ALIMERA SCIENCES INC
Form 10-K
March 25, 2011

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2010

or

o **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 o No þ

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 o No þ

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 þ No o

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 o No o

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. o

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

As of June 30, 2010, the aggregate market value of the Common Stock held by non-affiliates of the registrant was $17,376,806, 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.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s proxy statement with respect to the registrant s 2011 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, 2010, are incorporated by reference into Part III of this Form 10-K.

Alimera Sciences, Inc.
Form 10-K

Table of Contents

		Page
	PART I	
	Special Note Regarding Forward-Looking Statements and Projections	3
Item 1.	Business	3
Item 1A.	Risk Factors	31
Item 1B.	Unresolved Staff Comments	55
Item 2.	Properties	55
Item 3.	Legal Proceedings	56
Item 4.	(Removed and Reserved)	56
	PART II	
Item 5.	Market for Registrant s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities	56
Item 6.	Selected Consolidated Financial Data	58
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	59
Item 7A.	Qualitative and Quantitative Disclosures about Market Risk	76
Item 8.	Financial Statements and Supplementary Data	76
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	76
Item 9A.	Controls and Procedures	76
Item 9B.	Other Information	77
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	77
Item 11.	Executive Compensation	77
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	78
Item 13.	Certain Relationships and Related Transactions, and Director Independence	78
Item 14.	Principal Accountant Fees and Services	79
	PART IV	
Item 15.	Exhibits and Financial Statements Schedules	79
Signatures		80
Exhibit Index		107
EX-10.29		
EX-10.30		
EX-23.1		
EX-31.1		
EX-31.2		
EX-32.1		
EX-32.2		

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.

Table of Contents

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND PROJECTIONS

Various statements in this report are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may appear throughout this report, including without limitation, the following sections: Item 1 Business, Item 1A Risk Factors, and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations. Words such as, but not limited to, anticipate, believe, estimate, expect, intend, may, plan, contemplates, predict, project, targets, likely, potential, c should, could, or the negative of these terms and similar expressions or words, identify 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, and market acceptance of, the Company s product candidates;
- the extent of government regulations;
- 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 our outside sales force to successfully sell and market ILUVIEN in the U.S. 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 publicly update or revise 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.

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

Table of Contents

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 we are developing for the treatment of diabetic macular edema (DME). DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. In September 2010 we completed two Phase 3 pivotal clinical trials (collectively, our FAME™ Study) for 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. Based on our analysis of the month 24 clinical readout from our FAME Study in December 2009, we filed 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 in July 2010. In December 2010, we received a Complete Response Letter (CRL) from the FDA regarding our NDA. The FDA issued the CRL to communicate its decision that the NDA could not be approved in its present form. No new clinical studies were requested by the FDA in the CRL. However, the FDA asked us for analyses of the safety and efficacy data through the end of the FAME Study to further assess the relative benefits and risks of ILUVIEN. We are currently preparing the analyses the FDA requested having completed the FAME Study and publicly released data on February 3, 2011. The FDA is also seeking additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN, which we are in the process of compiling. We currently anticipate submitting our response to the CRL to the FDA early in the second quarter of 2011. Our submission to the FDA will be considered a Class 2 response, which will provide for a review period of up to an additional six months for our NDA. Based on our discussions with the FDA we anticipate that the FDA will call an advisory committee during this review. If our NDA for ILUVIEN is approved by the FDA, we plan to commercialize ILUVIEN in the U.S. by marketing and selling it to retinal specialists as early as late 2011.

Additionally, we plan to submit the additional safety and efficacy data through the final readout at the end of the FAME Study to regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the second quarter of 2011. If ILUVIEN is approved by the European regulatory authorities, we plan to commercialize ILUVIEN, directly or through a partnership, in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain.

According to the Centers for Disease Control and Prevention (CDC), the number of Americans diagnosed with diabetes had increased from approximately 8.1 million people in 1994 to approximately 18.8 million people in 2010. Per the International Diabetes Federation Atlas, the estimated prevalence of people diagnosed with diabetes for 2010 has increased to 285 million people worldwide and that this number is expected to reach 438 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. As reported by the American Diabetes Association, in the U.S. diabetic retinopathy causes approximately 12,000 to 24,000 new cases of blindness each year, making diabetes the leading cause of new cases of blindness in adults aged 20 to 74. 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. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a ten-year period approximately 19% of diabetics studied were diagnosed with DME. Based on this study and the current U.S. diabetic population, we estimate the incidence of DME in the U.S. to be approximately 340,000 cases annually. As the population of diabetics increases, we expect the annual incidence of diagnosed DME to increase.

There are no ophthalmic drug therapies currently approved by the FDA for the treatment of DME. 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 alternate off-label therapies for the treatment of DME, including injections of corticosteroids and anti-vascular endothelial growth factor (anti-VEGF) agents. Both corticosteroids and anti-VEGFs have shown improved visual acuity in DME patients in non-pivotal clinical trials but are

Table of Contents

limited by a need for multiple injections to maintain a therapeutic effect. 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.

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 with a device that employs a 25-gauge needle which allows for a self-sealing wound. In the U.S., this procedure is non-surgical and is performed in the retinal specialist s office. ILUVIEN is an intravitreal insert designed to provide a therapeutic effect for up to 36 months by delivering sustained sub-microgram levels of FAc. ILUVIEN has demonstrated efficacy in the treatment of DME in our FAME Study. Additionally, by providing lower exposure to corticosteroids and focusing the delivery to the back of the eye, we believe that the adverse events associated with the use of ILUVIEN are 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). In addition to our activities related to the development and commercialization of ILUVIEN, we are also conducting testing on two classes of nicotinamide adenine dinucleotide phosphate (NADPH) oxidase inhibitors for which we have acquired exclusive, worldwide licenses from Emory University. Our initial focus is on the use of NADPH oxidase inhibitors in the treatment of dry AMD. We plan to evaluate the use of NADPH oxidase inhibitors in the treatment of other diseases of the eye, including wet AMD and diabetic retinopathy. We will pursue the development, license and acquisition of rights to compounds and technologies with the potential to treat diseases of the eye that we believe are not well treated by current therapies.

Our commercialization strategy is to establish ILUVIEN as a leading therapy for the treatment of DME 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 in marketing eye-care products, by marketing and selling ILUVIEN to the approximately 1,600 retinal specialists practicing in the approximately 900 retina centers across the U.S. and Canada. If ILUVIEN is approved by the European regulatory authorities, we plan to commercialize ILUVIEN, directly or through a partnership, in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. Our commercialization strategy is subject to and dependent upon regulatory approval of ILUVIEN for the treatment of DME.

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:

Pursue FDA Approval for ILUVIEN. In June 2010, we filed an NDA for ILUVIEN for the treatment of DME based upon the month 24 clinical readout from our FAME Study. We received a CRL from the FDA in December 2010 requesting additional analyses and information for our NDA through the end of the FAME Study, and plan to submit a response early in the second quarter of 2011.

Maximize the Commercial Success of ILUVIEN. If approved by the FDA, we intend to capitalize on our management s past experience and expertise in marketing eye-care products including the launch and management of Visudyne (Novartis) by marketing and selling ILUVIEN through our outside sales force to the approximately 1,600 retinal specialists practicing in the approximately 900 retina centers in the U.S. and Canada. We intend to commercialize ILUVIEN, directly or through a partnership, outside North America.

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

Table of Contents

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.

Develop Our Existing Ophthalmic Product Pipeline. We have acquired exclusive, worldwide licenses of rights under patent applications for two classes of NADPH oxidase inhibitors from Emory University. We believe that the management of oxidative stress is an important strategy in managing the development and progression of diseases of the eye, and we believe that NADPH oxidase inhibitors have the potential to manage oxidative stress. Our initial focus is on the use of NADPH oxidase inhibitors in the treatment of dry AMD. We plan to evaluate the use of NADPH oxidase inhibitors in the treatment of other diseases of the eye, including wet AMD and diabetic retinopathy.

