occurred that would limit the Company's ability to utilize a portion of its NOL carry-forwards. If it is determined that significant ownership changes have occurred since the Company generated its NOL carry-forwards, it may be subject to annual limitations on the use of these NOL carry-forwards under Internal Revenue Code (IRC), Section 382 (or comparable provisions of state law). The issuance of the Series A Convertible Preferred Stock on October 2, 2012 constituted such a change in ownership. As a result of this change in ownership, the Company performed a formal analysis in connection with IRC Section 382 and determined that approximately \$13,700,000 of its NOLs generated prior to the change in ownership could not be utilized in the future.

As of December 31, 2014, the Company had cumulative book losses in foreign subsidiaries of \$42,795,000. The Company has not recorded a deferred tax asset for the excess of tax over book basis in the stock of its foreign subsidiaries. The Company anticipates that its foreign subsidiaries will be profitable and have earnings in the future. Once the foreign subsidiaries do have earnings, the Company intends to indefinitely reinvest in its foreign subsidiaries all undistributed earnings of and original investments in such subsidiaries. As a result, the Company does not expect to record deferred tax liabilities in the future related to excesses of book over tax basis in the stock of its foreign subsidiaries in accordance with ASC 740-30-25.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 16. FAIR VALUE

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

Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. An active market for the asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. The valuation under this approach does not entail a significant degree of judgment.

Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include: quoted prices for similar assets or liabilities in active markets, inputs other than quoted prices that are observable for the asset or liability, (e.g., interest rates and yield curves observable at commonly quoted intervals or current market) and contractual prices for the underlying financial instrument, as well as other relevant economic measures.

Level 3 inputs are unobservable inputs for the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

There have been no changes in the methodologies used at December 31, 2014 and 2013.

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

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents (1)	\$65,509	\$—	\$—	\$65,509
Assets measured at fair value	\$65,509	\$—	\$—	\$65,509
Liabilities:				
Derivative warrant liability (2)	\$—	\$16,098	\$—	\$16,098
Liabilities measured at fair value	\$—	\$16,098	\$—	\$16,098
	December 31, 2013			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents (1)	\$6,944	\$—	\$—	\$6,944
Assets measured at fair value	\$6,944	\$—	\$—	\$6,944
Liabilities:				
Derivative warrant liability (2)	\$—	\$16,381	\$—	\$16,381
Liabilities measured at fair value	\$—	\$16,381	\$—	\$16,381

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

(2)

The Company uses the Black-Scholes option pricing model and assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. Assumptions used are generally consistent with those disclosed for stock based compensation (see Note 12).

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

17. EMPLOYEE BENEFIT PLANS

The Company has a salary deferral 401(k) plan which covers substantially all U.S. employees of the Company. The Company matches participant contributions subject to certain plan limitations. Compensation expense associated with the Company's matching plan totaled \$107,000 and \$95,000 for the years ended December 31, 2014 and 2013, respectively. The Company may also make an annual discretionary profit-sharing contribution. No such discretionary contributions were made during the years ended December 31, 2014 and 2013, respectively.

In April 2010, the Company established an Employee Stock Purchase Plan (the "Purchase Plan"). Under the Company's Purchase Plan, eligible employees can participate and purchase common stock semi-annually through accumulated payroll deductions. The Purchase Plan is administered by the Company's board of directors or a committee appointed by the Company's board of directors. Under the Purchase Plan eligible employees may purchase stock at 85% of the lower of the fair market value of a share of Common Stock on the offering date or the exercise date. The Purchase Plan provides for two six-month purchase periods generally starting on the first trading day on or after October 31 and April 30 of each year. Eligible employees may contribute up to 15% of their eligible compensation. A participant may purchase a maximum of 2,500 shares of common stock per purchase period. The value of the shares purchased in any calendar year may not exceed \$25,000.

