ALIMERA SCIENCES INC
Form 10-K
March 30, 2012
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 001-34703

Alimera Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-0028718**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

6120 Windward Parkway, Suite 290

Alpharetta, GA	**30005**
(Address of principal executive offices)	**(Zip Code)**

(678) 990-5740

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

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

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (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 x

As of June 30, 2011, the aggregate market value of the Common Stock held by non-affiliates of the registrant was $72,361,063, based on the closing price of the registrant s Common Stock, 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.

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DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s proxy statement with respect to the registrant s 2012 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, 2011, are incorporated by reference into Part III of this Form 10-K.

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The term ILUVIEN is our trademark. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND PROJECTIONS

Various statements in this report are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report regarding 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 project, target, likely, potential, continue, will, would, should, could, or the negative of these terms and similar expressions or w forward-looking statements. The events and circumstances reflected in the Company s forward-looking statements may not occur and actual results could differ materially from those projected in the Company s forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to:

- delay in or failure to obtain regulatory approval of the Company s product candidates;
- uncertainty as to the Company s ability to commercialize (alone or with others), and market acceptance of, ILUVIEN in the EU;
- the extent of government regulations;
- uncertainty as to the pricing and reimbursement guidelines for the Company s product candidates, including ILUVIEN in the various EU countries;
- uncertainty as to the relationship between the benefits of the Company s product candidates and the risks of their side-effect profiles;
- dependence on third-party manufacturers to manufacture the Company s product candidates in sufficient quantities and quality;
- uncertainty of clinical trial results;
- limited sales and marketing infrastructure;
- inability of the Company to successfully market and sell ILUVIEN following regulatory approval; and
- the Company s ability to operate its business in compliance with the covenants and restrictions that it is subject to under its credit facility.

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.

We encourage you to read the discussion and analysis of our financial condition and our consolidated financial statements contained in this annual report on Form 10-K. We also encourage you to read Item 1A of Part 1 of this annual report on Form 10-K, entitled Risk Factors, which

contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of this report, other unknown or unpredictable factors also could affect our results. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

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ITEM 1. ***BUSINESS***

Overview

Alimera Sciences, Inc. (we, Alimera or the Company) is a biopharmaceutical 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 most advanced product candidate is ILUVIEN®, which received a positive outcome from the Decentralized Procedure with the issuance of a Final Assessment Report (FAR) from the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) indicating that that it is approvable for the treatment of vision impairment associated with diabetic macular edema (DME) considered insufficiently responsive to available therapies in seven European countries in February 2012. DME is a disease of the retina and is the main cause of blindness among patients with diabetes.

In September 2010, we completed two Phase 3 pivotal clinical trials (collectively, our FAME Study) on both a high and low dose of ILUVIEN involving 956 patients in sites across the U.S., Canada, Europe and India to assess the efficacy and safety of ILUVIEN in the treatment of DME over a 36 month period. Based on our analysis of the data through month 24 of the FAME Study in December 2009, we submitted a New Drug Application (NDA) in June 2010 for the low dose of ILUVIEN in the U.S. with the U.S. Food and Drug Administration (FDA), followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain under the European Union s (EU) decentralized procedure in July 2010 with the United Kingdom acting as the Reference Member State (RMS). The RMS is responsible for coordinating the review and approval process between itself and the other involved countries, or Concerned Member States (CMS).

In November 2010, we received a Preliminary Assessment Report (PAR) from the RMS and in December 2010, we received a Complete Response Letter (CRL) from the FDA regarding our respective registration filings. The primary concerns expressed in both the PAR and the CRL centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of our FAME Study data through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filings.

We submitted our response to the CRL to the FDA in May 2011, including additional safety and efficacy data through the final readout at month 36 of the FAME Study with an emphasis on the chronic DME subgroup. In July 2011, we submitted a draft response to the PAR to the MHRA, the regulatory body in the RMS, which included a similar data package.

In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its current form stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. The FDA has indicated that we will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. We expect to meet with the FDA in the second quarter of 2012 to discuss the CRL and the regulatory status of ILUVIEN.

After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a FAR from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries. During the national phase, labeling in each country s local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in patients with chronic DME.

According to the International Diabetes Federation Atlas, Fifth Edition, the estimated prevalence of people diagnosed with diabetes in 2011 was 366 million people worldwide, which is expected to increase to 522 million people by 2030. All patients with diabetes are at risk of developing some form of diabetic retinopathy, an ophthalmic condition of diabetes that presents with symptoms that include the swelling and leakage of blood vessels within the retina or the abnormal growth of new blood vessels on the surface of the retina. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the part of the eye responsible for central vision, the condition is called DME and is associated with inflammation and progressive vision loss leading to blindness. The prevalence of DME increases over time; up to 30% in patients suffering from diabetes for 25 years or more. In the EU countries in which ILUVIEN has been recommended for marketing authorization there are approximately 19.0 million diabetics of whom we estimate approximately 1.1 million suffer from DME.

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According to the U.S. Centers for Disease Control and Prevention (CDC), the number of Americans diagnosed with diabetes has increased to approximately 19.0 million people in 2010.

The current standard of care for the treatment of DME is laser photocoagulation. Laser photocoagulation is a retinal procedure in which a laser is used to cauterize leaky blood vessels or to apply a pattern of burns to reduce edema. This procedure has undesirable side effects including partial loss of peripheral and night vision. As a result of these side effects and a desire for improved visual outcomes, retinal specialists have supplemented laser photocoagulation with the use of both approved and off-label intravitreal injections of anti-vascular endothelial growth factor (anti-VEGF) and corticosteroid therapies. However, both corticosteroids and anti-VEGFs are limited by a need for multiple injections to maintain a therapeutic effect. There is no ophthalmic drug therapy currently approved by the FDA for the treatment of DME in the U.S. Lucentis, an anti-VEGF, has received marketing authorization for the treatment of vision loss associated with DME in the EU.

ILUVIEN is inserted in the back of the patient s eye to a placement site that takes advantage of the eye s natural fluid dynamics to deliver the non-proprietary corticosteroid fluocinolone acetonide (FAc). ILUVIEN is inserted in a non-surgical procedure employing a device with a 25-gauge needle which allows for a self-sealing wound. If approved, in the U.S. the non-surgical procedure will be performed in the retinal specialist s office, while in Europe it will be performed in a hospital or private clinic setting. ILUVIEN is an intravitreal implant that treats patients by delivering a consistent sub-microgram daily dose of FAc in the eye, which is sustained and therapeutically effective through 36 months. We believe that a sustained effect resulting in minimal side effects using a corticosteroid can only be achieved by providing lower exposure to corticosteroids and focusing the delivery to the back of the eye. Additionally, we believe that adverse events associated with ILUVIEN are predictable and manageable by a retinal physician, and within the acceptable limits of a drug for the treatment of DME.

ILUVIEN is also being studied in three Phase 2 clinical trials for the treatment of the dry form of age-related macular degeneration (AMD), the wet form of AMD and retinal vein occlusion (RVO).

Our commercialization strategy is to establish ILUVIEN as a leading therapy for vision loss in chronic DME patients and subsequently for any other indications for which ILUVIEN proves 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, a drug product sponsored by Novartis and the first pharmacological treatment indicated for patients with wet 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 plan to commercialize ILUVIEN, directly or with a partner, in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain initially, with potential expansion into other EU countries and non EU countries. If ILUVIEN is approved by the FDA, we intend to commercialize ILUVIEN directly to retina centers across the U.S.

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 intend to commercialize ILUVIEN, directly or with a partner, initially in the countries in which ILUVIEN has been recommended for marketing authorization, namely the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain.

Pursue FDA Approval for ILUVIEN. We expect to meet with the FDA in the second quarter of 2012 to discuss the CRL received in November 2011 and the regulatory status of ILUVIEN. If approved by the FDA, we intend to directly commercialize ILUVIEN to retina centers in the U.S.

Pursue Approval in Additional Countries. With approval of ILUVIEN in any of the initial seven EU countries, we will be eligible for a Mutual Recognition Procedure (MRP) under which we can submit ILUVIEN for approval in any or all of the remaining 20 EU countries. The International Diabetes Federation estimates there are approximately 11 million people suffering from diabetes in these remaining countries. We are also considering expansion into Middle Eastern markets and India.

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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 RVO. ILUVIEN is being studied in three Phase 2 clinical trials with retinal specialists to assess the safety and efficacy of ILUVIEN for the treatment of these diseases of the eye.

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 2011 increased to 366 million people and is expected to increase to 522 million people by 2030. In the EU countries in which ILUVIEN has been recommended for marketing authorization, according to the International Diabetes Foundation, Diabetes Atlas, Fifth Edition, there are approximately 19.0 million diabetics of whom we estimate approximately 1.1 million suffer from DME.

According to the CDC, the number of Americans diagnosed with diabetes has increased from approximately 8.1 million people in 1994 to approximately 18.8 million people in 2010. In addition to diagnosed cases, the CDC estimates that an additional 7.0 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. 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.

Diabetic macular edema (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 chronic 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.

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. We estimate there are approximately 1.1 million patients suffering from DME in the seven EU countries in which ILUVIEN has been recommended for marketing authorization.

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Limitations of Current Treatments for DME

The current standard of care for DME is laser photocoagulation, often combined with the use of both approved and off-label intravitreal injections of anti-VEGF agents and corticosteroid therapies. 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, although results are highly variable and it may take more than eight months for median visual acuity to improve. Further, this is a destructive procedure that has undesirable side effects including partial loss of peripheral and night vision. As a result of these side effects and a desire for improved visual outcomes, retinal specialists have supplemented laser photocoagulation with alternate therapies, including injections of corticosteroids and anti-VEGF agents.

Studies have also shown that both anti-VEGF inhibitors and corticosteroids, such as Lucentis (ranibizumab), Avastin and intravitreal triamcinolone acetonide (IVTA), are efficacious in some patients suffering from DME. However, both corticosteroids and anti-VEGFs are limited by a need for multiple injections to maintain a therapeutic effect and are not efficacious in all patients. This raises concerns not only for patients, but also for caregivers who are affected by frequent doctor visits, and healthcare providers who must monitor patients monthly. Furthermore, a subset of patients does not respond to these therapies, and the disease persists. In addition, these therapies have safety concerns. Corticosteroids have historically been associated with significant increases in intraocular pressure (IOP), which may increase the risk of glaucoma, and the acceleration of cataract formation. Anti-VEGF treatments increase the risk of endophthalmitis and have also been shown to raise IOP.

There are no ophthalmic drug therapies presently approved by the FDA for the treatment of DME in the U.S. Lucentis has recently been approved by the European Medicines Agency (EMA) for use in DME in the EU, and is the only ophthalmic drug therapy approved to treat DME in the initial seven EU countries in which ILUVIEN has been recommended for marketing authorization. However, in the United Kingdom, the National Institute for Health and Clinical Excellence has recently published final guidance on the use of Lucentis for this indication, stating that it is not recommended for the treatment of visual impairment due to DME and it is not yet receiving broad reimbursement in the remaining EU countries for the treatment of DME.

ILUVIEN

Overview

Our most advanced product candidate is ILUVIEN, an intravitreal implant providing a therapeutic effect for up to 36 months in the treatment of vision impairment associated with DME by delivering sustained sub-microgram levels of FAc, a non-proprietary corticosteroid with demonstrated efficacy in the treatment of ocular disease. 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 implanted in the back of the patient s eye in a non-surgical procedure using an implantation device (the ILUVIEN applicator) employing a 25-gauge needle, which allows for a self-sealing wound. This implantation is very similar to the administration of an intravitreal injection, a procedure commonly employed by retinal specialists. If approved, in the U.S. the non-surgical procedure will be performed in the retinal specialist s office, while in Europe it will be performed in a hospital or private clinic setting. 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 our FAME Study.

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

ILUVIEN delivers a therapeutic effect for up to 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 through 36 months.

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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 implantation into the back of the eye optimizes delivery of FAc to the retina by utilizing these natural currents, maximizes efficacy and mitigates possible side effects.

ILUVIEN is implanted using a 25-gauge needle. Needle gauge determines the size of the wound that is created. ILUVIEN is implanted 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 implantation procedure to create a self-sealing wound.

Fluocinolone Acetonide

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 commonly associated with the intraocular use of corticosteroids, which we believe is due to its implantation location in the posterior portion of the eye.

The side effect of increased IOP associated with corticosteroids in certain people is 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, corticosteroids result in a build-up of debris in this meshwork, increasing resistance to outflow, and increasing pressure inside the eye. 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 this positioning minimizes the anterior chamber exposure to FAc and mitigates the incidence of IOP elevations.

ILUVIEN Provides Sustained Sub-Microgram Delivery

ILUVIEN consists of a tiny polyimide tube with a membrane cap, licensed by us from pSivida US, Inc. (pSivida) that is filled with 190µg of FAc in a polyvinyl alcohol matrix. ILUVIEN is non-bioerodable; however, both polyimide and the polyvinyl alcohol matrix are biocompatible with ocular tissues and have histories of safe use within the eye. The low dose of ILUVIEN provides sustained sub-microgram levels of FAc and demonstrated a therapeutic effect for up to 36 months in our FAME Study. We believe that ILUVIEN s ability to deliver sub-microgram levels of FAc mitigates the incidence of IOP elevations commonly associated with the intraocular use of corticosteroids.

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 implanted into the back of the eye and the needle has been removed. We believe that a 25-gauge needle is the smallest needle capable of delivering ILUVIEN into the back of eye. If approved, in the U.S. the non-surgical procedure will be performed in the retinal specialist s office, while in Europe it will be performed in a hospital or private clinic setting.

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ILUVIEN Clinical Development Program

Development Program for the Treatment of DME

In September 2010, we completed two Phase 3 pivotal clinical trials (collectively, our FAME Study) on both a high and low dose of ILUVIEN involving 956 patients in sites across the U.S., Canada, Europe and India to assess the efficacy and safety of ILUVIEN in the treatment of DME over a 36 month period. Combined enrollment was completed in October 2007, and the month 24 clinical readout from our FAME Study was received in December 2009.

Based on our analysis of the data through month 24 of the FAME Study in December 2009, we filed a NDA in June 2010 for the low dose of ILUVIEN in the U.S. with the FDA, followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain under the EU s decentralized procedure in July 2010 with the United Kingdom acting as the RMS. The RMS is responsible for coordinating the review and approval process between itself and the other involved countries, or Concerned Member States.

In November 2010, we received a PAR from the RMS and in December 2010, we received a CRL from the FDA regarding our respective registration filings. The primary concerns expressed in both the PAR and the CRL centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of our FAME Study data through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filings.

We submitted our response to the CRL to the FDA in May 2011, including additional safety and efficacy data through the final readout at month 36 of the FAME Study with an emphasis on the chronic DME subgroup. In July 2011, we submitted a draft response to the PAR to the MHRA, the regulatory body in the RMS, which included a similar data package.

In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its current form stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. The FDA has indicated that we will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. We expect to meet with the FDA in the second quarter of 2012 to discuss the CRL and the regulatory status of ILUVIEN.

After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a FAR from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries. During the national phase labeling in each country s local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in patients with chronic DME.

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. Pre-clinical studies in two established rat models 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. Based on these results, we began enrollment of a pilot study in December 2008 to assess the safety and efficacy of ILUVIEN in patients with bilateral GA secondary to AMD. Our Phase 2 study (the MAP GA Trial) is comparing ILUVIEN and a higher dose of ILUVIEN to a sham injection in patients with bilateral GA secondary to AMD. The change from baseline in the size of GA will be assessed over time.

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Wet AMD. The size of the wet AMD market was $2 billion in 2008 according to visiongain, an independent competitive intelligence organization. We believe ILUVIEN will be synergistic with the market leading anti-VEGF therapies in the treatment of wet AMD. Anti-VEGFs require persistent dosing to maintain a therapeutic effect which is a burden on both the patient and the physician. Given that corticosteroids have been shown to suppress the production of VEGF, a Phase 2 investigator sponsored study (the MAP Trial) is assessing the safety and efficacy of ILUVIEN and a higher dose in conjunction with Lucentis in patients with wet AMD. The study involves patients who had been treated with Lucentis for at least six months and whose visual acuity has plateaued prior to enrollment. At baseline, subjects received either ILUVIEN or a higher dose of ILUVIEN and an injection of Lucentis. Subjects receive additional Lucentis injections during the study only if subretinal or intraretinal fluid persists. Outcome measures include the change from baseline visual acuity at six months, and mean number of injections of Lucentis over the six-month study period versus the six months prior to study entry.

Macular edema associated with non-ischemic RVO. According to GlobalData, a provider of global business intelligence, there are 16 million adults affected with RVO around the world. Retinal specialists have been using intravitreal injections of the corticosteroid triamcinolone acetonide on an off-label basis to treat non-ischemic RVO. In September 2009, Allergan introduced Ozurdex (a three to five month dexamethasone intravitreal implant) as the first approved product for macular edema following branch or retinal vein occlusion. The FDA s approval of Ozurdex provides additional evidence that lower levels of a steroid work effectively for RVO. In September 2009, we began enrollment for a Phase 2 study (the FAVOR Study) to assess the safety and efficacy of ILUVIEN in patients with macular edema secondary to RVO. The FAVOR Study is comparing ILUVIEN and a higher dose of ILUVIEN in patients with macular edema secondary to RVO.

ILUVIEN Registration Plan

U.S. Regulatory Requirements and Status

In the U.S., the FDA s requirement for the clinical evidence of the effectiveness of ILUVIEN for the treatment of DME from our FAME Study was based on two time-point comparisons. The primary efficacy variable was the proportion of patients who had visual acuity improvement in their study eye, referred to as the responder rate, based on the change from baseline in Best Corrected Visual Acuity (BCVA) as measured on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart. BCVA improvement is defined as an increase from baseline of 15 or more letters in BCVA as measured on the ETDRS eye chart. Our primary efficacy endpoint was defined at month 24 of our FAME Study using this variable. Based on the month 24 clinical readout, ILUVIEN demonstrated efficacy in the treatment of DME in our FAME Study. Then, as required by the FDA, another numerical comparison of the responder rates at months 18 and 24 of our FAME Study was conducted to demonstrate that the responder rates at month 24 are numerically greater than or equal to the month 18 responder rates. Patients enrolled in our FAME Study were followed for 36 months. Although we submitted the month 24 results to the FDA in our NDA for ILUVIEN for approval, we received a CRL from the FDA in December 2010, which, among other things, requested the additional 12 months of clinical data from the completed FAME Study through month 36 for review. The primary concerns expressed in the CRL centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of our FAME Study data through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filing. We submitted our response to the CRL to the FDA in May 2011, including additional safety and efficacy data through the final readout at month 36 of the FAME Study with an emphasis on the chronic DME subgroup. In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its current form stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. The FDA has indicated that we will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. We expect to meet with the FDA in the second quarter of 2012 to discuss the CRL and the regulatory status of ILUVIEN.

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Regulatory Requirements in Other Jurisdictions

There are no specific guidance documents for the clinical development of ophthalmic drug products outside of the U.S. for the treatment of diabetic retinopathy or DME. We met with regulatory authorities in Canada, Germany, Spain, France, Portugal and the United Kingdom and presented our overall preclinical, technical, clinical and statistical development plans which included the use of visual function as the primary efficacy endpoint and an anatomical measure as a co-primary efficacy endpoint or key secondary efficacy endpoint. In July 2010, we submitted a data package regarding the efficacy and safety of ILUVIEN through the end of the FAME Study to the applicable regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a FAR from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries. During the national phase labeling in each country s local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in patients with chronic DME.

Commercialization

ILUVIEN is the only single treatment drug therapy providing a sustained therapeutic effect of up to 36 months in the treatment of patients with chronic DME that is recommended for marketing authorization in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. ILUVIEN has not been approved by the FDA. We intend to continue pursuit of approval for ILUVIEN in the U.S. for use in the treatment of DME and other diseases of the retina. In the seven EU countries in which ILUVIEN has been recommended for marketing authorization for the treatment of DME, we intend to pursue approval of ILUVIEN for use in the treatment of other diseases of the retina. In addition, we intend to pursue approval in other countries of the EU and certain jurisdictions around the world for the use of ILUVIEN in the treatment of DME and other diseases of the retina. Our commercialization strategy is to establish ILUVIEN as a leading therapy for the treatment of vision loss in chronic DME patients and subsequently for other indications for which ILUVIEN proves safe and effective. In the EU countries in which we are currently recommended for marketing authorization, we plan to commercialize ILUVIEN, directly or with a partner. If approved in the U.S., we intend to distribute ILUVIEN to physicians and retina centers through specialty distributors and pharmacies. 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, a drug product sponsored by Novartis and the first pharmacological treatment indicated for the treatment of wet AMD.