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 in continuing to evaluate in-licensing and acquisition opportunities for compounds and technologies with applications in diseases affecting the eye.

Disease Overview and Market Opportunity

Diabetes and Diabetic Retinopathy

Diabetes mellitus, and its systemic and ophthalmic complications, represents an enormous public health threat in the U.S. According to the U.S. Centers for Disease Control and Prevention (CDC, the number of Americans diagnosed with diabetes has increased from approximately 8.1 million people in 1994 to approximately 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 diagnosis methodologies and improved public awareness, the number of persons diagnosed with and being treated for diabetes is expected to increase. Per the International Diabetes Federation Atlas, the estimated prevalence of diabetes for 2010 has increased to 285 million people worldwide and this number is expected to reach 438 million people by 2030.

All patients with diabetes are at risk of developing some form of diabetic retinopathy, an ophthalmic complication of diabetes that presents 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, microaneurysms, 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, 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. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a ten-year period approximately 19% of diabetics studied were diagnosed with DME. Based on this study and the current diabetic population in the U.S., we estimate the

Table of Contents

incidence of DME in the U.S. to be approximately 340,000 cases annually. As the population of diabetics increases, we expect the annual incidence of diagnosed DME to increase.

Limitations of Current Treatments for DME

There are no ophthalmic drug therapies presently approved by the FDA for the treatment of DME. 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. Visual acuity gains are seen with this therapy, although results are highly variable and we believe that it may take more than eight months for median visual acuity to improve. Further, 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 alternate off-label therapies for the treatment of DME, including injections of corticosteroids and anti- VEGF agents. Both corticosteroids and anti-VEGFs have shown improved visual acuity in DME patients in non-pivotal clinical trials but are limited by a need for multiple injections to maintain a therapeutic effect. 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.

ILUVIEN

Overview

Our most advanced product candidate is ILUVIEN, an intravitreal insert designed to provide a therapeutic effect for up to 36 months in the treatment of 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 inserted in the back of the patient s eye using an insertion device (the ILUVIEN inserter) employing a 25-gauge needle which allows for a self-sealing wound. This insertion is very similar to the administration of an intravitreal injection, a procedure commonly employed by retinal specialists. In the U.S., this procedure is non-surgical and is performed in the retinal specialist s office. Based on our analysis of the month 24 clinical readout from our FAME Study, we believe ILUVIEN improves vision while reducing 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 levels of a steroid to the eye. In our clinical trials we studied two doses of ILUVIEN (a high-dose with an initial release of approximately 0.45µg per day and a low-dose with an initial release of approximately 0.23µg per day) to determine the lowest dose possible that will provide efficacy for the treatment of DME. The dosage levels of ILUVIEN provide lower exposure to corticosteroids than other intraocular dosage forms currently available. Based on our analysis of the month 24 clinical readout from our FAME Study in December 2009, we are pursuing the approval of the low dose of ILUVIEN.

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 therapeutic effect in the treatment of DME for up to 36 months.

ILUVIEN s placement utilizes the eye s natural fluid dynamics. There are two natural currents of fluid within the eye; one to the front of the eye and the other to the back of the eye, or retina. We believe that ILUVIEN s

delivery of sustained sub-microgram levels of FAc and insertion into the back of the eye, a position that we believe optimizes delivery of FAc to the retina by utilizing these natural currents, maximizes efficacy and mitigates possible side effects.

Table of Contents

ILUVIEN is inserted using a 25-gauge needle. Needle gauge determines the size of the wound that is created. ILUVIEN is inserted into the eye 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 insertion procedure to create a self-sealing wound.

Fluocinolone Acetonide

Fluocinolone acetonide (FAc) is the active compound in ILUVIEN and a member of the class of steroids known as corticosteroids. FAc is a non-proprietary corticosteroid that has a history of use in treating ocular disease as the active compound in Bausch & Lomb Incorporated s product Retisert (a surgically implanted intravitreal drug delivery device approved for the treatment of chronic non-infectious posterior uveitis). Corticosteroids have demonstrated a range of pharmacological actions, including inhibition of inflammation, inhibition of leukostasis, up regulation of occludin, inhibition of 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 Reduce Side Effects

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 location in the posterior portion of the eye. Fluid, or aqueous humor, generated at the ciliary body, located just behind the iris, flows within the eye primarily via two currents. The predominant current flows through the iris into the anterior chamber and exits the eye mainly through the trabecular outflow pathway. Another current of outflow is directed toward the back 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 membrane caps, 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 demonstrates 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 Inserter

We developed the ILUVIEN inserter, a custom insertion system for ILUVIEN, which includes improvements over the modified syringe used during our two Phase 3 pivotal clinical trials (individually referred to as Trial A and Trial B, and collectively as our FAME Study). These improvements include ergonomic design features, a transparent window

to visually confirm ILUVIEN s presence within the inserter and a longer needle and markings to guide retinal specialists to the proper insertion point. As was the case with the modified

Table of Contents

syringe used during our FAME Study, the ILUVIEN inserter uses a 25-gauge needle which results in a wound that is small enough to seal itself after ILUVIEN has been inserted into the back of the eye and the needle has been removed. We believe that a 25-gauge needle is the smallest needle capable of delivering ILUVIEN into the back of eye. In the U.S., this procedure is non-surgical and is performed in the retinal specialist s office. The ILUVIEN inserter is also being used in our Phase 2 trial for the use of ILUVIEN in the treatment of RVO.

ILUVIEN Clinical Development Program

Development Program for the Treatment of DME

In September 2010, we completed the FAME Study for 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. 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 month 24 clinical readout from our FAME Study in December 2009, we filed a NDA with the FDA in June 2010 for the low dose of ILUVIEN in the U.S., followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in July 2010. In December 2010, we received a CRL from the FDA regarding our NDA. The FDA issued the CRL to communicate its decision that the NDA could not be approved in its present form. No new clinical studies were requested by the FDA in the CRL. However, the FDA asked us for analyses of the safety and efficacy data through the end of the FAME Study to further assess the relative benefits and risks of ILUVIEN. We are currently preparing the analyses the FDA requested having completed the FAME Study and publicly released data on February 3, 2011. The FDA is also seeking additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN, which we are in the process of compiling. We currently anticipate submitting our response to the CRL to the FDA early in the second quarter of 2011. Our submission to the FDA will be considered a Class 2 response, which will provide for a review period of up to an additional six months for our NDA. Based on our discussions with the FDA we anticipate that the FDA will call an advisory committee during this review.

Consistent with the FDA requirement for registration and approval of drugs being developed for diabetic retinopathy, including DME, the primary efficacy endpoint for our FAME Study was the difference in the percentage of patients whose best corrected visual acuity (BCVA) improved from baseline by 15 or more letters on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart between the treatment and control groups at month 24. The ETDRS eye chart is the standard used in clinical trials for measuring sharpness of sight as established by the National Eye Institute s Early Treatment Diabetic Retinopathy Study. In addition, the FDA required a numerical comparison of the percentage of patients with BCVA improvement of 15 or more letters between the month 24 and month 18 data to determine if the month 24 results are equal to or greater than the month 18 results. Patients enrolled in our FAME Study were followed for 36 months. Although we submitted the month 24 results to the FDA for approval, in the CRL the FDA requested the additional 12 months of clinical data from the completed FAME Study through month 36 for review. We are currently preparing a response to the CRL for submission early in the second quarter of 2011 including this additional efficacy and safety data. We also plan to submit efficacy and safety data through the end of the trial to the applicable regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the second quarter of 2011.

In the European Union, we are utilizing the decentralized registration procedure. The ILUVIEN insertion system will not require a separate device application, but it must meet the safety and regulatory requirements of the applicable regulatory authorities when evaluated as part of the drug product marketing application.