The Purchase Plan was effective upon the completion of the Company's IPO, at which time a total of 494,422 shares of the Company's common stock were made available for sale. As of January 1 of each year, starting in 2011, the reserve will automatically be restored to the original level. A total of 34,915 and 26,123 shares of the Company's common shares were acquired through the Purchase Plan during the years ended December 31, 2014 and 2013, respectively. As such, on January 1, 2015 and 2014, respectively, an additional 34,915 and 26,123 shares became available for future issuance under the Purchase Plan. In accordance with ASC 718-50, the ability to purchase stock at 85% of the lower of the fair market value of a share of Common Stock on the offering date or the exercise date represents an option. The Company estimates the fair value of such options at the inception of each offering period using the Black-Scholes valuation model. In connection with the Purchase Plan, the Company recorded \$47,000 and \$21,000 of compensation expense for the years ended December 31, 2014 and 2013, respectively.

Table of Contents

EXHIBIT INDEX

Exhibit Number	Exhibit Title
3.1	Restated Certificate of Incorporation of Registrant, as amended on various dates (filed as Exhibit 3.2 to Amendment No. 4 to the Registrant’s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.4 to Amendment No. 4 to the Registrant’s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
3.3	Certificate of Designation of Series A Convertible Preferred Stock (filed as Exhibit 3.5 to the Registrant’s Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (filed as Exhibit 3.6 to the Registrant’s Current Report on Form 8-K, as filed on December 15, 2014, and incorporated herein by reference)
3.5	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.7 to the Registrant’s Current Report on Form 8-K, as filed on November 28, 2014, and incorporated herein by reference)
4.1	Second Amended and Restated Investor Rights Agreement, dated March 17, 2008, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.3 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.2	Second Amended and Restated Stock Sale Agreement, dated March 17, 2008, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.4 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.3	Omnibus Amendment, dated August 25, 2009, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.5 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.4	Warrant to Purchase Stock dated October 14, 2010 issued to Silicon Valley Bank (filed as Exhibit 4.1 to the Registrant’s Current Report, as filed on October 18, 2010, and incorporated herein by reference)
4.5	



Edgar Filing: ALIMERA SCIENCES INC - Form 10-K

Warrant to Purchase Stock dated October 14, 2010 issued to MidCap Funding III, LLC (filed as Exhibit 4.2 to the Registrant's Current Report, as filed on October 18, 2010, and incorporated herein by reference)

4.6 Warrant to Purchase Stock dated May 16, 2011 issued to MidCap Funding III, LLC (filed as Exhibit 4.1 to the Registrant's Current Report, as filed on May 17, 2011, and incorporated herein by reference)

4.7 Warrant to Purchase Stock dated May 16, 2011 issued to Silicon Valley Bank (filed as Exhibit 4.2 to the Registrant's Current Report, as filed on May 17, 2011, and incorporated herein by reference)

4.8.A Warrant to Purchase Shares of Series A Preferred issued to Sofinnova Venture Partners VIII, L.P. (filed as Exhibit 4.10.A to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)

4.8.B Warrant to Purchase Shares of Series A Preferred issued to Growth Equity Opportunities Fund III, LLC (filed as Exhibit 4.10.B to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)

4.8.C Warrant to Purchase Shares of Series A Preferred issued to Micro Cap Partners, L.P. (filed as Exhibit 4.10.C to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)

4.8.D Warrant to Purchase Shares of Series A Preferred issued to Palo Alto Healthcare Master Fund, L.P. (filed as Exhibit 4.10.D to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)