In the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain we are currently evaluating commercializing ILUVIEN directly or with a partner. Currently we are engaged, with the assistance of local consultants, in the pricing and reimbursement process in select countries and are developing market access plans for all countries in which ILUVIEN has been recommended for marketing authorization. If we make the decision to commercialize ILUVIEN directly we expect to create a commercial infrastructure of approximately fifty people in management and the field combined including sales representatives, market access personnel and medical science liaisons.

In preparation for a potential U.S. commercial launch of ILUVIEN, we began recruiting sales and marketing infrastructure personnel with extensive ophthalmic-based sales experience in the fourth quarter of 2010. We hired our marketing and managed markets directors, three sales directors and our four field-based managed markets managers but did not add the personnel and incur the costs of hiring and training an internal sales force. We entered into a relationship with OnCall LLC, a contract sales force company, and would have utilized their employees to act as our sales representatives if we had received approval of the ILUVIEN NDA from the FDA. Due to the receipt of the second CRL, we have eliminated our sales management team and field-based managed markets managers at this time.

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

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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 our products. 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 rely on contract manufacturers to develop and manufacture our products 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 our product candidates.

Third party manufacturers will be responsible for the commercial-scale production of ILUVIEN and the ILUVIEN applicator. We have finalized long-term agreements with the manufacturer of FAc, the API in ILUVIEN (FARMABIOS SpA/Byron Chemical Company Inc.), the manufacturer of the ILUVIEN applicator (Flextronics International, Ltd or an affiliate of Flextronics International, Ltd. (Flextronics)) and the manufacturer of ILUVIEN (Alliance Medical Products Inc. (Alliance)), which are discussed below.

pSivida manufactured our clinical trial materials for our FAME Study, our pharmacokinetics study and the Phase 2 clinical trials being conducted for the use of ILUVIEN for the treatment of dry AMD and wet AMD. pSivida s manufacturing process is manual and labor intensive and not practical for commercial manufacturing. We worked with Flextronics and Alliance to develop a manufacturing process where automation is employed whenever feasible so that we have a process capable of being scaled-up to produce commercial quantities. The manufacturing process for ILUVIEN consists of filling the polyimide tube with a matrix consisting of FAc and polyvinyl alcohol (PVA), 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 transferred and validated at Alliance, the third-party contract manufacturer of ILUVIEN. Alliance is also the provider of the clinical trial materials for the Phase 2 clinical trial being conducted for the use of ILUVIEN in the treatment of RVO. We have discussed our approach to show equivalency of the pSivida manufacturing process to the commercial manufacturing process with the FDA, the MHRA and the German Bundeninstitut für Arneimittel und Medizinprodukte (BfArM). The CRLs we received from the FDA and the assessment reports received from the European Health Authorities did not raise any issue with our demonstration of equivalency between the manufacturing processes at pSivida and Alliance. However, in the CRL we received in December 2010, the FDA did notify us that the methods used in and the facilities and controls used for the manufacturing, processing, packing, or holding of the drug product at two of our manufacturers did not comply with cGMPs during pre-approval inspections. Both of these manufacturers have received confirmation from the FDA that the deficiencies have been resolved and that their respective facilities are acceptable.

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 our NDA and Marketing Authorization Application (MAA) for ILUVIEN, we provided the FDA and the EU regulatory authorities with a completed process validation package on three lots which described manufacturing and packaging procedures and in-process controls. Validation was conducted on small scale, 400 unit batches but in the U.S., this can be scaled up to 10 times. However, in the EU, the manufacturing process for ILUVIEN is considered a non-standard process. In order to scale-up to a larger batch size, a new validation package has to be submitted as a variation to the MAA. Plans are underway to start manufacturing three larger batches at Alliance in the second quarter of 2012 in order to fulfill this requirement in the EU.

In addition, we submitted up to 18 months of stability data from three primary stability batches to demonstrate that the product manufactured using the process as described meets required product specifications.

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In preparation for commercial production, Alliance has successfully completed an engineering batch to demonstrate that the process can be scaled up to 800 unit batches. Two scaled-up batches were also successfully manufactured demonstrating that the critical steps up to and including application of the cap membranes are reproducible.

Competition

The development and commercialization of new drugs and drug delivery technologies is highly competitive. We will likely face competition with respect to ILUVIEN and any products 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 been recommended for marketing authorization or becomes approved for use in the treatment of DME, it will compete against laser photocoagulation and the use of anti-VEGF and corticosteroid injections, 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:

Genentech Inc. s (Genentech) products Lucentis (ranibizumab injection) and Avastin (bevacizumab) are both anti-VEGF antibodies. Lucentis is currently approved for the treatment of patients with neovascular wet AMD and the treatment of macular edema following RVO in the U.S. and the EU and has recently received marketing authorization by the EMA for use in DME in Europe. However, in the United Kingdom, the National Institute for Health and Clinical Excellence has recently published final guidance stating that Lucentis is not recommended for reimbursement in the treatment of visual impairment due to DME. Genentech has also completed two Lucentis Phase 3 clinical trials for the treatment of DME and has submitted a NDA for approval of Lucentis for the treatment of DME in the U.S. Avastin, an oncology product, is used by retinal specialists in both the U.S. and the EU in the treatment of numerous retinal diseases but is not indicated for any ophthalmic use. Genentech is a wholly-owned member of the Roche Group.

Allergan, Inc. s (Allergan) product Ozurdex (dexamethasone intravitreal implant), is a bioerodable extended release implant that delivers the corticosteroid dexamethasone. Ozurdex is approved for 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. Ozurdex demonstrates peak efficacy at 60 days and duration of therapy of three to five months.

Regeneron/Bayer s Eyelea (aflibercept) was recently approved by the FDA for neovascular wet AMD in the U.S. and has filed for marketing authorization in neovascular wet AMD in the EU. Phase 2 trials of Eyelea for use in the treatment of DME are currently being conducted in the U.S. and EU.

Alcon, Inc. s (Alcon) product TRIESENCE (triamcinolone acetonide injectable suspension), a preservative free synthetic corticosteroid for visualization during vitrectomy, is approved for the treatment of sympathetic ophthalmia, temporal arteritis, uveitis and other inflammatory conditions unresponsive to topical corticosteroids in the U.S. TRIESENCE is not indicated for the treatment of DME, dry AMD, wet AMD or RVO.

In addition, there are a number of other companies, including MacuSight, Inc., Thrombogenics NV and Novagali Pharma S.A., 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.

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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.

In February 2005, we entered into an agreement with pSivida 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.

We made initial license fee payments totaling $750,000 to pSivida in 2004, and made additional license fee payments of $750,000 to pSivida in 2005 upon the initiation of the FAME Study.

Under the February 2005 agreement, we and pSivida agreed to collaborate on the development of ILUVIEN with FAc for DME, and share equally in ILUVIEN s development expenses. We and pSivida also agreed that after commercialization of such product, profits, as defined in that agreement, would be shared equally.

In March 2008, we and pSivida amended and restated the agreement to provide us with 80% of the net profits and pSivida with 20% of the net profits. In connection with the March 2008 agreement we agreed to:

- pay $12.0 million to pSivida upon execution;
- issue a $15.0 million promissory note to pSivida;
- forgive all outstanding development payments, penalties and interest as of the effective date, which totaled $6.8 million;
- continue responsibility for regulatory, clinical, preclinical, manufacturing, marketing and sales for the remaining development and commercialization of the products;
- assume all financial responsibility for the development of the products and assume 80% of the commercialization costs of the products (instead of 50% as provided under the February 2005 agreement);
- make an additional milestone payment of $25.0 million after the first product has been approved by the FDA; and
- share 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined by the agreement.

The $15.0 million promissory note was subsequently repaid pursuant to its terms using the proceeds from our initial public offering (IPO).

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) 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, 2011.

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Emory University

In July 2009, we entered into an agreement with Emory University (Emory) related to the fulvene class of NADPH oxidase inhibitors. Under such agreement, Emory granted to us an exclusive, worldwide license to rights under intellectual property rights related to the fulvene class of NADPH oxidase inhibitors for the development, manufacturing, marketing and selling of pharmaceutical products containing such compounds for therapeutic and prophylactic uses for the treatment of diseases and disorders of the eye in humans. In August 2009, we entered into a second agreement with Emory University related to the triphenylmethane class of NADPH oxidase inhibitors. Under such agreement, Emory granted to us an exclusive, worldwide license to rights under intellectual property rights related to the triphenylmethane class of NADPH oxidase inhibitors for the development, manufacturing, marketing and selling of pharmaceutical products containing such compounds for therapeutic and prophylactic uses for the treatment of diseases and disorders of the eye in humans. In connection with these agreements, we made payments to Emory totaling $135,000 in cash and issued to Emory shares of our common stock with a total fair value of $300,000. In September 2011, we discontinued our agreement with Emory due to inactivity of the molecules in clinical testing and have returned the rights back to Emory.

We continue to evaluate alternative NADPH oxidase inhibitors in preclinical models.

Dainippon Sumitomo

In November 2007, we entered into a license agreement with Dainippon Sumitomo Pharma Co., Ltd. (Dainippon) whereby it granted to us a non-exclusive, worldwide, royalty free license to patent rights under specific patents and patent applications for the development, manufacturing and marketing in the field of ophthalmology an injectable polymer tube implantable into an eye containing a mixture of a polymer and FAc (or derivative or pharmaceutically acceptable salt of FAc) with a polyvinyl alcohol or other polymer coating or layer at each end of the tube. In addition, Dainippon granted to us an option to acquire a non-exclusive, worldwide license to patent rights and know-how related to specific patents and patent applications for the development, manufacturing and marketing of other pharmaceutical products in the field of ophthalmology. In exchange for the license and option granted to us by Dainippon, we paid $200,000 to Dainippon shortly after the execution of the license agreement, and we are expected to pay another $200,000 to Dainippon within thirty days following the first regulatory approval of the licensed product in the U.S. by the FDA. Dainippon may terminate the license agreement if we materially fail to fulfill or breach certain terms and conditions of the license agreement and fail to remedy such failure or breach within thirty days after receipt of notice from Dainippon. In addition, Dainippon may terminate the license agreement in the event that we contest the validity of the patent rights related to Dainippon s specific patents and patent applications. In the event of termination of the license agreement by Dainippon, owing to our breach of the agreement or to our contesting the validity of Dainippon s patent rights, we are still expected to make the payment described above.

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.

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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.

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 $1.5 million in 2011, increasing to $1.8 million in 2012.

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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 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 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.

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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.

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 initial CRL, the FDA notified us that the methods used in and the facilities and controls used for the manufacturing, processing, packing, or holding of the drug product at two of our manufacturers did not comply with cGMPs during pre-approval inspections. Both of these manufacturers have received confirmation from the FDA that the deficiencies have been resolved and that their respective facilities are acceptable.

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 the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain 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 that coordinates the review process with the Concerned Member States.

Based on our analysis of the data through month 24 of the FAME Study, in July 2010, we submitted a data package regarding the efficacy and safety of ILUVIEN to the applicable regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain with the United Kingdom acting as the RMS. In November 2010, we received a PAR from the RMS regarding our registration filings. The primary concerns expressed in the PAR centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of our FAME Study data through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filings. In July 2011, we submitted a draft response to the PAR to the MHRA, the regulatory body in the RMS, including additional safety and efficacy data through the final readout at month 36 of the FAME Study with an emphasis on the chronic DME subgroup. After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a FAR from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries Concerned Member States. During the national phase labeling in each country s local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in patients with chronic DME.

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A mutual recognition procedure of nationally approved decisions is available to pursue marketing authorizations for ILUVIEN 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.

Third-party reimbursement and pricing controls

In the EU, U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. In the U.S., following regulatory approval, if any, it will be 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.

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 our 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 all of our product candidates are 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, 2011, we owned or have licensed three U.S. utility patents, one U.S. design patent and five 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 one European patent from pSivida directed to our low-dose device and have an application pending directed to an 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, with no currently pending or issued corresponding European applications or patents. Our licensed patent portfolio also includes a U.S. patent and a pending U.S. patent application directed to our high-dose ILUVIEN insert.

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 three U.S. patents that expire between March 2019 and April 2020 and counterpart filings to these patents in a number of other jurisdictions. A single European patent is licensed to us from pSivida directed to our low-dose device that expires in April of 2021. No patent term extension will be available for any of these U.S. patents or any of our licensed U.S. pending patent 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

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competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before such product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Research and Development

We have built a research and development organization that includes extensive expertise with ophthalmic products including the launch and management of Visudyne, a drug product sponsored by Novartis and 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 use rigorous project management techniques to assist us in making disciplined strategic research and development program decisions and to help limit the risk profile of our product pipeline. 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 portions of our 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 $7.1 million, $12.6 million and $15.1 million in research and development in 2011, 2010 and 2009, respectively.

Employees

As of March 30, 2012, we had 21 employees, two of whom hold Ph.Ds. Nine of these employees are engaged in research, development and regulatory activities, and 12 are 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 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.

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Copies of each of our filings with the SEC on Form 10-K, Form 10-Q and Form 8-K and all amendments to those reports, can be viewed and downloaded free of charge at our website, www.alimerasciences.com as soon as reasonably practicable after the reports and amendments are electronically filed with or furnished to the SEC.

Our code of ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee and Nominating/Corporate Governance Committee are available through our website at www.alimerasciences.com.

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ITEM 1A Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of 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, with respect to any investment in shares of our common stock. If any of the following risks actually occur, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

Risks Related to Our Dependence on ILUVIEN®

We are heavily dependent on the commercial success of our lead product candidate, ILUVIEN, which only recently received a positive outcome from the Decentralized Procedure with the issuance of a Final Assessment Report (FAR) from the Medicines and Healthcare products Regulatory Agency in the United Kingdom (MHRA) indicating that it is approvable in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain, and on the regulatory approval of ILUVIEN for the treatment of DME in the U.S. and other countries, which may never occur.

We are a biopharmaceutical company with no products yet available for commercial sale. As a result, our future success is currently dependent upon the commercial and regulatory success of ILUVIEN, our lead product candidate, for the treatment of DME in Europe and the U.S. In February 2012, ILUVIEN received a positive outcome from the Decentralized Procedure with the issuance of a FAR from the MHRA indicating that it is approvable for commercial use to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. ILUVIEN has not been approved by the FDA in the U.S. and may never receive such approval. The timing of the commercial launch of ILUVIEN in the EU countries is dependent upon each specific EU country pricing and reimbursement timelines, and we do not anticipate commercial sales of ILUVIEN until late 2012, at the earliest. Because we do not currently have any product candidates available for sale or in clinical development other than ILUVIEN, our future success is dependent upon either building a commercial operation in the EU or partnering with a company that has an established commercial operation there to successfully commercialize ILUVIEN in the EU, obtaining regulatory approval from the FDA to market ILUVIEN for the treatment of DME in the U.S., and if approved by the FDA, successfully commercializing ILUVIEN in the U.S.

We anticipate that in the near term our ability to generate revenues will depend solely on the successful commercialization of ILUVIEN in the seven EU countries in which it has been recommended for marketing authorization. If we do not successfully commercialize ILUVIEN in the EU and/or receive regulatory approval in the U.S. for ILUVIEN for the treatment of DME, our ability to generate revenue will be jeopardized and, consequently, our business will be seriously harmed. We may not succeed in our commercial efforts in the EU; we may not receive regulatory approval in the U.S. for ILUVIEN; and if we do receive regulatory approval in the U.S. for ILUVIEN, we may not be able to commercialize ILUVIEN successfully, all of 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 of the EU countries, including obtaining unfavorable pricing and/or reimbursement, which could negatively affect our stock price. We may continue to experience delays in obtaining regulatory approval in the U.S. for ILUVIEN, if it is approved at all, and our stock price may be negatively affected.

In addition, we have and expect to continue to incur significant expenses and to utilize a substantial portion of our existing cash resources as we prepare for the commercial launch of ILUVIEN in the EU countries in which ILUVIEN has been recommended for marketing authorization, continue to pursue the approval of ILUVIEN in the U.S. 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 product candidates for the reasons stated in Risks Related to Our Business and Industry. 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.

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Although we have a Final Assessment Report from the Medicines and Healthcare products Regulatory Agency in the United Kingdom indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete, ILUVIEN has not received formal marketing approval in such countries. Any failure or delay in obtaining such approvals in the EU countries could severely harm our business.

In February 2012, we received a FAR from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries. During the national phase, labeling in each country s local language is finalized.

The process for receiving formal marketing approval in these seven countries varies from country to country. We believe that the timing for formal approval can be anywhere from 30 days to 6 months following the issuance of a FAR, depending on the jurisdiction. However, we can provide no assurances that we will receive approvals during such time period.

Our revenue from sales of ILUVIEN in the EU countries in which it has been recommended for marketing authorization is dependent upon the pricing and reimbursement guidelines adopted in each of such countries, which levels may fall well below our current expectations.

We have not currently priced ILUVIEN in any jurisdiction, but have developed estimates of anticipated pricing in countries in which ILUVIEN has 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 chronic DME, our perception of the overall cost to benefit ratio of ILUVIEN and the current pricing in the EU of therapies to treat DME and other retinal diseases such as AMD and RVO. However, due to numerous factors beyond our control, including efforts to provide for containment of health care costs, one or more EU 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 in the EU, which would negatively impact anticipated revenue from ILUVIEN in the EU.

Expansion of our commercial infrastructure in the EU is a significant undertaking that requires substantial financial and managerial resources, and we may not be successful in our efforts. We may also encounter unexpected or unforeseen delays in establishing a commercial infrastructure in the EU, which may negatively impact our commercial efforts for ILUVIEN.

In February 2012, ILUVIEN was recommended for marketing authorization in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapy. We anticipate that in the near term our ability to generate revenues will depend solely on the successful commercialization of ILUVIEN in the seven EU countries in which it has been recommended for marketing authorization. Subject to EU country-specific reimbursement timelines, we currently plan to engage in pricing and reimbursement discussions for ILUVIEN in the third quarter of 2012 and launch in those countries as soon as possible after concluding discussions. We currently plan to launch ILUVIEN in late 2012, at the earliest. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources. At present, we have no established commercial infrastructure in the EU, and are evaluating either building a commercial operation or partnering with an organization that has an established commercial operation there to successfully commercialize ILUVIEN in the EU.

If we choose to build our own commercial infrastructure in the EU we will need to create a commercial infrastructure and hire managerial, sales and marketing personnel there. The expansion of our workforce into the EU will require additional financial resources and require significant management attention.

We may not be able to establish a commercial operation in a cost-effective manner or realize a positive return on this investment. In addition, we will 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 without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe our products;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating a commercial organization in the EU.

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If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into appropriate collaboration arrangements with third-parties, we will have difficulty commercializing ILUVIEN and our other product candidates, which would adversely affect our business, operating results and financial condition.

We may not be successful in establishing a commercial operation in the EU for numerous reasons, including, but not limited to, failing to attract, retain and motivate the necessary skilled personnel and failing to develop a successful marketing strategy. Failure to establish a commercial operation in the EU will have a negative outcome on our ability to commercialize ILUVIEN and generate revenue.

Additionally, we may encounter unexpected or unforeseen delays in establishing our commercial operations that delay the commercial launch in one or more EU countries in which ILUVIEN has been recommended for marketing authorization. These delays may increase the cost of and the resources required for successful commercialization of ILUVIEN in the EU. Given our limited commercial history, we do not have experience in a commercial launch of this size in the EU.

Although we may choose to pursue a partnership to establish a commercial operation for the launch of ILUVIEN in the EU, we have not yet entered into any agreements related to the marketing of ILUVIEN in any EU market and we may not be able to enter into any arrangements with respect to EU collaborations on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed ILUVIEN entirely on our own. If we are unable to enter into appropriate marketing arrangements for ILUVIEN in the EU, we may not be able to develop an effective international sales force to successfully commercialize ILUVIEN in the EU.

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;
- 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.

Because we have not yet commercialized ILUVIEN, we have limited 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.

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The activities of competitive drug companies, or others, may limit ILUVIEN s revenue potential or render it obsolete.

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 expect that ILUVIEN may compete in the EU, and, if approved by the FDA, in the U.S., with other products that are being developed for the treatment of DME. There are no ophthalmic drug therapies currently approved by the FDA for the treatment of DME. Lucentis, a drug sponsored by Genentech, Inc., a wholly-owned member of the Roche Group is approved for the treatment of visual impairment due to DME in the EU and has filed for approval in the U.S. Lucentis is expected to provide competition for ILUVIEN. 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. Additional treatments for DME are in various stages of preclinical or clinical testing. Later stage products for the treatment of DME include Ozurdex, a drug sponsored by Allergan, Inc. and Eyelea, a drug sponsored by Regeneron Pharmaceuticals, Inc. and Bayer HealthCare. If approved, these treatments would also compete 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, 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 our 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;

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- weaker intellectual property protection in some countries;
- political instability, including war and terrorism or the threat of war and terrorism; and
- adverse economic conditions, including the stability and solvency of business financial markets, financial institutions and sovereign nations.