FAME Study

We initiated our FAME Study in September 2005. Trial A and Trial B had identical protocols and completed enrollment in October 2007 with a total of 956 patients across 101 academic and private practice centers. Trial A drew patients from sites located in the northern regions of the U.S., Europe and India and all sites in Canada, while sites in the southern regions of the U.S., India and Europe comprise Trial B.

Table of Contents

Our FAME Study was designed to assess the safety and efficacy of ILUVIEN in patients with DME involving the center of the macula, and who had at least one prior macular laser treatment 12 weeks or more before study entry. The inclusion criteria for our FAME Study were designed to select DME patients with BCVA between 20/50 (68 letters on the ETDRS eye chart) and 20/400 (19 letters on the ETDRS eye chart) in the study eye and no worse than 20/400 in the non-study eye. Patients who had received steroid drug treatments for DME within three months of screening or anti-VEGF injections within two months of screening, and patients with glaucoma, ocular hypertension, IOP greater than 21mmHg or concurrent therapy with IOP-lowering agents in the study eye at screening were not eligible to participate in this trial.

Patient characteristics, such as age, gender and baseline BCVA, were balanced across the treatment and control groups. As part of randomization, the patients were divided into two separate groups, those with a baseline BCVA score greater than or equal to 49 letters on the ETDRS eye chart and those with a baseline BCVA score of less than 49 letters on the ETDRS eye chart.

We randomly assigned patients participating in our FAME Study to one of three groups at a ratio of 2:2:1. The first two of these groups were assigned to an active drug formulation and the third group served as the control group, undergoing a sham insertion procedure designed to mimic an intravitreal insertion. The treatment groups consisted of one group receiving a low dose of ILUVIEN and another group receiving a high dose of ILUVIEN. To reduce potential bias, these trials used a randomized, double-masked study design so that neither the patient nor the investigational staff involved with assessing the patient knew to which group the patient belonged. In order to simulate an insertion and help to maintain proper patient masking, the sham insertion procedure included all steps involved in the insertion procedure, except that a blunt inserter without a needle was used to apply pressure to the anesthetized eye.

As part of our FAME Study, investigators were able to re-treat each patient with ILUVIEN following their month 12 follow up visit if certain criteria were met. Through the end of the FAME Study, 25.6% of patients were treated with more than one ILUVIEN insert and 4.0% of patients were treated with three or more ILUVIEN inserts.

Primary Efficacy Endpoint. The primary efficacy endpoint for our FAME Study was the difference in the percentage of patients with improved BCVA from baseline of 15 or more letters on the ETDRS eye chart at month 24 between the treatment and control groups.

Full Analysis Set. In December 2009, we received the month 24 clinical readout for our FAME Study and analyzed the full data set consistent with the recommendations regarding the appropriate population for primary analysis as described in the FDA-adopted International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidance E9, Statistical Principles for Clinical Trials. ICH is a joint initiative involving regulatory authorities and pharmaceutical industry representatives from Europe, Japan and the U.S. who discuss scientific and technical aspects of product registration.

The full data set includes all 956 patients randomized into our FAME Study, with data imputation employed, using last observation carried forward (LOCF), for data missing because of patients who discontinued the trial or are unavailable for follow-up (the Full Analysis Set. As part of our analyses, we determined statistical significance based on the Hochberg-Bonferroni procedure (H-B procedure), which is a procedure employed to control for multiple comparisons. We also made a target p-value adjustment of 0.0001 to account for each of the nine instances our independent data safety monitoring board reviewed unmasked interim clinical data. These adjustments resulted in a required p-value of 0.0491 or lower for each of Trial A and Trial B to demonstrate statistical significance for both the low dose and high dose of ILUVIEN. Based upon the H-B procedure, if either dose of ILUVIEN in a trial did not meet statistical significance, the alternate dose was required to achieve a p-value of 0.02455 or lower in that trial to demonstrate statistical significance.

In the Full Analysis Set, the primary efficacy endpoint was met with statistical significance for both the low dose and the high dose of ILUVIEN in Trial A and Trial B, as well as on a combined basis. The table below summarizes the primary efficacy variable results.

Table of Contents

Patients Gaining At Least 15 Letters At Month 24

	Trial A			Trial B		
Study Group	**Individuals**	**%**	**P-Value**	**Individuals**	**%**	**P-Value**
Control	14/95	14.7%		16/90	17.8%	
Low Dose	51/190	26.8%	0.029	57/186	30.6%	0.030
High Dose	51/196	26.0%	0.034	62/199	31.2%	0.027

	Combined		
Study Group	**Individuals**	**%**	**P-value**
Control	30/185	16.2%	
Low Dose	108/376	28.7%	0.002
High Dose	113/395	28.6%	0.002

Additionally, as required by the FDA, a numerical comparison of the responder rates at month 18 and month 24 in the Full Analysis Set demonstrated that the responder rates for both the low dose and high dose of ILUVIEN at month 24 were numerically greater than the month 18 responder rates in both Trial A and Trial B.

Based on these results, we filed an NDA in June 2010 for the low dose of ILUVIEN in the U.S., followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in July 2010. In December 2010, we received a CRL from the FDA regarding our NDA. The FDA issued the CRL to communicate its decision that the NDA could not be approved in its present form. No new clinical studies were requested by the FDA in the CRL. However, the FDA asked us for analyses of the safety and efficacy data through the end of the FAME Study to further assess the relative benefits and risks of ILUVIEN. We are currently preparing the analyses the FDA requested having completed the FAME Study and publicly released data on February 3, 2011.

The low dose of ILUVIEN, which we submitted to the FDA for approval, in the Full Analysis Set for Trial A demonstrated statistically significant differences between ILUVIEN patients gaining 15 or more letters at month 30 and month 33 and the control group. The therapeutic effect was maintained at month 36. The table below summarizes the primary efficacy variable results for Trial A at months 30, 33 and 36.

Patients Gaining At Least 15 Letters in Trial A

	At Month 30			At Month 33			At Month 36		
	Individuals	**%**	**P-Value**	**Individuals**	**%**	**P-Value**	**Individuals**	**%**	**P-Value**
Control	14/95	14.7%		16/95	16.8%		18/95	18.9%	

Low Dose	55/190	28.9%	0.011	54/190	28.4%	0.042	54/190	28.4%	0.106
High Dose	53/196	26.9%	0.023	56/196	28.6%	0.034	53/196	27.0%	0.142

Table of Contents

In Trial B, statistically significant differences between ILUVIEN patients gaining 15 or more letters over baseline were demonstrated at month 30 and month 33 and the control group. The table below summarizes the primary efficacy variable results for Trial B at months 30, 33 and 36.

Patients Gaining At Least 15 Letters in Trial B

	At Month 30			At Month 33			At Month 36		
	Individuals	**%**	**P-Value**	**Individuals**	**%**	**P-Value**	**Individuals**	**%**	**P-Value**
Control	14/90	15.6%		16/90	17.8%		17/90	18.9%	
Low Dose	63/186	33.9%	0.002	55/186	29.6%	0.046	54/186	29.0%	0.086
High Dose	58/199	29.1%	0.018	58/199	29.1%	0.057	57/199	28.6%	0.111

The FDA has confirmed that there is no requirement to demonstrate statistical significance in the two trials individually or in the aggregate at month 36. Therefore, we believe these results meet the criteria for replication of efficacy in the two studies.

Trial A and B data combined demonstrated statistically significant differences between ILUVIEN patients gaining 15 or more letters over baseline at month 30, month 33 and month 36 and the control group. The table below summarizes the primary efficacy variable results for Trial A and Trial B combined at months 30, 33 and 36.