Table of Contents

- 4.8.E Warrant to Purchase Shares of Series A Preferred issued to Palo Alto Healthcare Master Fund II, L.P. (filed as Exhibit 4.10.E to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)
- 4.9 Registration Rights Agreement dated October 2, 2012 between the Registrant and Palo Alto Healthcare Master Fund, L.P., Palo Alto Healthcare Master Fund II, L.P., Micro Cap Partners, L.P., Sofinnova Venture Partners VIII L.P. and Growth Equity Opportunities Fund III, LLC (filed as Exhibit 4.11 to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012, and incorporated herein by reference)
- 4.10 Amendment No. 1 to Warrant to Purchase Stock dated May 7, 2013 by and between Silicon Valley Bank and the Registrant (filed as Exhibit 4.10 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013, and incorporated herein by reference)
- 4.11 Irrevocable Waiver of Rights to Designate Series A Director dated May 16, 2014 (filed as Exhibit 4.11 to the Registrant's Current Report on Form 8-K, as filed on May 16, 2014, and incorporated herein by reference)
- 4.12 Warrant Agreement dated as of April 24, 2014 issued to Hercules Technology Growth Capital, Inc. (filed as Exhibit 4.11 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
- 10.1 Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.2 Alimera Sciences, Inc. 2004 Incentive Stock Plan, as amended (filed as Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.3 Form of Option Certificate under the Alimera Sciences, Inc. 2004 Incentive Stock Plan (filed as Exhibit 10.7.A to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.4 Alimera Sciences, Inc. 2005 Incentive Stock Plan (filed as Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.5 Form of Option Certificate under the Alimera Sciences, Inc. 2005 Incentive Stock Plan (filed as Exhibit 10.8.A to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.6 2010 Equity Incentive Plan (filed as Exhibit 10.9 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)

- 10.7 2010 Employee Stock Purchase Plan (filed as Exhibit 10.10 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
- 10.7.A\* Amendment No. 1 to 2010 Employee Stock Purchase Plan
- 10.8 Management Cash Incentive Plan (filed as Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.9 Compensation Program for Non-Employee Directors (filed as Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.10‡ Amended and Restated Collaboration Agreement by and between pSivida, Inc. (f/k/a/Control Delivery Systems, Inc.) and Alimera Sciences, Inc., dated as of March 14, 2008 (filed as Exhibit 10.13 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)
- 10.11 Office Lease by and between Rubicon, L.C. and Alimera Sciences, Inc., dated as of May 27, 2003, as amended (filed as Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)

Table of Contents

10.12‡	License Agreement between Alimera Sciences, Inc. and Dainippon Sumitomo Pharma Co., Ltd., dated November 4, 2007 (filed as Exhibit 10.25 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
10.13‡	Commercial Contract Manufacturing Agreement, between Alimera Sciences, Inc. and Alliance Medical Products, Inc., dated February 5, 2010 (filed as Exhibit 10.26 to Amendment No. 6 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 20, 2010, and incorporated herein by reference)
10.14	Form of Notice of Stock Option Grant and Stock Option Agreement under 2010 Equity Incentive Plan (filed as Exhibit 10.30 to Registrant's Annual Report on Form 10-K, as filed on March 25, 2011, and incorporated herein by reference)
10.15‡	Amendment to Manufacturing Agreement between Registrant and Alliance Medical Products, Inc. (filed as Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q, as filed on August 5, 2011, and incorporated herein by reference)
10.16	Form of Notice of Stock Unit Award and Stock Unit Agreement under 2010 Equity Incentive Plan (filed as Exhibit 10.34 to Registrant's Annual Report on Form 10-K, as filed on March 30, 2012, and incorporated herein by reference)
10.17‡	Manufacturing Agreement by and between the Registrant and Flextronics Medical Sales and Marketing, Ltd. (filed as Exhibit 10.35 to Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2012, and incorporated herein by reference)
10.18	Securities Purchase Agreement dated July 17, 2012 (filed as Exhibit 10.36 to the Registrant's Current Report, as filed on July 18, 2012, and incorporated herein by reference)
10.19	Amendment No. 1 to Securities Purchase Agreement dated September 21, 2012 (filed as Exhibit 10.37 to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
10.20	UK Sub-Plan of the 2010 Equity Incentive Plan of Alimera Sciences, Inc. (filed as Exhibit 10.38 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference)
10.21	Form of UK Sub-Plan Notice of Stock Option Grant and Stock Option Agreement (filed as Exhibit 10.39 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference)
10.22	Employment Contract dated November 3, 2012 by and between the Registrant and Philip Ashman (filed as Exhibit 10.40 to the Registrant's Annual Report on Form 10-K, as filed on March 28, 2013)
10.23‡	Master Services Agreement dated November 28, 2012 by and between the Registrant and Quintiles Commercial Europe Limited (filed as Exhibit 10.41 to the Registrant's Annual Report on Form 10-K, as filed on March 28, 2013)