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

Risks Related to Our Business and Industry

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.

We are not currently generating revenues and we cannot estimate with precision the extent of our future losses. Although ILUVIEN recently has been recommended for marketing authorization in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain, we do not currently have any products that are available for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of ILUVIEN. We currently do not expect to generate revenue from the sale of ILUVIEN in the EU until late 2012, at the earliest, if at all, and therefore do not expect to have cash flow from operations until 2013, if at all. ILUVIEN has not been approved for marketing in the U.S. and may never receive such approval. 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, 2011, we have accumulated a net deficit of $211.4 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and successfully marketed. 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.

As of December 31, 2011, we had approximately $33.6 million in cash, cash equivalents, and investments. In October 2010, we obtained a $32.5 million senior secured credit facility (Credit Facility) to help fund our working capital requirements. The Credit Facility consisted of a $20.0 million revolving line of credit and a $12.5 million term loan. The lenders have advanced $6.25 million under the term loan. In May 2011, the Credit Facility was amended to increase the term loan to $17.25 million, of which the remaining $11.0 million would have been advanced following FDA approval of ILUVIEN, but no later than December 31, 2011. Due to the issuance of the second CRL by the FDA in November 2011 regarding our NDA for ILUVIEN, the remaining $11.0 million is no longer available to us. Additionally, we may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which we would not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to us. We believe that we have sufficient funds available to fund our operations through the projected commercialization of ILUVIEN in the EU countries in which ILUVIEN has been recommended for marketing authorization and the expected generation of revenue in late 2012, at the earliest. In the EU countries in which ILUVIEN has been recommended for marketing authorization, we plan to commercialize ILUVIEN, directly or with a partner. If we choose to commercialize ILUVIEN directly, we will need to raise additional capital in the future to continue to fund our operations beyond commercialization. Even if we raise additional capital, the commercialization of ILUVIEN, directly or with a partner, is dependent upon numerous factors and we cannot be sure that future sales of ILUVIEN will generate enough revenue to fund our operations. If ILUVIEN is not approved 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.

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We face heavy government regulation, and regulatory approval of ILUVIEN and our other product candidates from the FDA and from similar entities in other countries is uncertain.

The research, testing, manufacturing and marketing of drug products are subject to extensive regulation by U.S. federal, state and local government authorities, including the FDA and similar entities in other countries. 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 the U.S. and other 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 FDA may make requests or suggestions regarding conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the U.S. For example, the FDA 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 product candidates, outside the U.S. and specifically 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 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 have not yet received regulatory approval to market any of our product candidates in any jurisdiction and any delay or failure by us to obtain regulatory approvals for our product candidates could diminish competitive advantages that we may attain and would adversely affect the marketing of our products.

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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 intraocular pressure (IOP), which may increase the risk of glaucoma. We have 36 months of clinical data from 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 patients with chronic DME. Although ILUVIEN has been recommended for marketing authorization in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain, the FDA s current position is that our FAME Study did not demonstrate that ILUVIEN has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. In the event the FDA maintains this conclusion, ILUVIEN may not receive regulatory approval from the FDA. Additionally if other regulatory bodies adopt a conclusion similar to the FDA s we may not receive approval in any other jurisdiction.

Even if we do receive additional regulatory approvals for ILUVIEN, the FDA or other 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.

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. For example, our potential market for ILUVIEN in the U.S. would be reduced if the FDA limited the indications of use to patients diagnosed with only clinically significant DME as opposed to DME, or restricted its use to patients exhibiting IOP below a certain level or having an artificial lens at the time of treatment. ILUVIEN has been recommended for marketing authorization in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies which 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. The marketing, distribution and manufacture of ILUVIEN in the EU, and if approved in the U.S., 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.

Our product candidates may never achieve market acceptance even if we obtain regulatory approvals.

Even if we receive regulatory approvals for the sale of our product candidates, the commercial success of these products will depend, among other things, on their acceptance by retinal specialists, patients, third-party payers and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. The degree of market acceptance of any of our product candidates will depend on a number of factors, including, among other things:

- the demonstration of its safety and efficacy,
- its cost-effectiveness,
- its potential advantages over other therapies,
- the reimbursement policies of government and third-party payers with respect to the product candidate, and
- the effectiveness of our marketing and distribution capabilities.

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If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our product candidates are not accepted by retinal specialists, patients, third-party payers and other members of the medical community, it is unlikely that we will ever become profitable.

Our ability to pursue the development and commercialization of ILUVIEN depends upon the continuation of our license from pSivida US, Inc.

Our license rights to pSivida US, Inc. s (pSivida) 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 our agreement with pSivida were terminated, we would lose our rights to develop and commercialize ILUVIEN, which would materially and adversely affect our business, results of operations and future prospects.

We will 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 will depend completely on a single third-party manufacturer for the manufacture of the ILUVIEN insert (Alliance Medical Products, Inc. (Alliance)), a single third-party manufacturer for the manufacture of the ILUVIEN applicator (Flextronics International, Ltd. or an affiliate of Flextronics International, Ltd. (Flextronics)) and a single third-party manufacturer for the manufacture of ILUVIEN s active pharmaceutical ingredient (FARMABIOS SpA./Byron Chemical Company Inc. (FARMABIOS)). Although we have long-term agreements for the manufacture of the ILUVIEN insert (with Alliance), the manufacture of the ILUVIEN applicator (with Flextronics) and for the supply of ILUVIEN s active pharmaceutical ingredient (with FARMABIOS), 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 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 inserts, 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.

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

We will rely on our manufacturers to purchase materials from third-party suppliers necessary to produce ILUVIEN and our other product candidates for our clinical trials and expected commercial distribution. 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 for our clinical trials, product testing and potential regulatory approval of ILUVIEN outside the seven EU countries in which it has been recommended for marketing authorization and our other product candidates could be delayed, significantly affecting our ability to develop ILUVIEN and our other product candidates. If we or our manufacturers are unable to purchase these materials in the EU for ILUVIEN, or elsewhere if and when applicable regulatory approval has been obtained for ILUVIEN and our other product candidates, the commercial launch of ILUVIEN and our other product candidates 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 and our other product candidates. Moreover, although we have finalized agreements for the commercial production of the ILUVIEN insert, 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.

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The manufacture and packaging of pharmaceutical product candidates 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 product candidates such as ILUVIEN and our 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 our 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. In December 2010, we received a CRL from the FDA in which the FDA indicated that it had observed deficiencies in cGMP during its facility inspections of two of our third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls would need to comply with cGMP. Both of these manufacturers received confirmation from the FDA in March 2011 that the deficiencies have been resolved and their respective facility facilities are acceptable. However, if our manufacturers fail to maintain compliance, the production of ILUVIEN could be interrupted, resulting in delays and additional costs. Any significant delays in the manufacture of ILUVIEN 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 substantial 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, in order to obtain approval of our product candidates by the FDA and foreign regulatory agencies, 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. With respect to ILUVIEN, although we have validated the manufacturing process at smaller scale batches, some of the steps in the manufacturing processes will need to be revalidated when we begin to manufacture larger commercial scale batches, including in connection with our anticipated commercial launch in the EU. If the required testing or process validation is delayed or produces unfavorable results, we may have to launch the product using smaller scale batches, which may impact our ability to fulfill demand for the product. 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. If we are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business.

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

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

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

If we fail to successfully complete our clinical trials for any of our product candidates, we may not receive the regulatory approvals needed to market those product candidates. Therefore, any failure or delay in commencing or completing these 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;
- 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, or CROs, and other third parties.

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

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In order to establish our sales and marketing infrastructure in the EU or the U.S., we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2011, we had 21 employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize ILUVIEN and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth and related costs. We may not be able to effectively manage a rapid pace of growth and timely implement improvements to our management infrastructure and control systems.

ILUVIEN and our other potential products 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 may be reimbursed or the frequency at which they may be administered.

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 the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain, as well as many other foreign 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. 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.

In the U.S., in the event that ILUVIEN is approved, 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 other potential products. Some of these changes and proposed changes could result in reduced reimbursement rates for ILUVIEN and our other potential products, which would adversely affect our business strategy, operations and financial results.

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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. Although drugs that are not self-administered are covered by Medicare, the Medicare program has taken the position that it can decide not to cover particular drugs if it determines that they are not reasonable and necessary for Medicare beneficiaries. 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 our future products 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.

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 will depend on several factors, including, but not limited to, its efficacy and side effect profile, authorization for reimbursement by foreign regulatory bodies, private insurers and Medicare, acceptance of pricing, the development of our sales and marketing organization, an adequate payment to physicians for the insertion procedure (based on a cost assigned by the American Medical Association to the procedure, also known as a CPT code) and our ability to differentiate ILUVIEN from our competitors products. We will face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to ILUVIEN and to any products that we may develop or commercialize in the future. Our competitors may develop products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. The active pharmaceutical ingredient in ILUVIEN is FAc, which is not protected by currently valid patents. 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. 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.

Many of our competitors have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated by our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields.

We currently do not have any 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 such third-party is terminated or allowed to expire, we could be adversely affected financially or our business reputation could be harmed.

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Our business strategy includes entering into collaborations with corporate and academic collaborators for the research, development and commercialization of additional product candidates. We currently do not have any collaboration agreements with third-parties. Areas in which we anticipate potentially entering into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing of ILUVIEN in the EU 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 future arrangements might adversely affect our ability to develop, commercialize and market our products.

The success of our future 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.

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

A key element of our strategy is to commercialize a portfolio of new ophthalmic drugs in addition to ILUVIEN. We are seeking 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 are conducting involves 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. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates; or

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

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We may be unable to license or acquire suitable 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 clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable 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 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 will suffer.

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

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third-parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may have difficulty in developing, manufacturing and marketing the products of a newly acquired company that enhances the performance of our combined businesses or product lines to realize value from expected synergies. We cannot assure that, following an acquisition, we will achieve the revenues or specific net income that justifies the acquisition.

We face the risk of product liability claims and may not be able to obtain or maintain 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. If the use of one or more of our products harms people, we may be subject to costly and damaging product liability claims. We have primary product liability insurance that covers our clinical trials for a $5.0 million general aggregate limit and excess product liability insurance that covers our clinical trials for an additional $5.0 million general aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of the products that we may develop. We may not be able to obtain or maintain adequate protection against potential liabilities. 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.

In addition, our business is exposed to the risk of product liability claims related to our sale and distribution of our over-the-counter dry eye product prior to its acquisition by Bausch & Lomb Incorporated in July 2007. Our primary product liability insurance and excess product liability insurance policies cover product liability claims related to the product. To the extent this insurance is insufficient to cover any product related claims we may be exposed to significant liabilities which may materially and adversely affect our business and financial condition.

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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 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, Susan Caballa, our Senior Vice President of Regulatory Affairs, Kenneth Green, Ph.D., our Senior Vice President and Chief Scientific Officer, and Dave Holland, our Senior Vice President of Sales and Marketing. 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 would impair our ability to identify, develop and market new products.

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.

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 ILUVIEN or any of our other product candidates could be delayed.

We are dependent on CROs, third-party vendors and investigators for preclinical testing and clinical trials related to our discovery and development efforts with respect to our product candidates and we will likely continue to depend on them to assist in our future discovery and development efforts. 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 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 our product candidates could be delayed.

Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product for which we obtain marketing approval, including ILUVIEN in the EU, along with the manufacturing processes, post-approval pharmacovigilance, advertising and promotional activities for such product, will be subject to continual requirements, review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in:

- restrictions on such products or manufacturing processes;
- withdrawal of the products from the market;

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voluntary or mandatory recall;

fines;

suspension of regulatory approvals;

product seizure; and

injunctions or the imposition of civil or criminal penalties.

We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies.

Failure to obtain regulatory approval in additional foreign jurisdictions would prevent us from marketing our products abroad.

In February 2012, we received a positive outcome from the Decentralized Procedure with the issuance of a FAR from the MHRA indicating that ILUVIEN is approvable for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. However, we intend to continue to pursue additional market authorizations for ILUVIEN and other product candidates 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 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 seven EU countries in which ILUVIEN has been recommended for marketing authorization. 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 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 our products in any market. The failure to obtain these approvals could harm our business materially.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit their marketability.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. Possible side effects of ILUVIEN include, but are not limited to, extensive blurred vision, cataracts, eye irritation, eye pain, increased IOP, which may increase the risk of glaucoma, ocular discomfort, reduced visual acuity, visual disturbance, endophthalmitis, or long-standing vitreous floaters.

In addition, if following marketing approval in a jurisdiction, we or others later identify undesirable side effects caused by the product, we could face one or more of the following consequences:

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;

regulatory authorities may withdraw their approval of the product;

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- we may be required to change the way that the product is administered, conduct additional clinical trials or change the labeling of the product; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from its sale.

Risks Related to Intellectual Property and Other Legal Matters

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

Our success will depend in large part on our ability or the ability of our licensors to obtain and maintain protection in the U.S. and other countries for the intellectual property incorporated into our products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We or our licensors may not be able to obtain additional issued patents relating to our technology. Our success will depend in part on the ability of our licensors to obtain, maintain (including making periodic filings and payments) and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Under our license with pSivida, pSivida controls the filing, prosecution and maintenance of all patents. Our licensors may not successfully prosecute or continue to prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such litigation less aggressively than we ordinarily would. Without protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Moreover, FAc is an off-patent active ingredient that is commercially available in several forms including the extended release ocular implant Retisert.

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

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

Our products or potential products 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 one or more 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.

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

Our licenses are material to our business, and we expect to enter into additional licenses in the future. We hold a license from pSivida under intellectual property relating to ILUVIEN. This license imposes various commercialization, milestone payment, profit sharing, insurance and other obligations on us. We also hold a license from Dainippon Sumitomo Pharma Co., Ltd. under patents relating to ILUVIEN. This license imposes a milestone payment and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the applicable license, in which event we would not be able to market products, such as ILUVIEN, that may be covered by such license.

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

In addition to patented technology, we rely upon unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure or misappropriation by third-parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third-parties. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff were previously employed by other pharmaceutical or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their drug development activities for us.

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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 our product candidates, we rely upon intellectual property we own relating to our products, including patents, patent applications and trade secrets. As of December 31, 2011, we owned one pending non-provisional U.S. utility patent application, one European patent application, one issued U.S. design patent and corresponding applications in a number of other jurisdictions, relating to our applicator for ILUVIEN. 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, 2011, the patent rights relating to ILUVIEN licensed to us from pSivida include three U.S. patents that expire between March 2019 and April 2020, one European patent expiring in April of 2021, 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 April 2020 in the U.S. and April of 2021 in Europe, we will not be able to block others from marketing FAc in an insert similar to ILUVIEN in the U.S. 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 another product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize ILUVIEN and our other product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market ILUVIEN and our other 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 and our other product candidates 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 discovery, development and commercialization efforts with respect to ILUVIEN and our other 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.

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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 product, 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 other products until such patents expire.

In addition, third-parties may obtain patents in the future and claim that use of our product candidates or technologies 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 develop and commercialize one or more of our 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 developing or commercializing our product candidates and 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 our product candidates, 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 develop and commercialize one or more of our product candidates, which could harm our business significantly.

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. We face a risk of product liability exposure related to the testing of our product candidates in clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our products are inserted into the eye, and it is possible that we may be held liable for eye injuries of patients who receive our product. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products. Although we maintain primary product liability insurance and excess product liability insurance that cover our clinical trials, our aggregate coverage limit under these insurance policies is $10.0 million, 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. In addition, 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, which could prevent or inhibit the commercial production and sale of our products.

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 aggregated industry-wide fee is expected to total $28 billion through 2019, of which $2.5 billion will be payable in 2011. 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 new 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. If ILUVIEN is approved by the FDA, the legislation may also have a positive impact on our future net sales, if any, by increasing the aggregate number of persons with healthcare coverage in the U.S., but such increases are unlikely to be realized until approximately 2014, at the earliest.

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

Further, in some foreign countries, 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 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.

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 involve the controlled use of potentially hazardous substances, including chemical and biological materials. In addition, our operations 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.

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

At December 31, 2011, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $120.4 million and $103.8 million, respectively, which expire at various dates beginning in 2020 through 2031. Section 382 of the Internal Revenue Code limits the annual utilization of NOL carry-forwards and tax credit carry-forwards following an ownership change in our company. We periodically evaluate our NOL carry-forwards and whether certain changes in ownership, including our IPO, have occurred that would limit our ability to utilize a portion of our NOL carry-forwards. If it is determined that significant ownership changes have occurred since we generated these NOL carry-forwards, we 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). We have not performed a formal analysis of our NOLS in connection with IRC Section 382.

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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 that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and NASDAQ, has imposed various new 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 to allow management to report 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 will 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.

Risks Relating to Our Financial Results and Need for Financing

Fluctuations in our quarterly operating results and cash flows could adversely affect the price of our common stock.

We expect our operating results and cash flows to be subject to quarterly fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including, but not limited to:

- the commercial success of our product candidates;
- our ability to obtain regulatory approval of ILUVIEN in additional jurisdictions;
- the emergence of products that compete with our product candidates;
- the status of our preclinical and clinical development programs;
- variations in the level of expenses related to our existing product candidates or preclinical and clinical development programs;
- execution of collaborative, licensing or other arrangements, and the timing of payments received or made under those arrangements;
- any intellectual property infringement lawsuits to which we may become a party; and
- regulatory developments affecting our product candidates or those of our competitors.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results and cash flows may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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We may need additional financing in the event that we do not receive regulatory approval for ILUVIEN in the U.S. or the approval is delayed or, if approved in the U.S., the future sales of ILUVIEN in the U.S. and EU do not generate sufficient revenues to fund our operations. This financing may be difficult to obtain and may restrict our operations.

Prior to our IPO, we funded our operations through the private placement of common stock, preferred stock, warrants and convertible debt, as well as by the sale of certain assets of the non-prescription business in which we were previously engaged. As of December 31, 2011, we had approximately $33.6 million in cash, cash equivalents and investments.

In October 2010, we obtained a $32.5 million senior secured credit facility (Credit Facility) to help fund our working capital requirements. The Credit Facility consisted of a $20.0 million revolving line of credit and a $12.5 million term loan. The lenders have advanced $6.25 million under the term loan. In May 2011, the Credit Facility was amended to increase the term loan to $17.25 million, of which the remaining $11.0 million would have been advanced following FDA approval of ILUVIEN, but no later than December 31, 2011. Due to the issuance of the second CRL by the FDA in November 2011 regarding our NDA for ILUVIEN, the remaining $11.0 million is no longer available to us. Additionally, we may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which we would not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to us. On February 6, 2012, we received a letter from the lenders stating that they reserve the right to assert that recent events, including the issuance of the second CRL and a decrease in the market value of our public equity securities, may represent a material impairment of the value of the collateral under the loan agreements. To date, the lenders have not made such an assertion, and in our opinion a material impairment of the value of the collateral has not occurred.

We believe that we have sufficient funds available to fund our operations through the projected commercialization of ILUVIEN in the EU countries in which ILUVIEN has been recommended for marketing authorization and the expected generation of revenue in late 2012, at the earliest, if at all, and therefore do not expect to have cash flow from operations until 2013, if at all. In the EU countries in which ILUVIEN has been recommended for marketing authorization, we plan to commercialize ILUVIEN, directly or with a partner. If we choose to commercialize ILUVIEN directly, we will need to raise additional capital in the future to continue to fund our operations beyond commercialization. Even if we raise additional capital, the commercialization of ILUVIEN, directly or with a partner, is dependent upon numerous factors and we cannot be sure that future sales of ILUVIEN will generate enough revenue to fund our operations beyond its initial commercialization. Due to the uncertainty around the commercial launch of ILUVIEN, management cannot be certain that we will not need additional funds for its commercialization. If ILUVIEN is not approved 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 advisable, we may seek to fund our operations through the sale of equity securities, strategic collaboration agreements and additional 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 additional 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 our product candidates or operate our business. For example, under the Credit Facility, we 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. To secure the performance of our obligations under the Credit Facility, we pledged all of our assets, including our intellectual property to the lenders. Our failure to comply with the covenants under the Credit Facility could result in an event of default, the acceleration of our debt and the loss of our assets. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline.

Risks Related to 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:

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failure of ILUVIEN to be approved in any jurisdiction;

failure to successfully commercialize ILUVIEN in the EU;

failure of ILUVIEN or any of our other product candidates, to achieve commercial success;

results from our clinical trial programs;

FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;

quarterly variations in our results of operations or those of our competitors;

our ability to develop and market new and enhanced product candidates on a timely basis;

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 credit facility;

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 or management;

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 our 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 commercialization of our 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.