Patients Gaining At Least 15 Letters in Trial A and Trial B Combined

	At Month 30			At Month 33			At Month 36		
	Individuals	**%**	**P-Value**	**Individuals**	**%**	**P-Value**	**Individuals**	**%**	**P-Value**
Control	28/185	15.1%		32/185	17.3%		35/185	18.9%	
Low Dose	118/376	31.4%	<0.001	109/376	29.0%	0.004	108/376	28.7%	0.018
High Dose	111/395	28.0%	0.001	114/395	28.9%	0.004	110/395	27.8%	0.029

We intend to submit these data from the final readout of the FAME Study through month 36 to the FDA in connection with our response to the CRL, which we anticipate submitting early in the second quarter of 2011. Our submission to the FDA will be considered a Class 2 response, which will provide for a review period of up to an additional six months for our NDA for ILUVIEN. Based on our discussions with the FDA we anticipate that the FDA will call an advisory committee during this review. Additionally, we plan to submit the additional safety and efficacy data through the final readout at the end of the FAME Study to regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the second quarter of 2011.

Additional Clinical Observations. In addition to the primary efficacy variable, we also observed a number of other clinically relevant results in the final readout from our FAME Study through month 36. These observations included, among others, the following:

patients with improved BCVA of 15 or more letters at each follow up visit;

patients with improved BCVA of 15 or more letters at any time point;

other levels of BCVA improvement at month 24;

BCVA improvement of 15 or more letters relative to baseline BCVA;

Mean change in BCVA letter score;

BCVA improvements beyond month 24; and

decrease in excess foveal thickness.

Table of Contents

The analyses of these Full Analysis Set observations set forth below are presented for Trial A and Trial B on a combined basis for patients who received the low dose of ILUVIEN in comparison to the control group. Statements regarding statistical significance do not reflect any adjustments to the p-values calculated for multiple comparisons and analyses.

Patients With Improved BCVA of 15 Letters or More at Each Follow Up Visit. Our analysis of the combined Trial A and Trial B results of the FAME Study through month 36 indicates that the low dose of ILUVIEN provides an improvement in BCVA as early as three weeks after insertion. The low dose of ILUVIEN was statistically significantly better than the control group in our FAME Study by week 3 of patient follow up, and maintained a statistically significant advantage over the control through month 36, with a peak efficacy of 31.4% achieving improved BCVA of 15 or more letters from baseline at month 30. The chart below demonstrates the treatment effect of the low dose of ILUVIEN versus the control group, as measured by an improvement in BCVA of 15 letters or more, at each scheduled follow up visit during the FAME Study.

Patients With Improved BCVA of 15 or More Letters at Any Time Point. Our analysis of the results of the FAME Study through month 36 indicates that a significantly greater percentage of patients receiving the low dose of ILUVIEN versus the control group had an improvement in BCVA of 15 letters or more when assessed at any follow up visit. During the 36 months of the FAME Study, 185 out of 376 patients randomized to receive the low dose of ILUVIEN, or 49.2%, demonstrated improved BCVA of 15 letters or more at any time point compared to 60 out of 185 patients, or 32.4%, randomized to the control group.

Other Levels of BCVA Improvement at Month 36. While the FDA s requirement for the registration and approval of drugs being developed for DME is that the primary efficacy variable be based on an improvement in BCVA of 15 letters or more, lesser degrees of improvement in BCVA are considered clinically significant

Table of Contents

by retinal physicians. The table below demonstrates the low dose of ILUVIEN s statistically significant improvements in BCVA versus the control group at month 36 of our FAME Study.

	Trial A & Trial B Combined		
BCVA Improvement	**Control**	**Low Dose**	**P-Value**
Greater than 1 letter	57.8%	69.7%	
Greater than 5 letters	45.4%	58.8%	
Greater than 10 letters	33.5%	43.4%	

BCVA Improvement of 15 or More Letters Relative to Baseline BCVA. Our analysis of the results of the FAME Study at month 36 indicates that ILUVIEN has a statistically significant advantage over the control group irrespective of the severity of a patient s baseline BCVA. The table below demonstrates the statistically significant treatment effect of ILUVIEN versus the control group in patients with baseline BCVA of more than 49 letters on the EDTRS eye chart, and patients with BCVA of 49 letters or less on the EDTRS eye chart at baseline.

	Trial A & Trial B Combined		
Baseline BCVA	**Control**	**Low Dose**	**P-Value**
Greater than 49 Letters	16.9%	21.8%	0.292
49 Letters or Less	24.5%	44.3%	0.022

Mean Change in BCVA Letter Score. Our analysis of the results of the FAME Study through month 36 indicates that the low dose of ILUVIEN provided a more beneficial improvement in visual acuity than the control group as analyzed by the mean change in the BCVA letter score from baseline. As demonstrated in the graph below, the mean change in BCVA for the patients receiving the low dose of ILUVIEN was an increase of 5.3 letters at month 36, peaking at an increase of 6.0 letters at month 6, compared to an increase of 2.0 letters in the control group, peaking at an increase of 2.6 letters at week 6. The low dose of ILUVIEN was statistically significantly better than the control group at month 36 (p-value 0.007).

Table of Contents

During our FAME Study, patients that were phakic (had a natural lens and no prior cataract surgery) at baseline, 61 of 121, or 50.4% of the control group and 192 of 235, or 81.7% of the low dose of ILUVIEN had cataract formation reported as an adverse event through month 36. For these same phakic patients, 27.3% of the control group and 80.0% of the low dose group underwent cataract surgery through month 24. For the patients in the low dose group the median time to reporting cataract formation as an adverse event was approximately 12 months from randomization into the FAME Study. The median time to cataract surgery was approximately 18 months. This interval, between the report of cataract formation as an adverse event and cataract surgery, accounts for the decrease in the mean change in BCVA in patients receiving the low dose of ILUVIEN from the month 6 follow up visit to the month 18 follow up visit.

The temporary effect of cataracts is further illustrated by comparing the mean change in BCVA of the 140 low dose patients that were pseudophakic (had an artificial lens) to the 235 that were phakic (natural lens and no prior cataract surgery) at baseline. The chart below shows the pseudophakic subset (those who would not have vision affected by a cataract) achieved a mean change in BCVA of more than 7 letters by month 6 and maintained this mean change through month 36 while the phakic subset experienced a decrease in the mean change in BCVA from the month 6 follow up visit to the month 18 follow up visit. The temporary decrease in mean change in BCVA in the phakic population is consistent with the total low dose population.

Decrease In Excess Foveal Thickness. In addition to the functional measures of BCVA, we assessed the ability of ILUVIEN to affect a decrease in excess foveal thickness, an anatomic outcome, as measured by optical coherence tomography. Excess foveal thickness is a measurement of the swelling of the macula at its center point (known as the fovea). We consider any measurement above 180 microns to represent excess foveal thickness. Based on a review of the final clinical readout through month 36, as summarized in the chart below, patients receiving the low dose of ILUVIEN demonstrated a statistically significant difference versus the control group in decreasing excess foveal thickness by week 1 of patient follow up of our FAME Study, and maintain a statistically significant advantage through month 36. At month 36, patients receiving the low

Table of Contents

dose of ILUVIEN demonstrated a mean decrease in excess foveal thickness of 168.3 microns versus 125.9 microns for the control group.

Safety. Our safety assessment in connection with the month 24 clinical readout of the FAME Study included all reported adverse events at that time, regardless of a patient s progression in the FAME Study. Some reported adverse events occurred beyond patients month 24 follow up visits. We also assessed safety through the completion of the FAME Study in month 36. ILUVIEN was well tolerated through this readout in both the low and high dose patient populations. Our assessment of adverse event data indicates that there is no apparent risk of systemic adverse events to patients as a result of the use of ILUVIEN. The use of corticosteroids in the eye is primarily associated with two undesirable side effects: increased IOP, which may increase the risk of glaucoma and require additional procedures to manage, and the acceleration of cataract formation. Excluding IOP related side effects and cataract formation and surgery, we observed no significant eye related adverse events when comparing both the low dose and high dose patient populations to the control group. Thus, we believe that the adverse events associated with the use of ILUVIEN are within the acceptable limits of a drug for the treatment of DME.