- 10.24 Loan and Security Agreement dated May 7, 2013 between Silicon Valley Bank and Alimera Sciences Limited (filed as Exhibit 10.42 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
- 10.25 Security Agreement entered into as of May 7, 2013 by and between Silicon Valley Bank and the Registrant (filed as Exhibit 10.43 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
- 10.26 Unconditional Guaranty entered into as of May 7, 2013 by Alimera Sciences B.V. in favor of Silicon Valley Bank (filed as Exhibit 10.44 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
- 10.27 Unconditional Guaranty entered into as of May 7, 2013 by AS C.V. in favor of Silicon Valley Bank (filed as Exhibit 10.45 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
- 10.28 Unconditional Guaranty entered into as of May 7, 2013 by the Registrant in favor of Silicon Valley Bank (filed as Exhibit 10.46 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
- 10.29 Second Loan Modification Agreement entered into as of May 7, 2013 by and between Silicon Valley Bank and the Registrant (filed as Exhibit 10.47 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2013)
- 10.30 Securities Purchase Agreement dated January 27, 2014 (filed as Exhibit 10.42 to the Registrant's Current Report, as filed on January 27, 2014, and incorporated herein by reference)

Table of Contents

10.31	Loan and Security Agreement dated as of April 24, 2014 by and among Alimera Sciences Limited, the several banks and other financial institutions or entities from time to time parties thereto and Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.49 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
10.32	Unconditional Guaranty entered into as of April 24, 2014 by the Registrant in favor of Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.50 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
10.33	Unconditional Guaranty entered into as of April 24, 2014 by Alimera Sciences B.V. in favor of Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.51 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
10.34	Unconditional Guaranty entered into as of April 24, 2014 by AS C.V. in favor of Hercules Technology Growth Capital, Inc. (filed as Exhibit 10.52 to the Registrant's Quarterly Report on Form 10-Q, as filed on August 11, 2014, and incorporated herein by reference)
10.35	Sales Agreement dated September 22, 2014 (filed as Exhibit 10.53 to the Registrant's Current Report on Form 8-K, as filed on September 22, 2014, and incorporated herein by reference)
10.36†	Amended and Restated Employment Agreement, effective as of October 23, 2014, by and between the Registrant and C. Daniel Myers (filed as Exhibit 10.53 to the Registrant's Current Report on Form 8-K, as filed on October 23, 2014, and incorporated herein by reference)
10.37†	Amended and Restated Employment Agreement, effective as of October 23, 2014, by and between the Registrant and Richard S. Eiswirth, Jr. (filed as Exhibit 10.54 to the Registrant's Current Report on Form 8-K, as filed on October 23, 2014, and incorporated herein by reference)
10.38†	Amended and Restated Employment Agreement, effective as of October 23, 2014, by and between the Registrant and Kenneth Green, Ph.D. (filed as Exhibit 10.55 to the Registrant's Current Report on Form 8-K, as filed on October 23, 2014, and incorporated herein by reference)
10.39†*	Amended and Restated Employment Agreement, effective as of October 23, 2014, by and between the Registrant and David Holland
10.40†*	Amended and Restated Employment Agreement, effective as of October 30, 2014, by and between the Registrant and Susan Caballa
10.41	Securities Purchase Agreement dated November 26, 2014 (filed as Exhibit 10.56 to the Registrant's Current Report on Form 8-K, as filed on November 28, 2014, and incorporated herein by reference)

21.1*	List of subsidiaries of the Registrant (including jurisdiction of organization and names under which subsidiaries do business)
23.1*	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
101.INS+*	XBRL Instance Document
101.SCH+*	XBRL Taxonomy Extension Schema Document
101.CAL+*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+*	XBRL Taxonomy Extension Presentation Linkbase Document

---

† Compensation Arrangement.

Table of Contents

- ‡ Confidential treatment has been granted with respect to certain portions of this document.
- \* Filed herewith.

100