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Certain of our existing 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.

As of December 31, 2011, our executive officers, key employees and directors and their affiliates beneficially owned, in the aggregate, approximately 71.6% of our outstanding common stock. As a result, these stockholders, if acting together, may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions, and this concentration of voting power may have the effect of delaying or impeding actions that could be beneficial to you, including actions that may be supported by our board of directors.

We currently do not intend to pay dividends on our common stock and, consequently, your only opportunity to achieve a return on your investment is if the price of our common stock appreciates.

We do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

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. 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 early investors in our company 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, 2011, there were a total of 2,607,446 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options granted under our equity incentive plans. Upon the exercise of these options, in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under the SEC s Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

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

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

To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. 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.

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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, 2012, an additional 1,257,095 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 increases 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, 2012, an additional 21,910 shares became available for future issuance under our 2010 Employee Stock Purchase Plan.

Anti-takeover provisions in our charter and bylaws and in Delaware law could prevent or delay acquisition bids for us that you might consider 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;
- limit who may call special meetings of stockholders;
- prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders; and
- establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

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

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

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ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

Not applicable.

ITEM 2. ***PROPERTIES***

Our current headquarters are located in Alpharetta, Georgia, consisting of approximately 14,000 square feet of office space. Our lease for this facility expires in December 2012. 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 lease, 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.

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, 2011	September 30, High	September 30, Low
First quarter 2011	$ 10.92	$ 6.81
Second quarter 2011	$ 9.82	$ 7.50
Third quarter 2011	$ 9.07	$ 6.40
Fourth quarter 2011	$ 8.77	$ 1.09

Year Ended December 31, 2010	September 30, High	September 30, Low
Second quarter 2010	$ 11.30	$ 7.33
Third quarter 2010	$ 9.74	$ 6.30
Fourth quarter 2010	$ 12.70	$ 8.69

Holders

As of March 26, 2012 there were 44 holders of record of our common stock.

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Dividends

The Company has not declared or paid any cash dividends on its common stock since its inception. The Company does not plan to pay dividends in the foreseeable future. In addition, under the Company s Credit Facility, it has agreed not to pay any dividends so long as it has any outstanding obligations thereunder. For further discussion of the Company s Credit Facility, see *Our Credit Facility* on page 57. The Company currently intends to retain earnings, if any, to finance the growth of the Company. Consequently, stockholders will need to sell shares of our common stock to realize a return on their investment, if any.

Market Price of and Dividends on the Registrant s Common Equity and Related Stockholder Matters

The following graph shows the cumulative total return, assuming the investment of $100 on April 22, 2010 (the date of the Company s initial public offering) on an investment in each of the Company s common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of the Company s common stock. All values assume reinvestment of the full amount of dividends and are calculated as of December 31, 2011. The Company has not declared or paid any cash dividends on its common stock since its inception and does not plan to pay dividends in the foreseeable future. The following graph and related information is being furnished solely to accompany this Form 10-K pursuant to Item 201(e) of Regulation S-K and shall not be deemed soliciting materials or to be filed with the SEC (other than as provided in Item 201), nor shall such information be incorporated by reference into any of our filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, and irrespective of any general incorporation language in any such filing.

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Recent Sales of Unregistered Securities

Sales of Unregistered Securities

During the year ended December 31, 2011, we issued 4,705 shares of our common stock upon the exercise of warrants for an aggregate of $19,000.

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, Rule 701 promulgated under Section 3(b) of the Securities Act or Regulation S 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.

Use of Proceeds from Public Offering of Common Stock

On April 21, 2010, our Registration Statement on Form S-1 (File No. 333-162782) was declared effective by the SEC for our IPO, pursuant to which we sold 6,550,000 shares of our common stock at a public offering price of $11.00 per share. We received net proceeds of approximately $66.1 million from this transaction, after deducting underwriting discounts, commissions and other offering costs. The underwriters of the offering were Credit Suisse Securities (USA) LLC, Citigroup Global Markets Inc., Cowen and Company, LLC, and Oppenheimer & Co., Inc. On April 27, 2010 we paid $15.2 million to pSivida to satisfy our $15.0 million note payable and accrued but unpaid interest thereon. There have been no material changes in our use or planned use of proceeds from the initial public offering from that described in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, filed with the SEC on June 7, 2010.

ITEM 6 ***SELECTED CONSOLIDATED FINANCIAL DATA***

The tables below summarize our financial data. The following statements of operations data for fiscal years 2011, 2010 and 2009, and the balance sheet data as of December 31, 2011 and 2010 have been derived from our audited financial statements and related notes and are included elsewhere in this annual report on Form 10-K. The statement of operations data for fiscal years 2008 and 2007, and the balance sheet data as of December 31, 2009, 2008 and 2007 are derived from our audited financial statements not included herein. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

The following summary financial data should be read together with our financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report on Form 10-K.

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Statement of Operations Data

	Years Ended December 31,				
	September 30, 2011	September 30, 2010	September 30, 2009	September 30, 2008	September 30, 2007
	(In thousands, except per share data)				
Operating expenses					
Research and development	$ 7,100	$ 12,581	$ 15,057	$ 43,764	$ 8,363
General and administrative	6,203	4,610	3,407	5,058	3,184
Marketing	8,104	4,880	752	1,259	969
Total operating expenses	21,407	22,071	19,216	50,081	12,516
Interest and other income	16	73	37	585	1,079
Interest expense	(1,125)	(848)	(1,897)	(1,514)	(2)
Gain on early extinguishment of debt		1,343			
Decrease (increase) in fair value of preferred stock conversion feature		3,644	(23,142)	(10,454)	1
Loss from continuing operations	(22,516)	(17,859)	(44,218)	(61,464)	(11,438)
Income from discontinued operations (1)		4,000			5,733
Net loss	(22,516)	(13,859)	(44,218)	(61,464)	(5,705)
Beneficial conversion feature of preferred stock			(355)		
Preferred stock accretion		(466)	(623)	(718)	(248)
Preferred stock dividends		(2,638)	(7,225)	(6,573)	(4,685)
Net loss attributable to common stockholders	$ (22,516)	$ (16,963)	$ (52,421)	$ (68,755)	$ (10,638)
Basic and diluted loss per share attributable to common stockholders	$ (0.72)	$ (0.77)	$ (34.56)	$ (45.50)	$ (7.09)
Weighted average number of shares used to compute basic and diluted loss per share attributable to common stockholders	31,363	22,168	1,517	1,511	1,500

(1) Refer to a discussion of our discontinued non-prescription business on page 58.

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Balance Sheet Data

	September 30, 2011	September 30, 2010	September 30, 2009	September 30, 2008	September 30, 2007
			Years Ended December 31, (In thousands)		
Cash and cash equivalents	$ 33,108	$ 28,514	$ 4,858	$ 17,875	$ 20,847
Investments	500	26,330			
Working capital (deficit)	27,783	49,777	(4,428)	14,551	19,862
Total assets	34,698	56,414	6,561	20,264	24,519
Long-term liabilities	3,002	4,785	47,909	28,217	31
Preferred stock			113,389	103,017	67,990
Additional paid-in capital	235,619	233,338	4,836	3,474	2,867
Accumulated deficit	(211,370)	(188,854)	(171,891)	(119,470)	(50,715)
Total stockholders equity (deficit)	24,978	45,212	(165,472)	(115,887)	(47,738)

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

We are a biopharmaceutical 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 most advanced product candidate is ILUVIEN®, which received a positive outcome from the Decentralized Procedure with the issuance of a Final Assessment Report (FAR) from the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) indicating that it is approvable for the treatment of vision impairment associated with diabetic macular edema (DME) considered insufficiently responsive to available therapies in seven European Union (EU) countries in February 2012. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness.

In September 2010, we completed two Phase 3 pivotal clinical trials (collectively, our FAME Study) on both a high and low dose of ILUVIEN involving 956 patients in sites across the U.S., Canada, Europe and India to assess the efficacy and safety of ILUVIEN in the treatment of DME over a 36 month period. Based on our analysis of the data through month 24 of the FAME Study in December 2009, we submitted a New Drug Application (NDA) in June 2010 for the low dose of ILUVIEN in the U.S. with the U.S. Food and Drug Administration (FDA), followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain under the European Union s (EU) decentralized procedure in July 2010 with the United Kingdom acting as the Reference Member State (RMS). The RMS is responsible for coordinating the review and approval process between itself and the other involved countries, or Concerned Member States.

In November 2010, we received a Preliminary Assessment Report (PAR) from the RMS and in December 2010, we received a Complete Response Letter (CRL) from the FDA regarding our respective registration filings. The primary concerns expressed in both the PAR and the CRL centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of our FAME Study data through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filings.

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We submitted our response to the CRL to the FDA in May 2011, including additional safety and efficacy data through the final readout at month 36 of the FAME Study with an emphasis on the chronic DME subgroup. In July 2011, we submitted a draft response to the PAR to the MHRA, the regulatory body in the RMS, which included a similar data package.

In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its current form stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. The FDA has indicated that we will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. We expect to meet with the FDA in the second quarter of 2012 to discuss the CRL and the regulatory status of ILUVIEN.

After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a Final Assessment Report (FAR) from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries. During the national phase labeling in each country s local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in patients with chronic DME.

ILUVIEN is also being studied in three Phase 2 clinical trials for the treatment of the dry form of age-related macular degeneration (AMD), the wet form of AMD and retinal vein occlusion (RVO).

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of December 31, 2011, we have accumulated a deficit of $211.4 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

- complete the clinical development and registration of ILUVIEN;
- prepare for the anticipated commercial launch of ILUVIEN in the EU in late 2012, at the earliest;
- continue to seek regulatory approval of ILUVIEN in the U.S. and other jurisdictions;
- evaluate the use of ILUVIEN for the treatment of other diseases; and
- advance the clinical development of other new product candidates either currently in our pipeline, or that we may license or acquire in the future.

Prior to our initial public offering (IPO), we funded our operations through the private placement of common stock, preferred stock, warrants and convertible debt, as well as by the sale of certain assets of the non-prescription business in which we were previously engaged. On April 21, 2010, our Registration Statement on Form S-1 (as amended) was declared effective by the Securities and Exchange Commission (SEC) for our IPO, pursuant to which we sold 6,550,000 shares of our common stock at a public offering price of $11.00 per share. We received net proceeds of approximately $66.1 million from this transaction, after deducting underwriting discounts, commissions and other offering costs.

As of December 31, 2011, we had approximately $33.6 million in cash, cash equivalents and investments in trading securities.

In October 2010, we obtained a $32.5 million senior secured credit facility (Credit Facility) to help fund our working capital requirements. The Credit Facility consisted of a $20.0 million revolving line of credit and a $12.5 million term loan. The lenders have advanced $6.25 million under the term loan. In May 2011, the Credit Facility was amended to increase the term loan to $17.25 million, the remaining $11.0 million which would have been advanced following FDA approval of ILUVIEN, but no later than December 31, 2011. As a result of the issuance of the second CRL by the FDA in November 2011 regarding our NDA for ILUVIEN, the remaining $11.0 million is no longer available to us. Additionally, we may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which we would not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may

never be, available to us. On February 6, 2012, we received a letter from the lenders stating that the they reserve the right to assert that recent events, including the issuance of the second CRL and a decrease in the market value of our public equity securities, may represent a material impairment of the value of the collateral under the loan agreements. To date, the lenders have not made such an assertion, and in our opinion a material impairment of the value of the collateral has not occurred.

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We believe that we have sufficient funds available to fund our operations through the projected commercialization of ILUVIEN in the EU countries in which it has been recommended for marketing authorization and the expected generation of revenue in late 2012, at the earliest, if at all, and therefore do not expect to have cash flow from operations until 2013, if at all. In addition, we expect to continue to seek regulatory approval of ILUVIEN in the U.S. In the EU countries in which ILUVIEN has been recommended for marketing authorization, we plan to commercialize ILUVIEN, directly or with a partner. If we choose to commercialize ILUVIEN directly, we will need to raise additional capital in the future to continue to fund our operations beyond commercialization. Even if we raise additional capital, the commercialization of ILUVIEN, directly or with a partner, is dependent upon numerous factors and we cannot be sure that future sales of ILUVIEN will generate enough revenue to fund our operations beyond its commercialization. Due to the uncertainty around the commercial launch of ILUVIEN, management cannot be certain that we will not need additional funds for its commercialization. If ILUVIEN is not approved 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.

Our Agreement with pSivida US, Inc.

In February 2005, we entered into an agreement with pSivida US, Inc. (pSivida) for the use of fluocinolone acetonide (FAc) in pSivida s proprietary delivery device. 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 for 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.

Under the February 2005 agreement, we and pSivida agreed to collaborate on the development of ILUVIEN for DME, and share financial responsibility for the development expenses equally. Per the terms of the agreement, we each reported our monthly expenditures on a cash basis, and the party expending the lesser amount of cash during the period was required to make a cash payment to the party expending the greater amount to balance the cash expenditures. We retained primary responsibility for the development of the product, and therefore, were generally the party owed a balancing payment. Between February 2006 and December 2006, pSivida failed to make payments to us for its share of development costs totaling $2.0 million. For each payment not made, pSivida incurred a penalty of 50% of the missed payment and interest began accruing at the rate of 20% per annum on the missed payment and the penalty amount. In accordance with the terms of the agreement, pSivida was able to remain in compliance with the terms of the February 2005 agreement as long as the total amount of development payments past due did not exceed $2.0 million, and pSivida began making payments again in December 2006 in order to maintain compliance with the agreement.

The February 2005 agreement provided that after commercialization of ILUVIEN, profits, as defined in the agreement, would be shared equally. In March 2008, we and pSivida amended and restated the agreement to provide us with 80% of the net profits and pSivida with 20% of the net profits.

Total consideration to pSivida in connection with the execution of the March 2008 agreement was $33.8 million, which consisted of a cash payment of $12.0 million, the issuance of a $15.0 million note payable, and the forgiveness of $6.8 million in outstanding receivables. The $15.0 million promissory note was repaid pursuant to its terms with the proceeds from our IPO. We will owe pSivida an additional milestone payment of $25.0 million if ILUVIEN is approved by the FDA.

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Our Credit Facility

Term Loan Agreement

On October 14, 2010 (Effective Date), we entered into a Loan and Security Agreement (Term Loan Agreement) with Silicon Valley Bank and MidCap Financial LLP (Lenders). Pursuant to the original terms of the Term Loan Agreement, we were entitled to borrow up to $12.5 million, of which $6.25 million (Term Loan A) was advanced to us on the Effective Date. We were entitled to draw down the remaining $6.25 million under the Term Loan (Term Loan B and together with Term Loan A, the Term Loan) if the FDA approved our NDA for ILUVIEN prior to or on July 31, 2011. On May 16, 2011, the Lenders and we amended the Term Loan Agreement (Term Loan Modification) to, among other things, extend until December 31, 2011 the date by which the FDA must have approved the NDA in order for us to draw down Term Loan B and increase the amount of Term Loan B by $4.75 million to $11.0 million. In addition, the maturity date of the Term Loan was extended from October 31, 2013 to April 30, 2014 (Term Loan Maturity Date). As a result of the issuance of the second CRL by the FDA in November 2011, we did not drawn down Term Loan B by December 31, 2011 and the availability to draw down Term Loan B expired.

We were required to pay interest on Term Loan A at a rate of 11.5% on a monthly basis through July 31, 2011, and since August 2011, we have been required to repay the principal in 33 equal monthly installments plus interest at a rate of 11.5%.

If we repay Term Loan A prior to maturity, we must pay to the Lenders a prepayment fee equal to 5.0% of the total amount of principal then outstanding if the prepayment had occurred within one year after the funding date of Term Loan A (Term Loan A Funding Date), 3.0% of such amount if the prepayment occurs between one year and two years after the Term Loan A Funding Date and 1.0% of such amount if the prepayment occurs thereafter (subject to a 50% reduction in the event that the prepayment occurs in connection with an acquisition of us).

To secure the repayment of any amounts borrowed under the Term Loan Agreement, we granted to the Lenders a first priority security interest in all of our assets, including our intellectual property, however, the lien on our intellectual property will be released if we meet certain financial conditions. The occurrence of an event of default could result in the acceleration of our obligations under the Term Loan Agreement and an increase to the applicable interest rate, and would permit the Lenders to exercise remedies with respect to the collateral under the Term Loan Agreement. We also agreed not to pledge or otherwise encumber our intellectual property assets. Additionally, we must seek the Lenders approval prior to the payment of any cash dividends to our stockholders.

On the Effective Date, we issued to the Lenders warrants to purchase an aggregate of up to 39,773 shares of our common stock. Each of the warrants is exercisable immediately, has a per-share exercise price of $11.00 and has a term of 10 years. We estimated the fair value of warrants granted using the Black-Scholes option pricing model. The aggregate fair value of the warrants was estimated to be $389,000. We allocated a portion of the proceeds from the Term Loan Agreement to the warrants in accordance with Accounting Standards Codification (ASC) 470-20-25-2, *Debt Instruments with Detachable Warrants*. As a result, we recorded a discount of $366,000 which is being amortized to interest expense using the effective interest method. The Lenders will have certain registration rights with respect to the shares of common stock issuable upon exercise of all of their warrants. We paid to the Lenders an upfront fee of $62,500 on the Effective Date and an additional fee of $50,000 in connection with the Term Loan Modification. In accordance with ASC 470-50-40-17, *Debt Modifications and Extinguishments*, we are amortizing the unamortized discount on Term Loan A and the $50,000 modification fee over the remaining term of Term Loan A, as modified.

We are required to maintain our primary operating and other deposit accounts and securities accounts with Silicon Valley Bank, which accounts must represent at least 50% of the dollar value of our accounts at all financial institutions.

On February 6, 2012, we received a letter from the Lenders stating that they reserve the right to assert that recent events, including the issuance by the FDA of the second CRL and a decrease in the market value of our public equity securities, may represent a material impairment of the value of the collateral under the Loan Agreements. To date, the Lenders have not made such an assertion, and in our opinion a material impairment of the value of the collateral has not occurred.

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Working Capital Revolver

Also on the Effective Date, we entered into a Loan and Security Agreement with Silicon Valley Bank, pursuant to which we obtained a secured revolving line of credit (Working Capital Revolver) from Silicon Valley Bank with borrowing availability up to $20.0 million (Revolving Loan Agreement). On May 16, 2011, Silicon Valley Bank and we amended the Revolving Loan Agreement to extend the maturity date of the Working Capital Revolver from October 31, 2013 to April 30, 2014.

The Working Capital Revolver is a working capital-based revolving line of credit in an aggregate amount of up to the lesser of (i) $20.0 million, or (ii) 85% of eligible domestic accounts receivable. As of December 31, 2011 and 2010, respectively, no amounts under the Working Capital Revolver were outstanding or available to us. We may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which we would not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to us.

Amounts advanced under the Working Capital Revolver will bear interest at an annual rate equal to Silicon Valley Bank s prime rate plus 2.50% (with a rate floor of 6.50%). Interest on the Working Capital Revolver will be due monthly, with the balance due at the maturity date. On the Effective Date, we paid to Silicon Valley Bank an upfront fee of $100,000. In addition, if we terminate the Working Capital Revolver prior to maturity, we will be required to pay to Silicon Valley Bank a fee of $400,000 if the termination occurs within one year after the Effective Date and a fee of $200,000 if the termination occurs more than one year after the Effective Date (each a Termination Fee), provided in each case that such Termination Fee will be reduced by 50% in the event of an acquisition of us.

To secure the repayment of any amounts borrowed under the Revolving Loan Agreement, we granted to Silicon Valley Bank a first priority security interest in all of our assets, including our intellectual property, however, the lien on our intellectual property will be released if we meet certain financial conditions. The occurrence of an event of default could result in the acceleration of our obligations under the Revolving Loan Agreement and an increase to the applicable interest rate, and would permit Silicon Valley Bank to exercise remedies with respect to the collateral under the Revolving Loan Agreement. We also agreed not to pledge or otherwise encumber our intellectual property assets. Additionally, we must seek Silicon Valley Bank s approval prior to the payment of any cash dividends to our stockholders.