Table of Contents

The table below summarizes the IOP related adverse events occurring in all patients randomized and treated in our FAME Study at the time of the month 24 and month 36 clinical readouts

	As of the Month 24 Data Base Lock			As of Trial Completion		
	Control N=185	Low Dose N=375	High Dose N=393	Control N=185	Low Dose N=375	High Dose N=393
IOP > 30 mmHg(1)	2.7%	16.3%	21.6%	4.3%	18.4%	22.9%
Trabeculoplasty	0.0%	1.3%	2.5%	0.0%	1.3%	2.5%
IOP-Lowering Surgeries						
Trabeculectomy (filtration)	0.0%	2.1%	5.1%	0.0%	2.7%	5.6%
Vitrectomy	0.0%	0.3%	0.5%	0.0%	0.3%	0.5%
Other Surgery Performed	0.5%	1.6%	2.5%	0.5%	2.1%	3.3%
Percentage of Patients Requiring One or More IOP-Lowering Surgeries	0.5%	3.7%	7.4%	0.5%	4.8%	8.1%

(1) An IOP of 30 mmHg is a clinically significant level that we use in assessing adverse events.

According to the CDC, diabetic individuals aged 50 or older are 1.5 times more likely to develop cataracts than non-diabetic individuals. A review of the baseline characteristics of our patient population reflects this increased risk of cataracts for diabetic patients, with 34.8% of the patients treated in our FAME Study having previously undergone a cataract surgery in the study eye. The month 24 clinical readout from our FAME Study (which includes reported adverse events that occurred beyond the patients month 24 follow up visits) indicated that, of patients who had a natural lens (no prior cataract surgery) at baseline, 46.3% of the control group, 80.0% of the low dose and 87.5% of the high dose had cataract formation reported as an adverse event through month 24. Additionally, of the patients who had a natural lens at baseline, 23.1% of the control group, 74.9% of the low dose and 84.5% of the high dose underwent cataract surgery. The final clinical readout indicated that, of patients who had a natural lens at baseline, 50.4% of the control group and 81.7% of the low dose had cataract formation reported as an adverse event through month 36. Additionally, of the patients who had a natural lens at baseline, 27.3% of the control group and 80.0% of the low dose underwent cataract surgery.

PK Study

Regulatory agencies require carcinogenicity studies in animals to identify tumorigenic potential in animals to assess the relevant risk in humans as a result of systemic exposure. We initiated an open-label Phase 2 human pharmacokinetic clinical study (PK Study) in August 2007 to assess the systemic exposure of fluocinolone acetonide (FAc) by measuring plasma levels of FAc. Analysis of plasma levels through month 18 in September 2009 demonstrated no systemic exposure of FAc (plasma levels were below the limit of detection of 100 picograms per milliliter). Based on month 18 readouts from our open-label Phase 2 human pharmacokinetic clinical trial (PK Study), which indicate that there is negligible systemic absorption of FAc in patients being treated with ILUVIEN, we submitted a carcinogenicity waiver in our submissions to the FDA and European health authorities. Although the FDA did not specifically state in the CRL that the waiver has been granted, the CRL did not include any requirement to conduct a carcinogenicity study. In the Preliminary Assessment Report issued by the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA), the MHRA stated that the lack of single-dose, carcinogenicity and

reproductive and developmental toxicity studies with ILUVIEN is acceptable.

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. We believe that dry AMD patients account for 90% of AMD patients, with the greatest unmet need among these patients being a treatment for geographic atrophy (GA) for which there are currently no treatments available. Pre-clinical studies in two established rat models of retinal

Table of Contents

degeneration reported at the Association for Research in Vision and Ophthalmology meetings in 2006, 2007 and 2008, described the efficacious effects of a miniaturized version of ILUVIEN in two animal models of 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 the two doses of ILUVIEN to a sham injection in patients with bilateral GA secondary to AMD. The change from baseline in size of GA will be assessed over time.

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 in conjunction with Lucentis in patients with wet AMD. Patients will be enrolled who have been treated with Lucentis for at least six months and whose visual acuity has plateaued. At baseline, subjects will receive either the high-dose or the low-dose of ILUVIEN and an injection of Lucentis. Subjects will receive additional Lucentis injections during the study only if subretinal or intraretinal fluid persists. Outcome measures will 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. We believe that the prevalence of retinal vein occlusion in the U.S. range from approximately 800,000 to approximately 1.6 million. 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. In June 2010, Genentech s drug Lucentis received approval for this condition. Retinal specialists have been using intravitreal injections of the corticosteroid triamcinolone acetonide on an off-label basis to treat non-ischemic RVO. The FDA 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 the two doses of ILUVIEN in patients with macular edema secondary to RVO.

ILUVIEN Registration Plan

U.S. Regulatory Requirements

In the U.S., clinical evidence of the effectiveness of ILUVIEN for the treatment of DME from our FAME Study is based on two time-point comparisons. The primary efficacy variable is the proportion of patients who have visual acuity improvement in their study eye, referred to as the responder rate, based on the change from baseline in BCVA as measured on the 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 is defined at month 24 of our FAME Study using this variable. Based on the month 24 clinical readout, ILUVIEN has 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, in the CRL the FDA requested the additional 12 months of clinical data from the completed FAME Study through month 36 for review. We are currently preparing a response to the CRL for submission early in the second quarter of 2011 including this additional efficacy and safety data.

Table of Contents

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 have 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. We also plan to submit efficacy and safety data through the end of the FAME Study to the applicable regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the second quarter of 2011.

Commercialization

We believe that ILUVIEN will be the first ophthalmic drug approved by the FDA for the treatment of DME and the only single treatment drug therapy providing a sustained therapeutic effect of longer than six months. Our commercialization strategy will be to establish ILUVIEN as a leading therapy for the treatment of DME and subsequently for other indications. In the U.S. and Canada we intend to distribute ILUVIEN to physicians and through wholesalers and specialty pharmacies utilizing our outside sales force. 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. ILUVIEN is not approved by the FDA. Our commercialization strategy is subject to and dependent upon the regulatory approval of ILUVIEN for the treatment of DME.

Sales and Marketing

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 the treatment of wet AMD. We intend to capitalize on our management s experience and expertise in marketing eye-care products by marketing and selling ILUVIEN to the approximately 1,600 retinal specialists practicing in the approximately 900 retina centers in the U.S. and Canada through our outside sales force. The concentration of retinal specialists in a small number of retina centers and ILUVIEN s expected status as the only ophthalmic drug therapy approved by the FDA for the treatment of DME and its long term sustained release characteristic are factors that we believe will accelerate the adoption of ILUVIEN by retinal specialists. We intend to seek a commercialization partner for sales and marketing activities outside North America.

Our plan has been to ensure that influential retinal specialists are presenting our FAME Study data at key retina meetings, to develop our medical marketing, promotion and communication materials and to build our own specialized domestic sales and marketing infrastructure, comprised of approximately 40 people, to market ILUVIEN and other ophthalmic products that we acquire or develop in the future. In preparation for the commercial launch of ILUVIEN previously anticipated to occur in the first half of 2011, we began recruiting our sales and marketing infrastructure personnel with extensive ophthalmic based sales experience in the fourth quarter of 2010. We have hired our three field directors but have determined not to add the personnel and incur the costs of hiring and training an internal sales force at this time. We entered into a relationship with OnCall LLC, a contract sales force company, who will utilize their employees to act as our sales representatives if we receive approval of the ILUVIEN NDA from the FDA. We expect that following an FDA approval of our NDA, the OnCall sales force will be able to access and form relationships with retinal specialists in the approximately 900 retina centers for the commercial launch of ILUVIEN. In connection with the commercial launch of ILUVIEN, we expect to hire additional personnel to support the activities of customer service, post-marketing pharmacovigilance, medical affairs and regulatory compliance.

Table of Contents

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 depend heavily on third-party contract manufacturers to produce and package our products. We require that these manufacturers produce active pharmaceutical ingredients, or APIs, and finished drug products in accordance with 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.

We are in the process of finalizing long-term agreements with the manufacturer of the API in ILUVIEN (FARMABIOS SpA/Byron Chemical Company Inc.) and the manufacturer of the ILUVIEN inserter (Flextronics International, Ltd or an affiliate of Flextronics International, Ltd. (Flextronics)). We have finalized a long-term agreement with the manufacturer of ILUVIEN (Alliance Medical Products Inc.) which is discussed below.

pSivida manufactured our clinical trial materials for our FAME Study, our PK Study and for 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 inserter, 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 fur Arneimittel und Medizinprodukte (BfArM). The CRL 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 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 recent inspections. One of the manufacturers received confirmation from the FDA in March 2011 that their facility is acceptable and the second manufacturer is in discussions with the FDA to resolve its deficiencies.

In February 2010, we entered into a commercial manufacturing agreement with Alliance Medical Products, Inc. (Alliance) whereby Alliance agreed to manufacture and package ILUVIEN for us at its Irvine, California facility. We purchased certain equipment and loaned such equipment to Alliance 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 inserter and the active pharmaceutical ingredient. 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 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 current term.

Table of Contents

In our NDA for ILUVIEN, we provided the FDA 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. 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 the product specifications. The same process validation package was submitted in the Marketing Authorization Application (MAA) in Europe. Validation was based on small scale batches and we will be limited to this batch size for product sold in Europe.

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. If ILUVIEN is approved for use in the treatment of DME, it will compete against laser photocoagulation and off-label use of anti-VEGF and corticosteroid injections, or other therapies that may be approved in the future. While we believe that ILUVIEN will be the first ophthalmic drug therapy approved by the FDA for the treatment of DME, 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 our product candidates:

Allergan, Inc. s (Allergan) product Ozurdex (dexamethasone intravitreal implant), is a bioerodable extended release implant that delivers the corticosteroid dexamethasone. Ozurdex was approved in 2009 for macular edema following branch or central RVO and non-infectious uveitis affecting the posterior segment of the eye in September 2010 and showed duration of therapy of three to five months. In addition, Allergan s product Trivaris (triamcinolone acetonide injectable suspension) is approved for sympathetic ophthalmia, temporal arteritis, uveitis and other inflammatory conditions unresponsive to topical corticosteroids. Trivaris is not indicated for the treatment of DME, dry AMD, wet AMD or RVO.

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

Table of Contents

topical corticosteroids. TRIESENCE is not indicated for the treatment of DME, dry AMD, wet AMD or RVO.

Genentech Inc. s (Genentech) products Lucentis (ranibizumab injection) and Avastin (bevacizumab), both antibodies that block all isoforms of VEGF, are being studied for the treatment of DME. 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 European Union, and for the treatment of DME in the European Union. However, Lucentis is currently enrolled in Phase 3 clinical trials for the treatment of DME in the U.S. . Avastin is currently marketed as an oncology product and is not indicated for the treatment of DME, dry AMD or RVO. Genentech is a wholly-owned member of the Roche Group.

Eyetech, Inc. s product Macugen (pegaptanib sodium injection) is an anti-VEGF aptamer against VEGF 165. It has been FDA-approved for treatment of all subtypes of choroidal neovascularization in patients with AMD. Macugen is not indicated for the treatment of DME, dry AMD or RVO.

In addition, there are a number of other companies, including Regeneron, Inc., MacuSight, Inc., Thrombogenics NV. and Novagali Pharma S.A., that are developing drug therapies or sustained delivery platforms for the treatment of ocular disease. 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. For a generic pharmaceutical competitor to ILUVIEN, bioequivalency must be established through the demonstration of an equivalent pharmacodynamic endpoint in a clinical trial. We believe conducting such a clinical trial would be cost prohibitive and time consuming.

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

Other Pipeline Products

NADPH Oxidase Inhibition

We believe that the management of oxidative stress is an important strategy in managing the development and progression of diseases of the eye, and we believe that NADPH oxidase inhibitors have the potential to manage oxidative stress. Oxidative stress is a condition where excess reactive oxygen intermediates generally referred to as reactive oxygen species (ROS), are produced. The production of ROS is not always pathogenic, however, many researchers believe that when the level of ROS becomes excessive, pathogenic processes are initiated, resulting in diseased tissue.

NADPH oxidase has been identified as an enzyme system that generates ROS as its primary function. NADPH oxidase has been identified in almost every tissue type and there is a significant amount of scientific literature associating NADPH oxidase activation with many systemic and ocular conditions. In the eye, the inhibition of NADPH oxidase has been shown to prevent or slow pathology in various models of ocular disease, including retinal degeneration, retinal neovascularization, choroidal neovascularization and uveitis. In addition, the presence of NADPH oxidase in corneal epithelial cells implicates it as having a possible role in dry eye, and the activation of NADPH oxidase in certain pollen grains upon hydration implicates its role in allergic conjunctivitis.

In July and August 2009, we executed agreements with Emory University, whereby we acquired exclusive, worldwide licenses of rights under patent applications covering two classes of NADPH oxidase inhibitors. Our strategy around

NADPH oxidase inhibition will target, as the first indication, the treatment of dry AMD and specifically the end stage of this condition known as geographic atrophy. We have initiated a testing process to identify the optimal candidate for formulation in a sustained release dosage form for the treatment of geographic atrophy. In addition to studying NADPH oxidase inhibitors, and specifically an

Table of Contents

intraocular dosage form, to treat dry AMD, we believe that these compounds and this dosage form has the potential to treat other diseases of the eye including wet AMD, diabetic retinopathy and posterior uveitis.

Licenses and Agreements

pSivida US, Inc.

In February 2005, we entered into an agreement with pSivida to obtain rights and licenses to intellectual property rights related to pSivida s proprietary delivery technology. 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 provided 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 Phase 3 trials for ILUVIEN for the treatment of DME.

Under the February 2005 agreement, we and pSivida agreed to collaborate on the development of ILUVIEN with FAc for DME, and share equally in the 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 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 $15.0 million 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 our common stock greater than $75.0 million), the occurrence of an event of default under our 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 we were required to begin making principal payments of $500,000 per month. On April 27, 2010, we paid pSivida

approximately $15.2 million in principal and interest to satisfy the note payable with the proceeds from our initial public offering.

Table of Contents

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, 2010.

Emory University

In July 2009, we entered into an agreement with Emory University 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.

Under such agreements, we pay Emory University royalties in the mid-single digits of net sales of products containing such fulvene or triphenylmethane compounds, in countries in which a claim in a pending patent application or an unexpired patent that covers the applicable product exists. We also pay Emory University royalties in the low-single digits of net sales of products containing such fulvene or triphenylmethane compounds, in countries in which a claim in a pending patent application or an unexpired patent that covers the applicable product does not exist, if at least one patent that covers the applicable product has issued in the U.S. Furthermore, under each agreement, we will be required to make annual minimum royalty payments in the amount of $250,000 the first calendar year after regulatory approval of the product in a major market country (i.e., the U.S., Japan, China, India or any European country), $500,000 the second calendar year after regulatory approval of the product in such major market country, $1.0 million the third calendar year after regulatory approval of the product in such major market country and $2.5 million the fourth year after regulatory approval of the product in such major market country and each subsequent year thereafter for the remainder of the term of such agreement. If we terminate the agreements in India, China or Japan after we obtain regulatory approval for a licensed product, the minimum royalty in the calendar year of the termination, and in each subsequent calendar year thereafter, will increase by $250,000 for each such country in which termination occurred. We will also be required to make payments of up to $5.8 million under the fulvene license agreement and up to $5.9 million under the triphenylmethane license agreement depending upon which regulatory milestones we achieve. If we do not make any milestone payments to Emory University under the license agreements prior to the third anniversary of the effective date of the applicable license agreement, and we do not elect to terminate that license agreement in accordance with its terms, then we will be required to pay Emory University annual license maintenance fees ranging from $500,000 to $2.0 million (depending on when such payment is made) until a milestone payment is made under the applicable license agreement or such license agreement is terminated in accordance with its terms. As an upfront license fee for the licenses granted by Emory University to us, we issued to Emory University (and its inventors), that number of shares of our common stock with a fair market value equal to $150,000 on the date of issuance with respect to the fulvene license agreement and in December 2009 we issued that number of shares of our common stock with a fair market value equal to $150,000 on the date of issuance with respect to the triphenylmethane

license agreement. We must also reimburse Emory University for reasonable costs and expenses incurred by Emory University in filing, prosecuting and maintaining the licensed patents.