Our Discontinued Non-Prescription Business

At the inception of our company, we were focused primarily on the development and commercialization of non-prescription over-the-counter ophthalmic products. In October 2006, due to the progress and resource requirements related to the development of ILUVIEN, we decided to discontinue our non-prescription business. As a result, we received proceeds of $10.0 million from the sale of our allergy products in December 2006 and $6.7 million from the sale of our dry eye product in July 2007, both to Bausch & Lomb. If one of the allergy products receives FDA approval, we are entitled to an additional $8.0 million payment from Bausch & Lomb under the sales agreement. In January 2010 we received a $4.0 million option payment from Bausch & Lomb upon the exercise by Bausch & Lomb of its option to extend the period during which it may continue to develop this allergy product by two years. In 2011, Bausch & Lomb informed us that it was no longer pursuing development of the product. As a result, we do not anticipate receiving any additional payments under the sales agreement. As a result of the discontinuance of our non-prescription business, all revenues and expenses associated with our over-the-counter portfolio are included in the loss from discontinued operations in the accompanying statements of operations.

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Financial Operations Overview

Revenue

To date we have only generated revenue from our dry eye non-prescription product. From the launch of that product in September 2004 to its sale in July 2007, we generated $4.4 million in net revenues. We do not expect to generate any significant additional revenue until, at the earliest, the anticipated EU commercial launch of ILUVIEN or unless or until we obtain regulatory approval in additional jurisdictions of, and commercialize, our product candidates or in-license additional products that generate revenue. 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 our product candidates and other intellectual property. We expect any revenue we generate will fluctuate from quarter to quarter as a result of the nature, timing and amount of any milestone payments we may receive from potential collaborative and strategic relationships, as well as revenue we may receive upon the sale of our products to the extent any are successfully commercialized.

Research 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. In the event the FDA approves our NDA for ILUVIEN, we will owe an additional milestone payment of $25.0 million to pSivida. 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 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;
- 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 our product candidates;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- costs related to upfront and milestone payments under in-licensing agreements;
- 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 our product candidates, test such formulations in preclinical studies for toxicology, safety and efficacy and to conduct clinical trials for each 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 product candidates or programs in order to focus our resources on more promising 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;

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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 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 most advanced product candidate is ILUVIEN, which has been recommended for marketing authorization in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. ILUVIEN has not been approved in the U.S. by the FDA or in any other jurisdiction. 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 our 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 which of our 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 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.

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Marketing Expenses

Marketing expenses consist primarily of compensation for employees responsible for assessing the commercial opportunity of and developing market awareness and launch plans for our product candidates. Other costs include professional fees associated with developing brands for our product candidates and maintaining public relations.

In the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain we are currently evaluating commercializing ILUVIEN directly or with a partner. Currently we are engaged, with the assisstance of local consultants, in the pricing and reimbursement process in select countries and are developing market access plans for all those countries in which ILUVIEN has been recommended for marketing authorization. If we make the decision to commercialize ILUVIEN directly we will create a commercial infrastructure of approximately fifty people in management and the field combined including sales representatives, market access personnel and medical science liaisons.

If we create a commercial infrastructure in the EU, we expect significant increases in our marketing and selling expenses as we hire additional personnel and establish our sales and marketing capabilities in anticipation of the commercialization of our product candidates.

In preparation for a potential U.S. commercial launch of ILUVIEN, we began recruiting sales and marketing infrastructure personnel with extensive ophthalmic-based sales experience in the fourth quarter of 2010. We hired our marketing and managed markets directors, three sales directors and our four field-based managed markets managers but did not add the personnel and incur the costs of hiring and training an internal sales force. We entered into a relationship with OnCall LLC, a contract sales force company, and would have utilized their employees to act as our sales representatives if we had received approval of the ILUVIEN NDA from the FDA. Due to the receipt of the second CRL, we have eliminated our sales management team and field-based managed markets managers at this time. We incurred $401,000 of personnel and severance costs related to this work force reduction in December of 2011.

Interest and Other Income

Interest income consists primarily of interest earned on our cash, cash equivalents and investments.

Interest Expense

Beginning in March 2008, we began recognizing interest on our $15.0 million note payable to pSivida at an effective interest rate of 12.64% per annum (this note accrued interest at the rate of 8% per annum from inception through March 31, 2010 and at the rate of 20% per annum effective as of April 1, 2010). On April 27, 2010, we paid pSivida approximately $15.2 million in principal and interest to satisfy the note payable. In October 2010, we drew the Initial Tranche of $6.25 million on our term loan from Silicon Valley Bank and MidCap Financial LLP which accrues interest at the rate of 11.5% per annum and is payable monthly.

Change in Fair Value of Preferred Stock Conversion Feature

Prior to being converted into common stock in connection with our IPO, our preferred stock contained certain conversion features which were considered embedded derivatives. We accounted for such embedded derivative financial instruments in accordance with ASC 815, *Derivatives and Hedging*. We recorded derivative financial instruments as assets or liabilities in our balance sheet measured at their fair value. We recorded the changes in fair value of such instruments as non-cash gains or losses in the statement of operations. The preferred stock conversion feature was eliminated upon the conversion of our preferred stock to common stock in connection with our IPO in April 2010.

Preferred Stock Accretion

Prior to our IPO, our preferred stock was recorded at issuance at the proceeds received net of any issuance discounts, issuance costs and the fair value of the conversion features at issuance. The difference between the amount recorded at issuance and the original issue price was accreted on a straight-line basis over a period extending from the date of issuance to the date at which the preferred stock would have become redeemable at the option of the holder. Accretion of the difference ceased upon the conversion of our preferred stock to common stock in connection with our IPO in April 2010.

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Preferred Stock Dividends

Prior to our IPO, our preferred stock accrued dividends at 8% per annum which were recorded as an increase in the carrying amount of the respective preferred stock. At the time our preferred stock was converted into common stock in connection with our IPO, $1.5 million of dividends accrued on our Series A preferred stock prior to November 17, 2005 were converted into 380,301 shares of our common stock. All other preferred stock dividends were eliminated upon conversion of the underlying preferred stock in April 2010.

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

We calculated net loss per share in accordance with ASC 260, *Earning Per Share*. We had a net loss from continuing operations 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. Potentially dilutive weighted average common stock equivalents totaled approximately 1,489,869, 9,131,451 and 22,149,592 for the years ended December 31, 2011, 2010 and 2009, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods of net loss from continuing operations because of their anti-dilutive effect. Therefore, for the years ended December 31, 2011, 2010 and 2009, 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 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 financial statements.

Clinical Trial Prepaid and Accrued Expenses

We record prepaid assets and accrued liabilities related to clinical trials associated with CROs, clinical trial investigators and other vendors based upon amounts paid and the estimated amount of work completed on each clinical trial. The financial terms of agreements vary from vendor to vendor and may result in uneven payment flows. As such, if we have advanced funds exceeding our estimate of the work completed, we record a prepaid asset. If our estimate of the work completed exceeds the amount paid, an accrued liability is recorded. All such costs are charged to research and development expenses based on these estimates. Our estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and discussions with our CROs and review of contractual terms. However, if we have incomplete or inaccurate information, we may underestimate or overestimate activity levels associated with various clinical trials at a given point in time. In this event, we could record significant research and development expenses in future periods when the actual level of activities becomes known. To date, we have not experienced material changes in these estimates. Additionally, we do not expect material adjustments to research and development expenses to result from changes in the nature and level of clinical trial activity and related expenses that are currently subject to estimation. In the future, as we expand our clinical trial activities, we expect to have increased levels of research and development costs that will be subject to estimation.

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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 FDA approval for our current 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

Effective January 1, 2005, we adopted the fair value recognition provisions of ASC 718, *Compensation Stock Compensation*, using the modified prospective application method. 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. For the calculation of expected volatility, because we lack significant company-specific historical and implied volatility information, we estimate our volatility by utilizing an average of volatilities of publicly traded companies, including our own, deemed similar to us in terms of product composition, stage of lifecycle, capitalization and scope of operations. We intend to continue to consistently apply this process using this same index until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

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.

Total stock-based compensation expense, related to all our stock-based awards for the years ended December 31, 2011, 2010 and 2009, was comprised of the following:

	Years Ended December 31,		
	September 30, 2011	**September 30, 2010**	**September 30, 2009**
	(In thousands)		
Marketing	$ 352	$ 127	$ 43
Research and development	376	209	161
General and administrative	1,078	458	307
Total employee stock-based compensation expense	$ 1,806	$ 794	$ 511

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Income Taxes

We recognize deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of its 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 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, 2011 we had federal NOL carry-forwards of approximately $120.4 million and state NOL carry-forwards of approximately $103.8 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 2023 and 2031 and the state NOL carry-forwards will expire at various dates between 2020 and 2031. We periodically evaluate our NOL carry-forwards and whether certain changes in ownership, including our IPO, 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). We have not performed a formal analysis of our NOLs in connection with 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.

Results of Operations

The following discussion should be read in conjunction with our financial statements.

	September 30, 2011	September 30, 2010	September 30, 2009
	Years Ended December 31,		
	(In thousands)		
RESEARCH AND DEVELOPMENT EXPENSES	$ 7,100	$ 12,581	$ 15,057
GENERAL AND ADMINISTRATIVE EXPENSES	6,203	4,610	3,407
MARKETING EXPENSES	8,104	4,880	752
OPERATING EXPENSES	21,407	22,071	19,216
INTEREST AND OTHER INCOME	16	73	37
INTEREST EXPENSE	(1,125)	(848)	(1,897)
GAIN ON EARLY EXTINGUISHMENT OF DEBT		1,343	
DECREASE (INCREASE) IN FAIR VALUE OF PREFERRED STOCK CONVERSION FEATURE		3,644	(23,142)
LOSS FROM CONTINUING OPERATIONS	$ (22,516)	$ (17,859)	$ (44,218)

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Year ended December 31, 2011 compared to the year ended December 31, 2010

Research and development expenses. Research and development expenses decreased by approximately $5.5 million, or 44%, to approximately $7.1 million for the year ended December 31, 2011 compared to approximately $12.6 million for the year ended December 31, 2010. The decrease was primarily attributable to decreases of $4.2 million in costs related to our FAME Study, $2.0 million in costs to file our NDA in the U.S. and marketing applications for ILUVIEN in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain, $1.1 million in technical transfer costs associated with establishing manufacturing capabilities with a third party manufacturer for ILUVIEN, and $350,000 in costs associated with our ancillary studies, offset by increases of $1.2 million in costs related to the physician utilization study which is being conducted to assess the safety and utility of the commercial version of the inserter for ILUVIEN, $540,000 in costs associated with contracting medical science liaisons to engage with retinal specialists in the study of ILUVIEN, and $340,000 in personnel costs. The decrease in costs for our FAME Study was primarily due to decreases of $2.9 million for our CROs, $960,000 for clinical trial site costs, and $370,000 for our third party reading center for the analysis of retinal images.

General and administrative expenses. General and administrative expenses increased by approximately $1.6 million, or 35%, to approximately $6.2 million for the year ended December 31, 2011 compared to approximately $4.6 million for the year ended December 31, 2010. The increase was primarily attributable to increases of $620,000 of noncash stock compensation expense, $450,000 in costs incurred after our IPO in April 2010 associated with operating as a public company including additional audit, tax and legal fees, increased directors and officers insurance costs, and board of directors compensation, and $350,000 in additional personnel costs.

Marketing expenses. Marketing expenses increased by approximately $3.2 million, or 65%, to approximately $8.1 million for the year ended December 31, 2011 compared to approximately $4.9 million for the year ended December 31, 2010. The increase was primarily attributable to increases of $1.3 million in costs related to the hiring of additional key personnel in advance of the previously anticipated U.S. commercial launch of ILUVIEN, $520,000 in costs associated with the establishment of our managed care programs, $480,000 in costs related to our advertising agency s development of a detailed advertising and promotional plan for the previously anticipated U.S. commercial launch of ILUVIEN, $320,000 in costs associated with pharmacoeconomic studies to evaluate the pricing of ILUVIEN in the U.S. and the EU, $240,000 of noncash stock compensation expense, and $170,000 in additional costs for medical marketing activity as we expand our presence at key industry events and prepare for entry into the EU.

Interest and other income. Interest and other income decreased by approximately $57,000, or 78%, to approximately $16,000 for the year ended December 31, 2011 compared to approximately $73,000 for the year ended December 31, 2010. The decrease was due to lower cash and investment balances as a result of our continuing operations.

Interest expense. Interest expense increased by approximately $280,000, or 33%, to approximately $1.1 million for the year ended December 31, 2011 compared to approximately $850,000 for the year ended December 31, 2010. The increase was primarily attributable to interest expense associated with our $6.3 million notes payable to Silicon Valley Bank and MidCap Financial LLP.

Decrease in fair value of preferred stock conversion feature. We did not have any income or loss from the change in fair value of preferred stock conversion feature for the year ended December 31, 2011 due to its elimination with our IPO in April of 2010. During the year ended December 31, 2010, we recognized a gain of approximately $3.6 million related to the decrease in the fair value of the conversion feature of our preferred stock. The changes in fair values were primarily due to changes in the estimated fair value of our common stock.

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Income from discontinued operations. We did not have any income or loss from discontinued operations for the year ended December 31, 2011. We recognized income from discontinued operations during the year ended December 31, 2010 of $4.0 million for a payment we received from Bausch & Lomb. This payment was related to the exercise by Bausch & Lomb of its option to extend by two years the period during which it may continue to develop an allergy product acquired from us in 2006.

Year ended December 31, 2010 compared to the year ended December 31, 2009

Research and development expenses. Research and development expenses decreased by approximately $2.5 million, or 17%, to approximately $12.6 million for the year ended December 31, 2010 compared to approximately $15.1 million for the year ended December 31, 2009. The decrease was primarily attributable to decreases of $3.6 million in costs related to our FAME Study, $1.1 million in technical transfer costs associated with establishing manufacturing capabilities with a third party manufacturer for ILUVIEN in 2009, and $300,000 related to license fees paid to Emory University in 2009 for two classes of NADPH oxidase inhibitors, offset by increases of $2.0 million in costs to file our NDA in the U.S. and marketing applications for ILUVIEN in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain, $410,000 in costs associated with contracting medical science liaisons to engage with retinal specialists in the study of ILUVIEN, and $100,000 in costs associated with our ancillary studies. The decrease in costs for our FAME Study was primarily due to decreases of $1.6 million for our CROs, $1.1 million for clinical trial site costs, $590,000 for our third party reading center for the analysis of retinal images, and $220,000 in costs reimbursable to pSivida for its costs to develop ILUVIEN as the FAME Study was completed in the third quarter of 2010.

General and administrative expenses. General and administrative expenses increased by approximately $1.2 million, or 35%, to approximately $4.6 million for the year ended December 31, 2010 compared to approximately $3.4 million for the year ended December 31, 2009. The increase was primarily attributable to increases of $940,000 in costs incurred after our IPO in April 2010 associated with operating as a public company including additional audit, tax and legal fees, increased directors and officers insurance costs, and board of directors compensation, and $120,000 of noncash stock compensation incurred in connection with evaluating financing options prior to our IPO.

Marketing expenses. Marketing expenses increased by approximately $4.1 million, or 513%, to approximately $4.9 million for the year ended December 31, 2010 compared to approximately $0.8 million for the year ended December 31, 2009. The increase was primarily attributable to increases of $1.1 million in costs related to our advertising agency s development of a detailed advertising and promotional plan for ILUVIEN, $640,000 for increased medical marketing to the physician community through medical publications, relationships with key opinion leaders, and increased presence at medical and scientific conferences, $580,000 in personnel costs as we increased the number of employees in our marketing department, $560,000 in increased corporate communications costs related to our post-launch message development and media management, $500,000 of pharmacoeconomic research to evaluate the pricing of ILUVIEN in the U.S., Canada and the EU, and $490,000 in costs related to consulting fees incurred to develop our managed market strategy.

Interest and other income. Interest and other income increased by approximately $36,000, or 97%, to approximately $73,000 for the year ended December 31, 2010 compared to approximately $37,000 for the year ended December 31, 2009. The increase was due to higher cash balances and investments as a result of the proceeds received from our IPO in April 2010.

Interest expense. Interest expense decreased by approximately $1.1 million, or 58%, to approximately $0.8 million for the year ended December 31, 2010 compared to approximately $1.9 million for the year ended December 31, 2009. The decrease was primarily attributable to a decrease of $1.3 million of interest on our $15.0 million promissory note to pSivida, offset by an increase of $230,000 of interest expense associated with our $6.3 million notes payable to Silicon Valley Bank and MidCap Financial LLP.

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Decrease (increase) in fair value of preferred stock conversion feature. During the year ended December 31, 2010, we recognized a gain of approximately $3.6 million related to the decrease in the fair value of the conversion feature of our preferred stock. During the year ended December 31, 2009, we recognized a loss of approximately $23.1 million related to the increase in the fair value of the conversion feature of our preferred stock. The changes in fair values were primarily due to changes in the estimated fair value of our common stock.

Income from discontinued operations. We recognized income from discontinued operations during the year ended December 31, 2010 of $4.0 million for a payment we received from Bausch & Lomb. This payment was related to the exercise by Bausch & Lomb of its option to extend by two years the period during which it may continue to develop an allergy product acquired from us in 2006. We did not have any income or loss from discontinued operations for the year ended December 31, 2009.

Liquidity and Capital Resources

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of $211.4 million from our inception through December 31, 2011. Prior to our IPO in April 2010, we funded our operations through the private placement of common stock, preferred stock, warrants and convertible debt, as well as by the sale of certain assets of the non-prescription business in which we were previously engaged.

On April 21, 2010, our Registration Statement on Form S-1 (as amended) was declared effective by the SEC for our IPO, pursuant to which we sold 6,550,000 shares of our common stock at a public offering price of $11.00 per share. We received net proceeds of approximately $68.4 million from this transaction, after deducting underwriting discounts and commissions.

In October 2010, we obtained a $32.5 million senior secured credit facility (Credit Facility) to help fund our working capital requirements. The Credit Facility consisted of a $20.0 million revolving line of credit and a $12.5 million term loan. The lenders advanced $6.25 million under the term loan in October 2010. To secure the repayment of any amounts borrowed under the Credit Facility, we granted to the lenders a first priority security interest in all of our assets, including our intellectual property, however, the lien on our intellectual property will be released if we meet certain financial conditions. We also agreed not to pledge or otherwise encumber our intellectual property assets. In May 2011, the Credit Facility was amended to increase the term loan to $17.25 million, of which the remaining $11.0 million would have been advanced following FDA approval of ILUVIEN, but no later than December 31, 2011. Due to the issuance of the second CRL by the FDA in November 2011 regarding our NDA for ILUVIEN, the remaining $11.0 million is no longer available to us. Additionally, we may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which we would not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to us. On February 6, 2012, we received a letter from the lenders stating that the they reserve the right to assert that recent events, including the issuance of the second CRL and a decrease in the market value of our public equity securities, may represent a material impairment of the value of the collateral under the loan agreements. To date, the lenders have not made such an assertion, and in our opinion a material impairment of the value of the collateral has not occurred.

As of December 31, 2011, we had approximately $33.6 million in cash, cash equivalents and investments in marketable securities. We believe that we have sufficient funds available to fund our operations through the projected commercialization of ILUVIEN in the seven EU countries in which ILUVIEN has been recommended for market authorization and the expected generation of revenue in late 2012, at the earliest, if at all, and therefore do not expect to have cash flow from operations until 2013, if at all. In the EU countries in which ILUVIEN has been recommended for marketing authorization, we plan to commercialize ILUVIEN, directly or with a partner. If we choose to commercialize ILUVIEN directly, we will need to raise additional capital in the future to continue to fund our operations beyond commercialization. Even if we raise additional capital, the commercialization of ILUVIEN, directly or with a partner, is dependent upon numerous factors and we cannot be sure that future sales of ILUVIEN will generate enough revenue to fund the Company s operations beyond the initial commercialization. Due to the uncertainty around the commercial launch of ILUVIEN, management cannot be certain that we will not need additional funds for its commercialization. If ILUVIEN is not approved 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.

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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 our product candidates or operate our business.

For the twelve months ended December 31, 2011, cash used in our continuing operations of $20.7 million was primarily due to our net loss from continuing operations of $22.5 million decreased by non-cash charges of $1.9 million for stock compensation expense, and $130,000 for depreciation and amortization expense. Further increasing our net cash used in continuing operations was a decrease in accounts payable, accrued liabilities and other current liabilities of $1.0 million offset by a decrease in prepaid and other current assets of $390,000. The decrease in accounts payable, accrued expenses and other current liabilities was primarily due to decreases of $1.1 million payable to the investigators in our FAME Study and ancillary clinical studies, $210,000 of amounts payable to providers of corporate communications and medical marketing services for pre-launch activities and $180,000 in amounts payable to our CROs, offset by increases of $220,000 in amounts payable to our vendors associated with the establishment of our managed care programs, $150,000 of amounts payable to vendors performing pharmaeconomic studies to evaluate the pricing of ILUVIEN in the U.S. and EU and $100,000 in employee expenses that were not paid until 2012. The decrease in prepaid and other current assets was primarily due to decreases of $240,000 in cash receivable for the U.S. government s Qualifying Therapeutic Discovery Project Tax Credit and $200,000 in interest receivable on our investments in marketable securities.