Table of Contents

In connection with the Emory license agreements, we obtained an exclusive option to acquire an exclusive, worldwide license to rights under intellectual property rights related to the covered compounds 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 in humans outside the eye. The option will include the right to sublicense to a third-party and will last for a period of up to six years. In order to retain the option over the six-year period, we will be required to make maintenance payments of $550,000 in the aggregate over a four-year period commencing two years after the effective date of the license agreement. If we exercise the option during the six-year period with respect to a license agreement and subsequently enter into an amendment to such license agreement in connection therewith, then the license granted under such license agreement will be expanded to cover the development, manufacturing, marketing and selling of products that contain the covered compounds for therapeutic and prophylactic uses for the treatment of diseases and disorders in humans outside the eye. We may grant sublicenses of the intellectual property rights granted to us under such license agreements to sublicensees. We will, however, be required to remit 25% of any royalty amounts and 20% to 45% (depending upon when the applicable sublicense is granted by us) of other payments we receive from a sublicensee to Emory University.

As a licensee, we are expected to diligently develop and commercialize the covered compounds, and failure to meet certain milestones may result in the termination of our licenses. Under the agreements, the performance of our sublicensees is deemed to be performance by us toward fulfillment of our diligence obligations. The agreements will expire on a country by country basis upon the later of (i) the expiration of the last to expire of the licensed patents in a particular country and (ii) ten years after the date of the first sale of a licensed product in such country. In addition, Emory University may terminate a license agreement if (i) we fail to cure a breach of a material term of such license agreement within 30 days after notice of such breach; (ii) a material proceeding is instituted against or by us under any bankruptcy, insolvency, moratorium or dissolution law that is not dismissed within 90 days; (iii) we assign substantially all of our assets for the benefit of creditors; (iv) we place our assets in the hands of a trustee, assignee or receiver and the receivership or trust is not dissolved or such placement is not reversed within 60 days; (v) we notify Emory University in writing that we are quitting the business of developing or selling products containing the covered compounds or (vi) we challenge the validity, enforceability and/or scope of any claim within a patent or patent application licensed to us by Emory University under such license agreement in a court or other government agency.

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 in the field of ophthalmology other pharmaceutical products. 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, we are still expected to make the payment described above.

Table of Contents

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, our products may be seized, injunctions and monetary fines may be imposed, and we may be criminally prosecuted.

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting the safety and efficacy as well as detailed information on the manufacture and composition of the product and proposed labeling. The testing and collection of data and the preparation of the necessary applications are expensive and time consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approval that could delay or preclude us from marketing our products. The drug approval process in the U.S. generally involves the following:

- completion of preclinical laboratory and animal testing and formulation studies conducted under Good Laboratory Practices (GLP) regulations;
- submission of an Investigational New Drug Application (IND) which must become effective before human clinical trials may begin;
- completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational drug for its intended use; the studies must be conducted under Good Clinical Practices (GCP) regulations;
- submission of an 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 current Good Manufacturing Practice (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 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 the 30-day 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.

Table of Contents

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

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

Phase 3 trials further evaluate clinical efficacy and test further for safety in an expanded patient population at geographically dispersed test sites. Completion of two adequate and well-controlled Phase 3 studies with results that replicate each other is the norm before an application can be 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 2 and 10 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 the NDA that contains the results of non-clinical and clinical trials, together with detailed information on the chemistry, manufacturing and controls of 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 is substantial and increases every year. In fiscal year 2011, the fee will be $1.5 million.

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 3 months of the PDUFA goal date. If the FDA s evaluation of the NDA and audit/inspection of clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or Complete Response Letter (CRL). A CRL is issued if the FDA determines that it will not approve the application in its present form. The CRL will describe all of the specific deficiencies the FDA has identified and when possible, the FDA will recommend actions that the applicant can take before the application may be approved.

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

- resubmit the NDA addressing all deficiencies identified in the CRL;
- withdraw the NDA without prejudice to a subsequent submission; or
- request an opportunity for a hearing on the question of whether there are grounds for denying approval of the NDA. Within 60 days of the date of request, the FDA will either approve or refuse to approve the NDA.

Responses to the CRL can be classified as Class 1 or Class 2. Class 1 and Class 2 resubmissions have a 2-month and a 6-month review cycle, respectively, beginning on the date 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

Table of Contents

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 recently enacted 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, limitation on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug.

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

Post-Marketing Requirements. There are post-marketing safety surveillance requirements that we will need to meet to continue to market 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 promotional activities involving the Internet. The FDA has very broad enforcement authority under the FD&C Act, and failure to abide by these regulations can result in penalties, including the issuance of warning letters directing the sponsor to correct deviations from FDA standards, a requirement that future advertising and promotional materials are pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

The manufacturing facility that produces our product must maintain compliance with cGMP and is subject to periodic inspections by the FDA. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal and regulatory action, including Warning Letters, seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. In the CRL 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 recent inspections. One of the manufacturers received confirmation from the FDA in March 2011 that its facility is acceptable and the second manufacturer is in discussions with the FDA to resolve its deficiencies.

Foreign Regulations

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

Under the European Union regulatory system, applications for drug approval may be submitted either in a centralized or decentralized procedure. Under the centralized procedure, a single application to the European

Table of Contents

Medicines Agency (EMA) leads to an approval granted by the European Commission which permits marketing of the product throughout the European Union (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 at the European Union community level may also be submitted under this procedure. We believe ILUVIEN would potentially qualify for this procedure as a product that constitutes a significant therapeutic, scientific or technical innovation.

The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for products that do not comply with the requirements for the centralized procedure. Under the decentralized procedure, the holders of national marketing authorization in one of the countries within the European Union may submit further applications to other countries within the European Union, who will be requested to recognize the original authorization based on an assessment report provided by the country in which marketing authorization is held.

We used the decentralized procedure in Europe. The MHRA is our Reference Member State. A Reference Member State is responsible for coordinating the review and approval process between the United Kingdom and the six other European Union countries where we intend to seek marketing authorization.

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.

We own or have licensed three U.S. utility patents, one U.S. design patent and seven U.S. patent applications as well as numerous foreign counterparts to many of these patents and patent applications relating to ILUVIEN or the ILUVIEN inserter. We licensed our patent rights relating to ILUVIEN from pSivida. Pursuant to our licensed rights, 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 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. Our licensed patent portfolio also includes a U.S. patent and a corresponding issued European patent directed to our low-dose ILUVIEN device and a pending U.S. patent application directed to our high-dose ILUVIEN device. In addition, we have patent applications directed to an inserter system for ILUVIEN.

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. 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 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

Table of Contents

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 any of our products 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 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 engage 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 $12.6 million, $15.1 million, and $43.8 million for research and development during the years ended December 31, 2010, 2009, and 2008, respectively.

Employees

As of March 1, 2011, we had 27 employees, two of whom hold Ph.D.s, and one of whom holds an O.D. Ten of these employees were engaged in research, development and regulatory activities, and 17 were engaged in administrative support, human resources, 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 web site address is http://www.alimerasciences.com. The information contained in, or that can be accessed through, our Web site is not part of this report and should not be considered part of this report.

Available Information

Alimera files 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.

We also make available free of charge on our Internet website at www.alimerasciences.com our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and, if applicable,

Table of Contents

amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it 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 Internet website at www.alimerasciences.com.