For the twelve months ended December 31, 2010, cash used in our continuing operations of $22.1 million was primarily due to our net loss from continuing operations of $17.9 million increased by non-cash gains of $3.6 million related to the change in fair value of our preferred stock conversion feature and $1.3 million associated with the repayment of our $15.0 million promissory note to pSivida in April 2010, offset by non-cash charges of $960,000 for stock compensation expense and $190,000 for depreciation and amortization expense. Further increasing our net cash used in continuing operations was an increase in prepaid and other current assets of $570,000 offset by an increase in accounts payable, accrued liabilities and other current liabilities of $130,000. The increase in prepaid and other current assets was primarily due to increases of $240,000 in cash receivable for the government s Qualifying Therapeutic Discovery Project Tax Credit, $210,000 in interest receivable on our investments offset by a reduction of $110,000 of prepaid costs related to our FAME and ancillary clinical studies as work on these studies continued. The increase in accounts payable, accrued expenses and other current liabilities was primarily due to increases of $730,000 of amounts payable to providers of corporate communications and medical marketing services for pre-launch activities and $450,000 of accrued bonuses as 2010 employee bonuses were not paid until January 2011, offset by a decrease of $1.1 million payable to the investigators in our FAME Study and ancillary clinical studies.

For the twelve months ended December 31, 2009, cash used in our continuing operations of $17.5 million was primarily due to our net loss from continuing operation of $44.2 million offset by non-cash charges including $23.1 million related to the change in fair value of our preferred stock conversion feature, $1.1 million in depreciation and amortization expense associated primarily with equipment used for the manufacture of our ILUVIEN registration batches, $550,000 in stock compensation and other expense and $300,000 in non-cash research and development expense paid to Emory University with our common stock as an initial license fee for two classes of NADPH oxidase inhibitors. Further offsetting our net losses from continuing operations were increases in accounts payable, accrued liabilities and other current liabilities of $890,000 and other long-term liabilities of $150,000, and a decrease in prepaid expenses and other current assets of $590,000. Accounts payable, accrued liabilities and other current liabilities increased due to increases of $1.1 million in amounts payable to our clinical trial sites and $550,000 in interest accrued on our $15.0 million promissory note to pSivida, partially offset by decreases of $420,000 in professional fees payable in connection with the preparation for an initial public offering of our common stock in 2008 and $390,000 in amounts payable to one of our third party manufacturers. The increase in other long term liabilities is due to interest being accrued on our promissory note to pSivida. Prepaid expenses and other current assets decreased primarily due to the progression of the technology transfer of ILUVIEN and the utilization of prepayments to our third party manufacturer.

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Net cash used in the investing activities of our continuing and discontinued operations in the years ended December 31, 2011, 2010 and 2009 was as follows:

	September 30, 2011	September 30, 2010	September 30, 2009
	Years Ended December 31, (In thousands)		
Continuing Operations	$ 25,720	$ (26,460)	$ (65)
Discontinued Operations		4,000	
Total	$ 25,720	$ (22,460)	$ (65)

For the year ended December 31, 2011, net cash provided by our investing activities of our continuing operations was $25.7 million, which was primarily due to the maturities of $25.8 million of investments in marketable securities, offset by purchases of $110,000 of property and equipment.

For the year ended December 31, 2010, net cash used in our investing activities of our continuing operations was $26.5 million, which was primarily due to the purchases of $26.4 million of investments, net of maturities, and $130,000 of computer equipment and software to facilitate the filing of our NDA for ILUVIEN and for use by new employees. Net cash provided in our discontinued operations was $4.0 million, which was due to the exercise by Bausch & Lomb of its option to extend by two years the period during which it may continue to develop an allergy product acquired from us in 2006.

For the year ended December 31, 2009, net cash used in the investing activities of our continuing operations was $65,000, which was attributable to purchases of property and equipment.

For the year ended December 31, 2011, net cash used in our financing activities was $410,000, which was primarily due to payments of $760,000 of principal on our notes payable to Silicon Valley Bank and MidCap Financial LLP, offset by proceeds of $390,000 from the exercises of stock options and purchases of common stock from our employee stock purchase plan.

For the year ended December 31, 2010, net cash provided by our financing activities was $68.2 million, which was due primarily to the receipt of net proceeds of $68.5 million, after underwriting discounts and commissions, from the sale of common stock in our IPO and our employee stock purchase program, net proceeds of $10.0 million from the exercise of warrants to purchase shares of our Series C-1 preferred stock, proceeds of $6.3 million from the issuance of our notes payable to Silicon Valley Bank and MidCap Financial LLP and $710,000 from the exercise of options and warrants to purchase shares of our common stock offset by the payment of $1.9 million of costs related to our IPO and the repayment of our $15.0 million promissory note to pSivida.

For the year ended December 31, 2009, net cash provided by our financing activities was $4.6 million, which was primarily due to net proceeds of $4.9 million received from the issuance of our Series C-1 preferred stock and warrants for our Series C-1 preferred stock.

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Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2011:

	September 30, Total	September 30, Less than 1 Year	September 30, Payments Due by Future Period 1 3 Years	September 30, 3 5 Years	September 30, 5+ Years
			(In thousands)		
Note payables	$ 5,492	$ 2,462	3,030	$	$
Operating lease	267	267			
Capital leases	18	18			
Total	$ 6,077	$ 2,747	3,030	$	$

The following amounts have not been included in the table above as the timing of the payments is uncertain:

In connection with our March 2008 agreement with pSivida we are obligated to make a milestone payment of $25.0 million upon FDA approval of ILUVIEN.

In connection with our November 2007 agreement with Dainippon Sumitomo Pharma Co., Ltd. (Dainippon) we will be required to make a payment in the amount of $200,000 to Dainippon within 30 days following the first regulatory approval of a licensed product in the U.S. by the FDA.

In January 2006, we entered into an agreement with a CRO for clinical and data management services to be performed in connection with our Phase 3 trial product for the treatment of DME in the U.S., Canada, and Europe. In accordance with the terms of the agreement, we incurred approximately $14.1 million in costs with the CRO through 2011. For the years ended December 31, 2011, 2010 and 2009, we incurred $134,000, $2.3 million, and $3.9 million, respectively, of expense associated with this agreement. There is no amount included in outsourced services payable at December 31, 2011. At December 31, 2010, $731,000 is included in outsourced services payable.

In July 2006, we entered into an agreement with a CRO for clinical services to be performed in connection with our Phase 3 trial of its product for the treatment of DME in India. In accordance with the terms of the agreement, we incurred approximately $1.4 million in costs with the CRO through 2011. For the years ended December 31, 2011, 2010, and 2009, we incurred $76,000, $242,000, and $240,000, respectively, of expense associated with this agreement. At December 31, 2011 and 2010, $1,000 and $110,000, respectively, are included in outsourced services payable.

In March 2011, we entered into an agreement with a CRO for clinical and data management services to be performed in connection with our physician utilization study which is being conducted to assess the safety and utility of the commercial version of the inserter for ILUVIEN. In accordance with the terms of the agreement, we will incur approximately $2.1 million in costs with the CRO through 2012. For the year ended December 31, 2011, we incurred $674,000 of expense associated with this agreement. At December 31, 2011, $657,000 is included in outsourced services payable.

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.

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ITEM 7A ***QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK***

We are exposed to market risk related to changes in interest rates. As of December 31, 2011, we had approximately $33.6 million in cash, cash equivalents and investments in marketable securities. Our interest income is exposed to market risk primarily due to changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

Our interest expense is exposed to market risk primarily due to the variability of interest on our revolving loan agreement which is calculated as the prime rate plus 2.50% (with a rate floor of 6.50%). As of December 31, 2011, we have not borrowed any funds available under the revolving loan agreement.

We contract for the conduct of some of our clinical trials and other research and development activities with CROs and investigational sites in the U.S., Europe and India. We may be subject to exposure to fluctuations in foreign exchange rates in connection with these agreements. We do not hedge our foreign currency exposures. We have not used derivative financial instruments for speculation or trading purposes.

ITEM 8 ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

The financial statements and related financial statement schedules required to be filed are indexed on page 77 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, 2011. 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, 2011, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officer and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Under the supervision and with the participation of management, including our principal executive and financial officers, we assessed our internal control over financial reporting as of December 31, 2011, based on criteria for effective internal control over financial reporting established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on this assessment, our management concluded that we maintained effective internal control over financial reporting as of December 31, 2011 based on the specified criteria.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fourth quarter of 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

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

ITEM 9B *Other Information*

None.

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PART III

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

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, 2011, 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, 2011, 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.

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ITEM 12 ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

Except for the information set forth below, the 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, 2011, under the caption Security Ownership by Certain Beneficial Owners and Management and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

Equity Compensation Plan Information

The following table provides information as of December 31, 2011, with respect to shares of our common stock that may be issued, subject to certain vesting requirements, under our existing equity compensation plans, including our 2010 Equity Incentive Plan (2010 Plan), 2005 Equity Incentive Plan (2005 Plan), 2004 Equity Incentive Plan (2004 Plan) and our 2010 Employee Stock Purchase Plan (ESPP).

Plan Category	September 30, A Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights	September 30, B Weighted-Average Exercise Price of Outstanding Options, Warrants, and Rights	September 30, C Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)
Equity compensation plans approved by security holders	2,690,161(1)	$ 3.97	3,115,038(2)
Equity compensation plans not approved by security holders			
Total	2,690,161	$ 3.97	3,115,038

(1) Of these shares, 580,398 were subject to options then outstanding under the 2010 Plan, 1,691,120 were subject to options then outstanding under the 2005 Plan and 335,928 were subject to options then outstanding under the 2004 Plan.

(2) Represents 2,642,526 shares of common stock available for issuance under our 2010 Plan and 472,512 shares of common stock available for issuance under our ESPP. No shares are available for future issuance under the 2005 Plan or 2004 Plan. In addition, our 2010 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year equal to the least of: (1) 2,000,000 shares of our common stock; (2) 4% of the shares of common stock outstanding at that time; and (3) such other amount as our board of directors may determine. On January 1, 2012, an additional 1,257,095 shares became available for future issuance under our 2010 Plan in accordance with the annual increase. In addition, our ESPP provides for annual increases in the number of shares available for issuance thereunder equal to such number of shares necessary to restore the number of shares reserved thereunder to 494,422 shares of our common stock. As such, on January 1, 2012, an additional 21,910 shares became available for future issuance under our ESPP. These additional shares from the annual increase under the 2010 Plan and the ESPP are not included in the table above.

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

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, 2011, under the caption Corporate Governance 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, 2011, 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.

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 77. 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.

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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 30, 2012.

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 30, 2012
/s/ Richard S. Eiswirth, Jr. Richard S. Eiswirth, Jr.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2012
/s/ Philip R. Tracy Philip R. Tracy	Chairman of the Board of Directors	March 30, 2012
/s/ Mark J. Brooks Mark J. Brooks	Director	March 30, 2012
/s/ Brian K. Halak, Ph.D. Brian K. Halak, Ph.D.	Director	March 30, 2012
/s/ James R. Largent. James R. Largent	Director	March 30, 2012
/s/ Peter J. Pizzo, III Peter J. Pizzo, III	Director	March 30, 2012
/s/ Calvin W. Roberts, M.D. Calvin W. Roberts, M.D.	Director	March 30, 2012
/s/ Glen Bradley, Ph.D. Glen Bradley, Ph.D.	Director	March 30, 2012

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ALIMERA SCIENCES, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Alimera Sciences, Inc.

Alpharetta, Georgia

We have audited the accompanying balance sheets of Alimera Sciences, Inc. (the Company) as of December 31, 2011 and 2010, and the related statements of operations, changes in stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2011. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

As described in Note 4, the accompanying 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, accumulated deficit, and current lack of a commercial product raise substantial doubt about its ability to continue as a going concern. Management s plans concerning these matters are also discussed in Note 4. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Deloitte & Touche LLP

Atlanta, Georgia

March 30, 2012

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ALIMERA SCIENCES, INC.

BALANCE SHEETS

AS OF DECEMBER 31, 2011 AND 2010

	September 30, 2011	September 30, December 31, 2010
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 33,108	$ 28,514
Investments in marketable securities	500	26,330
Prepaid expenses and other current assets	692	1,078
Deferred financing costs	201	272
Total current assets	34,501	56,194
PROPERTY AND EQUIPMENT at cost less accumulated depreciation	197	220
TOTAL ASSETS	$ 34,698	$ 56,414
CURRENT LIABILITIES:		
Accounts payable	$ 1,948	$ 1,677
Accrued expenses (Note 6)	1,638	2,731
Outsourced services payable	658	841
Note payable (Note 9)	2,462	1,157
Capital lease obligations	12	11
Total current liabilities	6,718	6,417
LONG-TERM LIABILITIES:		
Note payable, net of discount less current portion (Note 9)	2,868	4,767
Other long-term liabilities	134	18
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS EQUITY:		
Preferred stock, $.01 par value 10,000,000 shares authorized and no shares issued and outstanding at December 31, 2011 and at December 31, 2010		
Common stock, $.01 par value 100,000,000 shares authorized and 31,427,355 shares issued and outstanding at December 31, 2011 and 100,000,000 shares authorized and 31,255,953 shares issued and outstanding at December 31, 2010	314	313
Additional paid-in capital	235,619	233,338
Common stock warrants	415	415
Accumulated deficit	(211,370)	(188,854)
TOTAL STOCKHOLDERS EQUITY	24,978	45,212
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 34,698	$ 56,414

See Notes to Financial Statements.

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ALIMERA SCIENCES, INC.

STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31, 2011, 2010, AND 2009

	September 30, 2011	September 30, 2010	September 30, 2009
	Years Ended December 31, (In thousands, except share and per share data)		
RESEARCH AND DEVELOPMENT EXPENSES	$ 7,100	$ 12,581	$ 15,057
GENERAL AND ADMINISTRATIVE EXPENSES	6,203	4,610	3,407
MARKETING EXPENSES	8,104	4,880	752
OPERATING EXPENSES	21,407	22,071	19,216
INTEREST AND OTHER INCOME	16	73	37
INTEREST EXPENSE	(1,125)	(848)	(1,897)
GAIN ON EARLY EXTINGUISHMENT OF DEBT (NOTE 7)		1,343	
DECREASE (INCREASE) IN FAIR VALUE OF PREFERRED STOCK CONVERSION FEATURE		3,644	(23,142)
LOSS FROM CONTINUING OPERATIONS	(22,516)	(17,859)	(44,218)
INCOME FROM DISCONTINUED OPERATIONS (NOTE 3)		4,000	
NET LOSS	(22,516)	(13,859)	(44,218)
BENEFICIAL CONVERSION FEATURE OF PREFERRED STOCK (NOTE 11)			(355)
PREFERRED STOCK ACCRETION		(466)	(623)
PREFERRED STOCK DIVIDENDS		(2,638)	(7,225)
NET LOSS APPLICABLE TO COMMON SHAREHOLDERS	$ (22,516)	$ (16,963)	$ (52,421)
NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS Basic and diluted	$ (0.72)	$ (0.77)	$ (34.55)
WEIGHTED AVERAGE SHARES OUTSTANDING Basic and diluted	31,362,574	22,167,873	1,517,365

See Notes to Financial Statements.

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ALIMERA SCIENCES, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)

FOR THE YEARS ENDED DECEMBER 31, 2011, 2010, AND 2009

	September 30,	September 30,	September 30,	September 30,	September 30,	September 30,	September 30,
	Common Stock		Additional	Series C-1			
	Shares	Amount	Paid-In Capital	Preferred Warrants	Common Warrants	Accumulated Deficit	Total
	(In thousands, except share data)						
BALANCE December 31, 2008	1,490,113	51	3,474		58	(119,470)	(115,887)
Redeemable preferred stock accretion and dividends						(7,848)	(7,848)
Issuance of common stock	92,351	3	458				461
Exercise of stock options	3,860		6				6
Exercise of common stock warrants	12,247		31				31
Retirement of common stock warrants			1		(1)		
Issuance of series C-1 preferred stock warrants				1,472			1,472
Accretion of series C-1 preferred stock beneficial conversion feature (Note 11)			355			(355)	
Stock compensation expense			511				511
Net loss						(44,218)	(44,218)
BALANCE December 31, 2009	1,598,571	54	4,836	1,472	57	(171,891)	(165,472)
Redeemable preferred stock accretion and dividends						(3,104)	(3,104)
Issuance of common stock	29,421,942	256	192,707				192,963
Issuance of common warrants (Note 9)					366		366
Exercise of stock options	44,499	1	93				94
Exercise of common stock warrants	190,941	2	618		(8)		612
Exercise of series C-1 preferred stock warrants				(1,472)			(1,472)
IPO costs			(2,282)				(2,282)
Elimination of preferred stock conversion feature			36,528				36,528

upon conversion of preferred stock to common stock (Note 11)								
Stock compensation expense			838					838
Net loss						(13,859)		(13,859)
BALANCE December 31, 2010	31,255,953	$ 313	$ 233,338	$	$ 415	$ (188,854)	$	45,212
Issuance of common stock	21,910		154					154
Exercise of stock options	144,787	1	235					236
Exercise of common stock warrants	4,705		19					19
Stock compensation expense			1,873					1,873
Net loss						(22,516)		(22,516)
BALANCE December 31, 2011	31,427,355	$ 314	$ 235,619	$	$ 415	$ (211,370)	$	24,978

See Notes to Financial Statements.

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ALIMERA SCIENCES, INC.

STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2011, 2010, AND 2009

	September 30, 2011	September 30, 2010	September 30, 2009
	Years Ended December 31,		
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (22,516)	$ (13,859)	$ (44,218)
Income from discontinued operations (Note 3)		(4,000)	
Change in fair value of preferred stock conversion feature		(3,644)	23,142
Gain from early extinguishment of debt		(1,343)	
Depreciation and amortization	133	194	1,098
Stock compensation expense and other	1,873	957	551
Amortization of deferred financing costs and debt discount	286	73	
Unrealized investment (loss) gain	(2)	2	
Noncash research and development expense (Note 8)			300
Changes in assets and liabilities:			
Prepaid expenses and other current assets	386	(566)	591
Accounts payable	271	391	183
Accrued expenses and other current liabilities	(1,275)	(258)	705
Other long-term liabilities	128		153
Net cash used in operating activities of continuing operations	(20,716)	(22,053)	(17,495)
Net cash used in operating activities of discontinued operations			(43)
Net cash used in operating activities	(20,716)	(22,053)	(17,538)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of investments		(39,927)	
Proceeds from maturities of investments	25,830	13,595	
Purchases of property and equipment	(110)	(128)	(65)
Net cash provided by (used in) investing activities of continuing operations	25,720	(26,460)	(65)
Net cash provided by investing activities of discontinued operations (Note 3)		4,000	
Net cash provided by (used in) investing activities	25,720	(22,460)	(65)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from sale of Series C-1 preferred stock net		9,997	4,897
Proceeds from exercise of stock options	236	94	7
Proceeds from exercise of common stock warrants	19	613	31
Proceeds from sale of common stock	154	68,470	

Payment of common stock offering costs		(1,942)	(339)
Proceeds from issuance of notes payable (Note 9)		6,250	
Payment of debt issuance costs (Note 9)	(50)	(305)	
Repayment of pSivida note payable (Note 7)		(15,000)	
Payment of principal on note payable	(758)		
Payments on capital lease obligations	(11)	(8)	(10)
Net cash (used in) provided by financing activities	(410)	68,169	4,586
NET INCREASE (DECREASE) IN CASH	4,594	23,656	(13,017)
CASH Beginning of period	28,514	4,858	17,875
CASH End of period	$ 33,108	$ 28,514	$ 4,858
SUPPLEMENTAL DISCLOSURES:			
Cash paid for interest	$ 656	$ 681	$ 1,200
Supplemental schedule of noncash investing and financing activities:			
Reclassification of fair value of preferred stock conversion feature to additional paid-in capital	$	$ 36,528	$
IPO issuance costs charged to equity	$	$ 3,994	$
Notes payable issuance costs charged to equity (Note 9)	$	$ 366	$
Property and equipment acquired under capital leases	$	$ 36	$
Common stock issued for research and development expense (Note 8)	$	$	$ 300

There were no income tax or dividend payments made for the years ended December 31, 2011, 2010 and 2009.

See Notes to Financial Statements.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS Notes to Consolidated Financial Statements

1. NATURE OF OPERATIONS

Alimera Sciences, Inc. (the Company) is a biopharmaceutical 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 most advanced product candidate is ILUVIEN®, which is being developed for the treatment of diabetic macular edema (DME). DME is a disease of the retina which affects individuals with diabetes and can lead to severe vision loss and blindness.

In February 2012, ILUVIEN received a positive outcome from the Decentralized Procedure with the issuance of a Final Assessment Report (FAR) from the United Kingdom Medicines Healthcare products Regulatory Agency (MHRA) indicating that it is approvable for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain.

On April 21, 2010, the Company s Registration Statement on Form S-1 (as amended) was declared effective by the Securities and Exchange Commission (SEC) for the Company s initial public offering (IPO), pursuant to which the Company sold 6,550,000 shares of its common stock at a public offering price of $11.00 per share. The Company received net proceeds of approximately $68,395,000 from this transaction, after deducting underwriting discounts and commissions. In connection with its IPO, the Company effected a 1 for 3.4 reverse split of the Company s common and preferred stock. All share and per share amounts in the accompanying financial statements and notes have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

In September 2010, the Company completed two Phase 3 pivotal clinical trials (collectively, the FAME™ Study) on both a high and low dose of ILUVIEN involving 956 patients in sites across the U.S., Canada, Europe and India to assess the efficacy and safety of ILUVIEN in the treatment of DME over a 36 month period. Based on an analysis of the data through month 24 of the FAME Study in December 2009, the Company submitted a New Drug Application (NDA) in June 2010 for the low dose of ILUVIEN in the U.S. with the U.S. Food and Drug Administration (FDA), followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain under the European Union s (EU) decentralized procedure in July 2010 with the United Kingdom acting as the Reference Member State (RMS). The RMS is responsible for coordinating the review and approval process between itself and the other involved countries, or Concerned Member States.

In November 2010, the Company received a Preliminary Assessment Report (PAR) from the RMS and in December 2010, it received a Complete Response Letter (CRL) from the FDA regarding its respective registration filings. The primary concerns expressed in both the PAR and the CRL centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of the FAME Study data through its final readout at month 36, the Company determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filings.

The Company submitted its response to the CRL to the FDA in May 2011, including additional safety and efficacy data through month 36 of the FAME Study with an emphasis on the chronic DME subgroup. In July 2011, the Company submitted a draft response to the PAR to the MHRA, the regulatory body in the RMS, which included a similar data package.

In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its current form due primarily to concerns about the benefit to risk profile of ILUVIEN. Management expects to meet with the FDA in the second quarter of 2012 to discuss the second CRL and the regulatory status of ILUVIEN.

After meetings and discussions with the MHRA, the Company finalized and submitted its response to the PAR to the MHRA in November 2011. In February 2012, The Company received a FAR from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the DCP was complete. Upon receipt of the FAR, the Company entered the national phase with each of these seven countries. 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 patients with chronic DME.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

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

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.

Investments In accordance with ASC 320, *Debt and Equity Securities,* the Company classifies its investments as trading securities. The Company recognizes the investments at fair value and includes all unrealized holding gains and losses in the statement of operations.

Long-Lived Assets 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, five years; office equipment, three to five years; and software, three years.

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 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 provisions of ASC 740-10 were effective beginning January 1, 2008, but the Company early adopted effective January 1, 2007. 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 s adoption of ASC 740-10 did not result in a cumulative effect adjustment to retained earnings. 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 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 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.

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 values of such stock at the dates of grant. Compensation cost is recognized for all share-based awards granted subsequent to January 1, 2005 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.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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 s previously outstanding preferred stock (Note 11) contained certain features which were considered embedded derivatives. The Company accounted for such embedded derivative financial instruments in accordance with ASC 815, *Derivatives and Hedging*. The Company recorded derivative financial instruments as assets or liabilities in the Company s balance sheet measured at fair value. The Company recorded the changes in fair value of such instruments as noncash gains or losses in the consolidated statement of operations. The Company s embedded derivative financial instruments were eliminated in the Company s IPO in April, 2010. The Company held no derivative financial instruments at December 31, 2011 and 2010, respectively. The Company does not enter into derivatives for trading purposes.

Fair Value of Financial Instruments The carrying amounts of the Company s financial instruments, including cash and cash equivalents, receivables, and current liabilities approximate their fair value because of their short maturities. The carrying amounts of the Company s investments are stated at their fair market value in accordance with ASC 820, *Fair Value Measurements and Disclosures*.

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. Total securities that could potentially dilute basic EPS in the future 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,		
	September 30, 2011	**September 30, 2010**	**September 30, 2009**
Series A preferred stock and convertible accrued dividends		2,245,484	7,005,145
Series B preferred stock		2,291,242	7,147,894
Series C preferred stock		1,861,457	5,807,112
Series C-1 preferred stock		888,298	339,408
Series C-1 preferred stock warrants		42,426	678,820
Common stock warrants	26,313	97,757	45,297
Stock options	1,463,556	1,704,787	1,125,916
Total	1,489,869	9,131,451	22,149,592

Reporting Segments The Company does not report segment information as it operates in only one business segment.

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

Recent Accounting Pronouncements In January 2010, the FASB issued amendments to the existing fair value measurements and disclosures guidance which requires new disclosures and clarifies existing disclosure requirements. The purpose of these amendments is to provide a greater level of disaggregated information as well as more disclosure around valuation techniques and inputs to fair value measurements. The guidance was effective commencing with the Company s 2010 fiscal year. The adoption of this guidance did not have a material impact on the Company s financial statements.

In May 2011, the FASB amended the FASB Accounting Standards Codification to converge the fair value measurement guidance in U.S. GAAP and International Financial Reporting Standards. Some of the amendments clarify the application of existing fair value measurement requirements, while other amendments change particular principles in fair value measurement guidance. In addition, the amendments require additional fair value disclosures. The amendments are effective for fiscal years beginning after December 15, 2011 and should be applied prospectively.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. DISCONTINUED OPERATIONS

In October 2006, management and the board of directors of the Company approved a plan to discontinue the operations of its non-prescription ophthalmic pharmaceutical business (the OTC Business). The plan included the sale of the assets of the Company s OTC Business and also the termination of its sales and marketing personnel. The Company previously determined that the discontinued OTC Business comprised operations and cash flows that could be clearly distinguished, operationally and for financial reporting purposes, from the rest of the Company. Accordingly, the results of operations for the discontinued OTC Business have been presented as discontinued operations. During the year ended December 31, 2010, the Company received a $4,000,000 option payment from the acquirer of the assets of the OTC Business to provide it with an additional two years to develop one of the acquired products. In 2011, the acquirer informed the Company that it was no longer pursuing development of the product. There were no revenues or expenses from discontinued operations during the years ended December 31, 2011 and 2009, respectively. The following table presents basic and diluted earnings per share from discontinued operations for the year ended December 31, 2010 (in thousands except share and per share data):

	September 30,
Net income from discontinued operations	$ 4,000
Net income from discontinued operations per share Basic and diluted	$ 0.18
Weighted-average shares outstanding Basic and diluted	22,167,873

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

4. FACTORS AFFECTING OPERATIONS

To date the Company has incurred recurring losses, negative cash flow from operations, and has accumulated a deficit of $211,370,000 from the Company s inception through December 31, 2011. As of December 31, 2011, the Company had approximately $33,608,000 in cash, cash equivalents, and investments in marketable securities. In October 2010, the Company obtained a $32,500,000 senior secured credit facility (Credit Facility) to help fund its working capital requirements (Note 9). The Credit Facility consisted of a $20,000,000 working capital revolver and a $12,500,000 term loan. The lenders have advanced $6,250,000 under the term loan. In May 2011, the Credit Facility was amended to increase the term loan to $17,250,000, the remaining $11,000,000 which would have been advanced following FDA approval of ILUVIEN, but no later than December 31, 2011. As a result of the issuance of the second CRL by the FDA in November 2011 regarding the NDA for ILUVIEN, the remaining $11,000,000 is no longer available to the Company. Additionally, the Company may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which the Company would not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to the Company. On February 6, 2012, the Company received a letter from the lenders stating that they reserve the right to assert that recent events, including the issuance of the second CRL and a decrease in the market value of the Company s public equity securities, may represent a material impairment of the value of the collateral under the loan agreements. To date, the lenders have not made such an assertion, and in the opinion of management a material impairment of the value of the collateral has not occurred.

Management believes it has sufficient funds available to fund its operations through the projected commercialization of ILUVIEN in the EU countries and the expected generation of revenue in late 2012, at the earliest, if at all, and therefore does not expect to have cash flow from operations until 2013, if at all. In the EU countries in which ILUVIEN has been recommended for marketing authorization, the Company plans to commercialize ILUVIEN, directly or with a partner. If the Company chooses to commercialize ILUVIEN directly, it will need to raise additional capital in the future to continue to fund its operations beyond commercialization. Even if the Company raises additional capital, the commercialization of ILUVIEN, directly or with a partner, is dependent upon numerous factors and management cannot be sure that ILUVIEN will generate enough revenue to fund the Company s operations beyond its initial EU launch. Due to the uncertainty around the commercial launch of ILUVIEN, management also cannot be certain that the Company will not need additional funds for the commercial launch of ILUVIEN. If ILUVIEN is not approved or does not generate sufficient revenue, the Company may adjust its commercial plans so that it can continue to operate with its existing cash resources or seek to raise additional financing.

These matters raise substantial doubt about the Company s ability to continue as a going concern. The accompanying financial statements do not include any adjustments that may result from the outcome of these uncertainties.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	September 30, 2011	December 31, 2010
	(In thousands)	
Furniture and fixtures	$ 300	$ 292
Office equipment	377	415
Software	423	489
Leasehold improvements	45	12
Manufacturing equipment	52	40
Total property and equipment	1,197	1,248
Less accumulated depreciation and amortization	(1,000)	(1,028)
Property and equipment net	$ 197	$ 220

Depreciation and amortization expense associated with property and equipment of the continuing operations totaled $133,000, $194,000 and $1,098,000 for the years ended December 31, 2011, 2010 and 2009, respectively.

During the year ended December 31, 2009, the Company recognized $860,000 of depreciation and amortization expense associated with equipment used for the manufacture of registration batches of ILUVIEN.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	September 30, 2011	December 31, 2010
	(In thousands)	
Accrued clinical investigator expenses	$ 788	$ 1,911
Accrued severance expenses (1)	206	
Accrued other compensation expenses	621	730
Other accrued expenses	23	90
Total accrued expenses	$ 1,638	$ 2,731

(1) In connection with the FDA s CRL issued to the Company in November 2011 (Note 1), management and the board of directors of the Company approved a reduction in force pursuant to which the Company terminated the employment of 11 employees. The affected employees were notified in December 2011. The Company incurred $401,000 of severance expense in December 2011 in connection with the reduction in force of which $206,000 was payable at December 31, 2011. All amounts due at December 31, 2011 were paid to affected employees during the first quarter of 2012.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

7. PSIVIDA AGREEMENT

In March 2008, in connection with the Company s collaboration agreement with pSivida U.S., Inc. (pSivida), the licensor of the ILUVIEN technology, the Company and pSivida amended and restated the agreement to provide the Company with 80% of the net profits and pSivida with 20% of the net profits derived by the Company from the sale of ILUVIEN. In connection with the amended and restated agreement, the Company also agreed to:

- pay $12.0 million to pSivida upon the execution of the March 2008 agreement;
- issue a $15.0 million promissory note to pSivida;
- forgive all outstanding development payments, penalties and interest as of the effective date of the March 2008 agreement, which totaled $6.8 million;
- continue responsibility for regulatory, clinical, preclinical, manufacturing, marketing and sales for the remaining development and commercialization of the products;
- assume all financial responsibility for the development of the products and assume 80% of the commercialization costs of the products (instead of 50% as provided under the February 2005 agreement); and
- make an additional milestone payment of $25.0 million after the first product under the March 2008 agreement has been approved by the FDA.

The $15,000,000 promissory note accrued interest at 8% payable quarterly and was payable in full to pSivida upon the earlier of a liquidity event as defined in the note (including an initial public offering of the Company s common stock greater than $75,000,000), the occurrence of an event of default under the Company s agreement with pSivida or September 30, 2012. If the note was not paid in full by March 31, 2010, the interest rate was to increase to 20% effective as of April 1, 2010, and the Company would be required to begin making principal payments of $500,000 per month. On April 27, 2010, the Company paid pSivida $15,225,000 in principal and interest to satisfy the note payable. As a result, the Company recognized a gain of $1,343,000 on the extinguishment of this debt in the accompanying financial statements for the nine month period ended September 30, 2010.

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 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. As of December 31, 2011 and 2010, the Company was owed $4,064,000 and $2,224,000, respectively, in commercialization costs. Due to the uncertainty of future net profits, the Company has fully reserved these amounts in the accompanying financial statements.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

8. LICENSE AGREEMENTS

In November 2007, the Company entered into a license agreement with Dainippon Sumitomo Pharma Co., Ltd. (Dainippon) whereby Dainippon granted the Company a non-exclusive, worldwide, royalty free license to patent rights under specific patents and patent applications. The Company paid $200,000 to Dainippon shortly after the execution of this license agreement and will be required to make an additional payment in the amount of $200,000 to Dainippon within 30 days following the first regulatory approval of a licensed product in the U.S. by the FDA.

In August 2007, the Company entered into an exclusive option agreement with Emory University for the licensing of certain patents for a class of compounds that the Company intends to evaluate for the treatment of diseases of the eye, primarily the dry form of age related macular degeneration. The Company made an initial payment of $75,000 during the year ended December 31, 2007 for the option to license the compounds at the end of an evaluation period. The Company exercised its option and entered into an exclusive license in the field of ophthalmology in July 2009, and issued Emory University and its inventor $150,000 in common stock based on the estimated fair value at the time of issuance. The Company would have owed Emory University up to $5,775,000 in additional development and regulatory milestones under the terms of the license agreement. However, the Company elected to terminate this license agreement in accordance with its terms in September 2011.

In February 2008, the Company entered into a similar exclusive option agreement with Emory University for the patent rights to a second class of compounds which will be evaluated for the treatment of diseases of the eye, primarily the dry form of age related macular degeneration. The initial payment was $60,000. The Company expensed this amount as research and development expense in February 2008. The Company exercised its option and entered into an exclusive license in the field of ophthalmology in August 2009, and issued Emory University and its inventor $150,000 in common stock based on the estimated fair value at the time of issuance in December 2009. The Company would have owed Emory University up to $5,850,000 in additional development and regulatory milestones under the terms of this license agreement. However, the Company elected to terminate this license agreement in accordance with its terms in September 2011.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

9. TERM AND REVOLVING LOAN AGREEMENT

Term Loan

On October 14, 2010 (Effective Date), the Company entered into a Loan and Security Agreement (Term Loan Agreement) with Silicon Valley Bank and MidCap Financial LLP (Lenders). Pursuant to the original terms of the Term Loan Agreement, the Company was entitled to borrow up to $12.5 million, of which $6.25 million (Term Loan A) was advanced to the Company on the Effective Date. The Company was entitled to draw down the remaining $6.25 million under the Term Loan (Term Loan B and together with Term Loan A, the Term Loan) if the FDA approved the Company s NDA for ILUVIEN prior to or on July 31, 2011. On May 16, 2011, the Company and the Lenders amended the Term Loan Agreement (Term Loan Modification) to, among other things, extend until December 31, 2011 the date by which the FDA must approve the NDA in order for the Company to draw down Term Loan B and increase the amount of Term Loan B by $4.75 million to $11.0 million. In addition, the maturity date of the Term Loan was extended from October 31, 2013 to April 30, 2014 (Term Loan Maturity Date). As a result of the issuance of the second CRL by the FDA in November 2011 (Note 1), the Company did not drawn down Term Loan B by December 31, 2011 and the availability to draw down Term Loan B expired.

The Company was required to pay interest on Term Loan A at a rate of 11.5% on a monthly basis through July 31, 2011, and since August 2011, the Company has been required to repay the principal in 33 equal monthly installments plus interest at a rate of 11.5%.

If the Company repays Term Loan A prior to maturity, the Company must pay to the Lenders a prepayment fee equal to 5.0% of the total amount of principal then outstanding if the prepayment had occurred within one year after the funding date of Term Loan A (Term Loan A Funding Date), 3.0% of such amount if the prepayment occurs between one year and two years after the Term Loan A Funding Date and 1.0% of such amount if the prepayment occurs thereafter (subject to a 50% reduction in the event that the prepayment occurs in connection with an acquisition of the Company).

To secure the repayment of any amounts borrowed under the Term Loan Agreement, the Company granted to the Lenders a first priority security interest in all of its assets, including its intellectual property, however, the lien on the Company s intellectual property will be released if the Company meets certain financial conditions. The occurrence of an event of default could result in the acceleration of the Company s obligations under the Term Loan Agreement and an increase to the applicable interest rate, and would permit the Lenders to exercise remedies with respect to the collateral under the Term Loan Agreement. The Company also agreed not to pledge or otherwise encumber its intellectual property assets. Additionally, the Company must seek the Lenders approval prior to the payment of any cash dividends to its stockholders.

On the Effective Date, the Company issued to the Lenders warrants to purchase an aggregate of up to 39,773 shares of the Company s common stock. Each of the warrants is exercisable immediately, has a per-share exercise price of $11.00 and has a term of 10 years. The Company estimated the fair value of warrants granted using the Black-Scholes option pricing model. The aggregate fair value of the warrants was estimated to be $389,000. The Company allocated a portion of the proceeds from the Term Loan Agreement 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 is being amortized to interest expense using the effective interest method. The Lenders will have certain registration rights with respect to the shares of common stock issuable upon exercise of all of their warrants. The Company paid to the Lenders an upfront fee of $62,500 on the Effective Date and an additional fee of $50,000 in connection with the Term Loan Modification. In accordance with ASC 470-50-40-17, *Debt Modifications and Extinguishments*, the Company is amortizing the unamortized discount on Term Loan A and the $50,000 modification fee over the remaining term of Term Loan A, as modified. The Lenders also hold warrants to purchase an aggregate of up to 69,999 shares of the Company s common stock, which were exercisable only if Term Loan B had been advanced to the Company. Each of these warrants has a per share exercise price of $11.00 and a term of 10 years. In addition, the Lenders would have had certain registration rights with respect to the shares of common stock issuable upon exercise of all of their warrants.

The Company is required to maintain its primary operating and other deposit accounts and securities accounts with Silicon Valley Bank, which accounts must represent at least 50% of the dollar value of the Company s accounts at all financial institutions.

On February 6, 2012, the Company received a letter from the Lenders stating that they reserve the right to assert that recent events, including the issuance of the second CRL and a decrease in the market value of the Company s public equity securities, may represent a material impairment of

the value of the collateral under the Loan Agreements. To date, the Lenders have not made such an assertion, and in the opinion of management a material impairment of the value of the collateral has not occurred.

Working Capital Revolver

Also on the Effective Date, the Company and Silicon Valley Bank entered into a Loan and Security Agreement, pursuant to which the Company obtained a secured revolving line of credit (Working Capital Revolver) from Silicon Valley Bank with borrowing availability up to $20,000,000 (Revolving Loan Agreement). On May 16, 2011, the Company and Silicon Valley Bank amended the Revolving Loan Agreement to extend the maturity date of the Working Capital Revolver from October 31, 2013 to April 30, 2014.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The Working Capital Revolver is a working capital-based revolving line of credit in an aggregate amount of up to the lesser of (i) $20,000,000, or (ii) 85% of eligible domestic accounts receivable. As of December 31, 2011 and 2010, respectively, no amounts under the Working Capital Revolver were outstanding or available to the Company. The Company may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which it would not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to the Company.

Amounts advanced under the Working Capital Revolver will bear interest at an annual rate equal to Silicon Valley Bank s prime rate plus 2.50% (with a rate floor of 6.50%). Interest on the Working Capital Revolver will be due monthly, with the balance due at the maturity date. On the Effective Date, the Company paid to Silicon Valley Bank an upfront fee of $100,000. In addition, if the Company terminates the Working Capital Revolver prior to maturity, it will be required to pay to Silicon Valley Bank a fee of $400,000 if the termination occurs within one year after the Effective Date and a fee of $200,000 if the termination occurs more than one year after the Effective Date (each a Termination Fee), provided in each case that such Termination Fee will be reduced by 50% in the event of an acquisition of the Company.

To secure the repayment of any amounts borrowed under the Revolving Loan Agreement, the Company granted to Silicon Valley Bank a first priority security interest in all of its assets, including its intellectual property, however, the lien on the Company s intellectual property will be released if the Company meets certain financial conditions. The occurrence of an event of default could result in the acceleration of the Company s obligations under the Revolving Loan Agreement and an increase to the applicable interest rate, and would permit Silicon Valley Bank to exercise remedies with respect to the collateral under the Revolving Loan Agreement. The Company also agreed not to pledge or otherwise encumber its intellectual property assets. Additionally, the Company must seek Silicon Valley Bank s approval prior to the payment of any cash dividends to its stockholders.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

10. COMMITMENTS AND CONTINGENCIES

Term Note Payable In October 2010, the Company received proceeds of $6,250,000 from the issuance of a Note Payable to certain lenders (Note 9). As of December 31, 2011 a schedule of future minimum principal payments under the Note Payable is as follows (in thousands):

Years Ending December 31	September 30,
2012	$ 2,462
2013	2,273
2014	757
Total	$ 5,492

As of December 31, 2011, the Company had $183,000 of accrued and unpaid interest payable on the Note Payable. As of December 31, 2010, the Company had no accrued and unpaid interest payable on the Note Payable.

Operating Leases The Company leases office space and equipment under noncancelable 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 December 2011, the Company signed an extension of its lease for office space through December 31, 2012. The Company s future minimum payments under this operating lease from December 31, 2011 to December 31, 2012 are $267,000.

Rent expense under all operating leases totaled approximately $259,000, $256,000 and $229,000 for the years ended December 31, 2011, 2010, and 2009, respectively.

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

At December 31, 2011, 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	September 30,
2012	$ 13
2013	6
Total	19
Less amount representing interest	(1)
Present value of minimum lease payments	18

Less current portion	(12)
Noncurrent portion	$ 6

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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

	September 30, 2011	September 30, December 31, 2010
	(In thousands)	
Office equipment	$ 36	$ 60
Less accumulated amortization	(19)	(32)
Total	$ 17	$ 28

Depreciation expense associated with office equipment under capital leases was $10,000 for each of the years ended December 31, 2011, 2010 and 2009, respectively.

Significant Agreements In January 2006, the Company entered into an agreement with a CRO for clinical and data management services to be performed in connection with the Phase 3 trial product for the treatment of DME in the U.S., Canada, and Europe. In accordance with the terms of the agreement, the Company incurred approximately $14,600,000 in costs with the CRO through 2011. For the years ended December 31, 2011, 2010 and 2009, the Company incurred $134,000, $2,300,000 and $3,900,000, respectively, of expense associated with this agreement. There is no amount included in outsourced services payable at December 31, 2011. At December 31, 2010 $731,000 is included in outsourced services payable.

In July 2006, the Company entered into an agreement with a CRO for clinical services to be performed in connection with the Phase 3 trial of its product for the treatment of DME in India. In accordance with the terms of the agreement, the Company incurred approximately $1,400,000 in costs with the CRO through 2011. For the years ended December 31, 2011, 2010 and 2009, the Company incurred $76,000, $242,000 and $240,000, respectively, of expense associated with this agreement. At December 31, 2011 and 2010, $1,000 and $110,000, respectively, are included in outsourced services payable.

In February 2010, the Company entered into an agreement with a third party manufacturer for the manufacture of the ILUVIEN insert, 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 CRO for clinical and data management services to be performed in connection with a physician utilization study which is being conducted to assess the safety and utility of the commercial version of the ILUVIEN applicator. In accordance with the terms of the agreement, the Company will incur approximately $2,100,000 in costs with the CRO through 2012. For the year ended December 31, 2011, the Company incurred $670,000 of expense associated with this agreement. At December 31, 2011, $657,000 is included in outsourced services payable.

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, 2012 and 2011, the salaries ranged from $254,000 to $432,000, respectively. 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.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

11. PREFERRED STOCK

Prior to the Company s IPO, the Company had four series of preferred stock. On April 27, 2010 and in connection with the IPO, all outstanding shares of the Company s preferred stock were converted into 22,863,696 shares of common stock and all preferred stock dividends were eliminated. Significant terms of all series of the preferred stock were as follows:

Dividends were cumulative and accrued on a daily basis at the rate of 8% per annum beginning on the date of issuance and based on the original issue price, as adjusted for any stock dividend, stock split, combination, or other event involving the preferred stock. Dividends accrued, whether or not declared, annually and were due and payable when and if declared by the Board of Directors, upon a liquidating event, as defined in the Company s certificate of incorporation, upon redemption of the preferred stock, as defined in the Company s certificate of incorporation, or on the date that the preferred stock was otherwise acquired by the Company.

Upon any liquidation, dissolution, or winding up of the Company, the preferred stockholders were entitled to a liquidation preference payment equal to (i) the sum of the liquidation value plus all accumulated, accrued, and unpaid dividends and (ii) the pro rata share of any remaining amounts such holder would have been entitled to receive had such holder s shares been converted into common stock immediately prior to the liquidation, dissolution, or winding up.

At any time subsequent to March 17, 2013, the holders of a majority of the preferred stock could have required the Company to redeem all or any portion of the preferred stock. If the preferred stock was redeemed, the redemption would have occurred in equal installments over a three-year period. The price paid by the Company to redeem the shares would have been the greater of (i) the original issue price, plus all accumulated, accrued, and unpaid dividends, and (ii) the fair market value of the preferred stock being redeemed at the time of the redemption.

Because the preferred stock provided the holders the right to require the Company to redeem such shares for cash after March 17, 2013 at the greater of (i) the original issue price plus any accrued but unpaid dividends and (ii) the fair market value of the preferred stock being redeemed, the embedded conversion feature required separate accounting. Consequently, the conversion feature had to be bifurcated from the preferred stock and accounted for separately at each issuance date. The carrying value of the embedded derivative was adjusted to fair value at the end of each reporting period and the change in fair value was recognized in the statement of operations.

On January 8, 2010, warrants to purchase shares of the Company s Series C-1 preferred stock were exercised resulting in $10,000,000 in cash proceeds and the issuance of 1,935,700 additional shares of Series C-1 preferred stock. The Company recorded a derivative liability of $3,471,000 upon the exercise of the warrants and the issuance of such shares of Series C-1 preferred stock in January 2010.

At each reporting date and in connection with the Company s IPO, the Company adjusted the carrying value of the embedded derivatives to estimated fair value and recognized the change in such estimated value in its statement of operations. The estimated fair value of the derivatives at April 27, 2010, immediately prior to the conversion of the preferred stock to common stock in connection with the IPO, was $36,528,000. In connection with the IPO, the embedded derivatives were eliminated. The Company recognized a gain of $3,644,000 and a loss of $23,142,000 associated with the change in fair value for the years ended December 31, 2010 and 2009 respectively.

In connection with the conversion of the Company s preferred shares to common shares upon the completion of the Company s IPO in April 2010, the Company authorized 10,000,000 shares of $0.01 par value preferred stock. No shares of such preferred stock were issued or outstanding at December 31, 2011 and 2010, respectively.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

12. OPTIONS

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 10-year term. Options granted to directors typically vest immediately and have a 5-year term.

As of December 31, 2011, the Company was authorized to grant under the Company s plans up to 2,642,526 shares under the 2010 Equity Incentive Plan. 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:

	September 30, 2011		September 30, 2010		September 30, 2009	
	Years Ended December 31,					
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period	2,741,985	$ 3.81	2,225,778	$ 2.14	1,959,726	$ 1.80
Grants	155,000	7.83	575,150	10.17	295,463	4.35
Forfeitures	(144,752)	8.98	(14,444)	5.11	(25,551)	1.84
Exercises	(144,787)	1.63	(44,499)	2.10	(3,860)	1.70
Options outstanding at period end	2,607,446	3.88	2,741,985	3.81	2,225,778	2.14
Options exercisable at period end	2,058,585	2.74	1,722,281	1.88	1,427,649	1.70
Weighted average per share fair value of options granted during the period	$ 5.67		$ 7.92		$ 3.74	

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, 2011:

	September 30,	September 30, Weighted Average Exercise	September 30, Weighted Average Contractual	September 30,
	Shares	Price	Term	Aggregate Intrinsic Value

(In thousands)

Outstanding	2,607,446	$	3.88	6.14 years	$
Exercisable	2,058,585		2.74	5.54 years	
Expected to vest	532,303		8.28	8.42 years	

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The Company estimated the fair value of options granted using the Black-Scholes option-pricing model with the following weighted-average assumptions used for option grants:

	Years Ended December 31,		
	September 30, 2011	September 30, 2010	September 30, 2009
Risk-free interest rate	1.61%	1.77%	3.44%
Volatility factor	88.21%	97.32%	112.57%
Grant date fair value of common stock	$ 5.67	$ 7.92	$ 4.35
Weighted-average expected life	5.78 years	6.05 years	6.18 years
Assumed forfeiture rate	10.00%	10.00%	10.00%

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

	Years Ended December 31,		
	September 30, 2011	September 30, 2010	September 30, 2009
		(In thousands)	
Marketing	$ 352	$ 127	$ 43
Research and development	376	209	161
General and administrative	1,078	458	307
Total employee stock-based compensation expense	$ 1,806	$ 794	$ 511

The total estimated fair value of options granted during the years ended December 31, 2011, 2010, and 2009 was $879,000, $4,558,000 and $1,100,000, respectively. The total estimated intrinsic value of options exercised during the years ended December 31, 2011, 2010 and 2009 was $897,000, $364,000 and $9,000, respectively.

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, 2012, an additional 1,257,094 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, 2011:

	Options Outstanding		Options Exercisable	
Exercise Prices	September 30, Number Outstanding	September 30, Weighted Average Remaining Contractual Life	September 30, Number Exercisable	September 30, Weighted Average Remaining Contractual Life

$ 1.33	597,848	4.37	597,848	4.37
1.39	390,225	5.79	390,225	5.79
2.04	249,170	2.77	249,170	2.77
2.24	4,504	6.16	3,860	6.16
2.41	457,951	6.22	428,689	6.22
3.26	3,676	6.39	2,940	6.39
3.88	33,823	6.09	30,147	6.04
4.01	260,736	7.60	137,102	7.55
5.03	4,438	6.66	3,471	6.66
5.44	2,059	6.77	1,672	6.77
6.74	100,375	8.61	35,218	8.61
7.53	37,500	9.44	37,500	9.44
7.97	20,000	9.30		
8.47	52,618	8.88	11,826	8.03
9.87	21,873	8.75	21,873	8.75
11.00	50,000	8.32	18,748	8.32
11.15	302,650	8.84	81,964	8.84
11.91	18,000	8.93	6,332	8.93
	2,607,446		2,058,585	

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ALIMERA SCIENCES, INC.

NOTES TO 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 outstanding were 82,715 and 87,420 at December 31, 2011 and 2010, respectively, at exercise prices ranging from $1.70 to $11.00 per share. The warrants are exercisable for a period of seven to ten years from the issuance date.

Warrants to purchase 39,773 of the Company s common stock were granted during the year ended December 31, 2010 in connection the issuance of the term and revolving loan agreement (Note 9).

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

14. INCOME TAXES

The components of the income tax benefit were as follows:

	September 30, 2011	September 30, 2010	September 30, 2009
	Years Ended December 31, (In thousands)		
Deferred benefit (expense):			
Federal	$ 7,490	$ 5,738	$ 6,649
State	883	669	774
	8,373	6,407	7,423
Valuation allowance	(8,373)	(6,407)	(7,423)
Income tax benefit	$	$	$

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 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 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. Tax years since 2003 remain subject to examination in Georgia, Tennessee, and on the federal level. The Company does not anticipate any material changes to its uncertain tax positions within the next 12 months.

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, 2011 and 2010, the Company had federal net operating loss (NOL) carry-forwards of approximately $120,353,000 and $97,813,000 and state NOL carry-forwards of approximately $103,815,000, and $80,995,000 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 2023 and 2031 and the state NOL carry-forwards will expire at various dates between 2020 and 2031.

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 Company has not performed a formal analysis of its NOLs in connection with IRC Section 382.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Net deferred tax assets (liabilities) were as follows:

	September 30, 2011	September 30, December 31, 2010
	(In thousands)	
Depreciation and amortization	$ 150	$ 206
Other deferred tax assets	719	246
NOL carry-forwards	44,710	36,467
Research and development costs	8,179	9,165
Collaboration agreement receivable reserves	1,543	844
Valuation allowance	(55,301)	(46,928)
Total	$	$

The income tax benefit differs from the amount determined by applying the U.S. federal statutory income tax rate to the pre-tax accounting loss as follows:

	September 30, 2011	September 30, 2011	September 30, 2010	September 30, 2010	September 30, 2009	September 30, 2009
	Years Ended December 31,					
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax benefit at statutory rate	$ (7,655)	34.0%	$ (4,712)	34.0%	$ (15,035)	34.0%
State tax net of federal benefit	(892)	4.0	(549)	4.0	(1,751)	4.0
Permanent items	379	(1.7)	(1,166)	8.4	8,938	(20.2)
Change in state deferred tax rate						
Other	(205)	0.9	20		425	(1.0)
Increase in valuation allowance	8,373	(37.2)	6,407	(46.4)	7,423	(16.8)
Total tax expense	$	%	$	%	$	%

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

15. FAIR VALUE

The Company adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (ASC 820), effective January 1, 2008. 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.

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

	September 30, Level 1	September 30, Level 2	September 30, Level 3	September 30, Total
		December 31, 2011 (In thousands)		
Assets:				
Cash equivalents(1)	$ 32,438	$	$	$ 32,438
Investments in marketable debt securities(2)		500		500
Assets measured at fair value	$ 32,438	$ 500	$	$ 32,938

	September 30, Level 1	September 30, Level 2	September 30, Level 3	September 30, Total
		December 31, 2010 (In thousands)		
Assets:				
Cash equivalents(1)	$ 27,393	$	$	$ 27,393
Investments in marketable debt securities(2)		26,330		26,330

Assets measured at fair value	$ 27,393	$ 26,330	$	$ 53,723

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

(2) Valuations are based on quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly. These prices include broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Pricing sources include industry standard data providers, security master files from large financial institutions, and other third party sources which are input into a distribution-curve-based algorithm to determine a daily market value. This creates a consensus price or a weighted average price for each security.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

16. EMPLOYEE BENEFIT PLANS

The Company has a salary deferral 401(k) plan which covers substantially all employees of the Company. In May 2008, the Company established a plan to match participant contributions subject to certain plan limitations. The Company s matching plan took effect on July 1, 2008. Compensation expense associated with the Company s matching plan totaled $85,000, $68,000 and $70,000 for the years ended December 31, 2011, 2010 and 2009, respectively. The Company may also make an annual discretionary profit-sharing contribution. No such discretionary contributions were made during the years ended December 31, 2011, 2010 and 2009.

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 6-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 21,910 and 8,246 shares of the Company s common shares were acquired through the Purchase Plan during the year ended December 31, 2011 and 2010, respectively. As such, on January 1, 2012 and 2011, respectively, an additional 21,910 and 8,246 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 $66,000 and $43,000 of compensation expense for the years ended December 31, 2011 and 2010, respectively.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

17. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Selected quarterly financial data for years ended December 31, 2011 and 2010 are as follows (in thousands except per share data):

	September 30, 1st Quarter	September 30, 2nd Quarter	September 30, 3rd Quarter	September 30, 4th Quarter
		Year Ended December 31, 2011		
Selected quarterly financial data:				
Total operating expenses	$ 4,414	$ 4,926	$ 6,257	$ 5,810
Net loss	(4,697)	(5,208)	(6,540)	(6,071)
Net loss attributable to common stockholders	(4,697)	(5,208)	(6.540)	(6,071)
Net loss per common stockholder Basic and diluted(1)	$ (0.15)	$ (0.17)	$ (0.21)	$ (0.19)

	September 30, 1st Quarter	September 30, 2nd Quarter	September 30, 3rd Quarter	September 30, 4th Quarter
		Year Ended December 31, 2010		
Selected quarterly financial data:				
Total operating expenses	$ 4,216	$ 5,693	$ 6,119	$ 6,043
Net loss	2,577	(4,101)	(6,082)	(6,253)
Net loss attributable to common stockholders	193	(4,821)	(6,082)	(6,253)
Net loss per common stockholder Basic and diluted(1)	$ 0.12	$ (0.20)	$ (0.20)	$ (0.20)

(1) Net loss per common stockholder is computed independently for each of the quarters presented. Therefore the sum of the quarterly net loss per share will not necessarily equal the total for the year.

(2) The unaudited quarterly results of operations for the quarter ended December 31, 2011, includes $401,000 of personnel and severance costs related to our work force reduction (Note 6) which took place in December of 2011.

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ALIMERA SCIENCES, INC.

EXHIBIT INDEX

Exhibit Number	Exhibit Title
3.2	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 .4	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)
4 .3	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 .4	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 .5	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 .6	Warrant to Purchase Stock dated October 14, 2010 issued to Silicon Valley Bank (filed as Exhibit 4.1 to Registrant s Current Report, as filed on October 18, 2010, and incorporated herein by reference)
4 .7	Warrant to Purchase Stock dated October 14, 2010 issued to MidCap Funding III, LLC (filed as Exhibit 4.2 to Registrant s Current Report, as filed on October 18, 2010, and incorporated herein by reference)
4 .8	Warrant to Purchase Stock dated May 16, 2011 issued to MidCap Funding III, LLC (filed as Exhibit 4.1 to Registrant s Current Report, as filed on May 17, 2011, and incorporated herein by reference)
4 .9	Warrant to Purchase Stock dated May 16, 2011 issued to Silicon Valley Bank (filed as Exhibit 4.2 to Registrant s Current Report, as filed on May 17, 2011, 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	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and C. Daniel Myers (filed as Exhibit 10.2 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	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and Richard Eiswirth (filed as Exhibit 10.3 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	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and David Holland (filed as Exhibit 10.4 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	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and Susan Caballa (filed as Exhibit 10.5 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	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and Kenneth Green (filed as Exhibit 10.6 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)

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Exhibit Number	Exhibit Title
10.7	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)
10.7.A	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 .8	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)
10.8.A	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 .9	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 .10	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 .11	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 .12	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)
10.13	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)
10.14	Asset Purchase Agreement between Bausch & Lomb Incorporated and Alimera Sciences, Inc., dated as of December 20, 2006 (filed as Exhibit 10.14 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)
10.15	Asset Purchase Agreement between Bausch & Lomb Incorporated and Alimera Sciences, Inc., dated as of February 16, 2007 (filed as Exhibit 10.15 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)
10.16	License and Option Agreement by and between Emory University and Alimera Sciences, Inc., dated as of July 16, 2009 (filed as Exhibit 10.16 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)
10.17	License and Option Agreement by and between Emory University and Alimera Sciences, Inc., dated as of August 31, 2009 (filed as Exhibit 10.17 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 .18	Office Lease by and between Rubicon, L.C. and Alimera Sciences, Inc., dated as of May 27, 2003, as amended (filed as Exhibit 10.18 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.25	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)

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Exhibit Number	Exhibit Title
10.26	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 .27	Loan and Security Agreement dated October 14, 2010 between Registrant, Silicon Valley Bank and MidCap Funding III, LLC (filed as Exhibit 10.1 to Registrant s Current Report on Form 8-K, as filed on October 18, 2010, and incorporated herein by reference)
10 .28	Loan and Security Agreement dated October 14, 2010 between Registrant and Silicon Valley Bank (filed as Exhibit 10.2 to Registrant s Current Report on Form 8-K, as filed on October 18, 2010, and incorporated herein by reference)
10.29	Contract Sales Agreement dated October 4, 2010 between the Registrant and OnCall LLC (filed as Exhibit 10.29 to Registrant s Annual Report on Form 10-K, as filed on March 25, 2011, and incorporated herein by reference)
10 .30	Form of Notice of Stock Option Grant and Stock Option Agreement under 2010 Equity Incentive Plan (filed as Exhibit 10.30 to Registrants Annual Report on Form 10-K, as filed on March 25, 2011, and incorporated herein by reference)
10 .31	First Loan Modification Agreement dated May 16, 2011 between Registrant, Silicon Valley Bank and MidCap Funder III, LLC (filed as Exhibit 10.1 to Registrant s Current Report on Form 8-K, as filed on May 17, 2011, and incorporated herein by reference)
10 .32	First Loan Modification Agreement dated May 16, 2011 between Registrant and Silicon Valley Bank (filed as Exhibit 10.2 to Registrant s Current Report on Form 8-K, as filed on May 17, 2011, and incorporated herein by reference)
10.33	Amendment to Manufacturing Agreement between Registrant and Alliance Medical Products, Inc. (filed as Exhibit 10.3 to Registrants Quarterly Report on Form 10-Q, as filed on August 5, 2011, and incorporated herein by reference)
10 .34	Form of Notice of Stock Unit Award and Stock Unit Agreement under 2010 Equity Incentive Plan
23 .1	Consent of Deloitte & Touche 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

Compensation Arrangement.

Confidential treatment has been granted with respect to certain portions of this document.

* Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions of this exhibit.