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 occurs, 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 Business and Industry

We are heavily dependent on the success of our lead product candidate, ILUVIEN, which is still under development. If we are unable to commercialize ILUVIEN, or experience significant delays in doing so, our business will be materially harmed.

We are a biopharmaceutical company with no products approved for commercial sale. We have incurred, and will continue to incur, significant costs relating to the regulatory approval and commercialization of ILUVIEN, our only product candidate in development. We anticipate that in the near term our ability to generate revenues will depend solely on the successful development and commercialization of ILUVIEN. We have not yet obtained regulatory approval to market this product candidate in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize this product candidate successfully.

Based on our analysis of the month 24 clinical readout from our Phase 3 pivotal clinical trials for the use of ILUVIEN in the treatment of diabetic macular edema, or DME (collectively, our FAME Study), in June 2010 we filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the low dose of ILUVIEN in the U.S., followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in July 2010. The European Marketing Authorization Application (MAA) was submitted through the Decentralized Procedure with the United Kingdom Medicines and Health products Regulatory Agency (MHRA) as the Reference Member State. In December 2010, we received a Complete Response Letter (CRL) from the FDA regarding our NDA. The FDA issued the CRL to communicate its decision that the NDA could not be approved in its present form. No new clinical studies were requested by the FDA in the CRL. However, the FDA asked us for analyses of the safety and efficacy data through the end of the FAME Study to further assess the relative benefits and risks of ILUVIEN. We are currently preparing the analyses the FDA requested having completed the FAME Study and publicly released data on February 3, 2011. The FDA is also seeking additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN, which we are in the process of compiling. We currently anticipate submitting our response to the CRL to the FDA early in the second quarter of 2011. Our submission to the FDA will be considered a Class 2 response, which will provide for a review period of up to an additional six months for our NDA. However, the FDA may request additional information from us, and, ultimately, may not grant marketing approval for ILUVIEN. In addition, although we believe the final clinical readout from our FAME Study demonstrates that ILUVIEN is safe and effective in the treatment of DME, clinical data often is susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. Furthermore, even if we receive FDA approval, we

might not be successful in commercializing ILUVIEN. If we are not successful in commercializing ILUVIEN, or are significantly delayed in doing so, our

Table of Contents

business will be materially harmed and we may need to curtail or cease operations. Our ability to successfully commercialize ILUVIEN will depend, among other things, on our ability to:

- produce batches of ILUVIEN in quantities sufficiently large to permit successful commercialization;
- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- establish commercial manufacturing arrangements with third-party manufacturers;
- launch commercial sales of ILUVIEN; and
- secure acceptance of ILUVIEN in the medical community and with third-party payers.

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 have a limited operating history. We are not currently generating revenues and we cannot estimate with precision the extent of our future losses. We do not currently have any products that have been approved 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, particularly as we increase our research, clinical development, administrative and sales and marketing activities. Assuming FDA approval of our NDA in 2011, we currently do not expect to generate revenue from the sale of ILUVIEN until late 2011 at the earliest, if at all. As a result, 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, 2010, we have accumulated a net deficit of $188.9 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 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.

We face heavy government regulation, and 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 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 and the regulations applicable to that particular drug candidate. Regulatory agencies, including those in the U.S., Canada, the European Union 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 process;

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.

Table of Contents

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 risk/benefit relationship. Further, we intend to market ILUVIEN, and may market other product candidates, outside the U.S. and specifically in the European Union 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 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 submitted an NDA in the U.S. for the low dose of ILUVIEN in June 2010 with 24 months of clinical data from our FAME Study, followed in July 2010 by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. Consistent with recommendations regarding the appropriate population for primary analysis as described in the FDA-adopted International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidance E9, Statistical Principles for Clinical Trials, we believe that the FDA considers the most relevant population for determining safety and efficacy to be the full data set of all 956 patients randomized into our FAME Study, with data imputation employed using last observation carried forward, for data missing because of patients who discontinued the trial or are unavailable for follow-up (the Full Analysis Set). The primary efficacy endpoint was met with statistical significance for both the low dose and the high dose of ILUVIEN in both trials using the Full Analysis Set and we submitted an analysis based on this data set for the low dose to the FDA. However, our FAME Study protocol did not include the Full Analysis Set and provides that the primary assessment of efficacy will be based on another data set that excludes from the Full Analysis Set three patients who were enrolled but never treated as well as data collected for patients subsequent to their use of treatments prohibited by our FAME Study protocol (the Modified ART Data Set). Statistical significance was not achieved for either the low dose or the high dose in one trial using the Modified ART Data Set. In December 2010, we received a CRL from the FDA. The FDA issued the CRL to communicate its decision that the NDA for ILUVIEN could not be approved in its present form. No new clinical studies were requested by the FDA, and our use of the Full Analysis Set was not questioned in the CRL. However, the FDA asked us for analyses of the safety and efficacy data through the final readout at the end of the FAME Study to further assess the relative benefits and risks of ILUVIEN. We are currently preparing the analyses the FDA requested and currently anticipate submitting our response to the CRL early in the second quarter of 2011. Our submission to the FDA will be considered a Class 2 response which will provide for a review period of up to an additional six months for our NDA. There is no assurance that the FDA will utilize the Full Analysis Set and not the Modified ART Data Set or another data set in determining whether ILUVIEN is safe and effective, any of which could result in the FDA not granting marketing approval for ILUVIEN.

In July 2010, we submitted in Europe a MAA using the Decentralized Procedure with the U.K. MHRA as the Reference Member State (RMS). Applications were submitted concurrently to the Concerned Member States (CMS) listed as follows: Germany, Spain, Italy, France, Portugal and Austria.

We received the initial assessment reports from the RMS and the CMS in December 2010. The issues raised were similar to the issues raised by the FDA. We plan to submit the additional safety and efficacy data through the final readout at the end of the FAME Study to regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the second quarter of 2011.

Regulatory agencies require carcinogenicity studies in animals to identify tumorigenic potential in animals to assess the relevant risk in humans. Based on month 18 readouts from our open-label Phase 2 human pharmacokinetic clinical trial (PK Study), which indicate that there is negligible systemic absorption of fluocinolone acetonide (FAc) in patients being treated with ILUVIEN, we submitted a carcinogenicity waiver in our submissions to the FDA and European health authorities. Although the FDA did not specifically state in the CRL that the waiver has been granted, the CRL did not include any requirement to conduct a carcinogenicity study. In the Preliminary

Table of Contents

Assessment Report issued by the UK MHRA, the MHRA stated that the lack of single-dose, carcinogenicity and reproductive and developmental toxicity studies with ILUVIEN is acceptable. If we are required to perform carcinogenicity studies in animals, the approval of ILUVIEN could be delayed by up to 36 months.

In the 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 recent inspections. One of the manufacturers received confirmation from the FDA in March 2011 that their facility is acceptable and the second manufacturer is in discussions with the FDA to resolve its deficiencies. Failure for our manufactures to comply with cGMP may have an adverse effect on our business.

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. We have not yet received regulatory approval to market any of our product candidates in any jurisdiction.

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 received the final month 36 clinical readout from our FAME Study, but the extent of ILUVIEN s long-term side effect profile beyond month 36 is not yet known. Upon review of our NDA for the low dose of ILUVIEN in the treatment of DME, the FDA may conclude that our FAME Study did not demonstrate that ILUVIEN has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. Conversely, the FDA may conclude that ILUVIEN s side-effect profile does not demonstrate an acceptable risk/benefit relationship in line with ILUVIEN s demonstrated efficacy. In the event of such conclusions, we may not receive regulatory approval from the FDA or from similar regulatory agencies in other countries.

Even if we do receive regulatory approval 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 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 the use to patients exhibiting IOP below a certain level or having an artificial lens at the time of treatment. Product approvals, once granted, may be withdrawn if problems occur after initial marketing. If and when ILUVIEN does receive regulatory approval or clearance, the marketing, distribution and manufacture of ILUVIEN will be subject to regulation in the U.S. by the FDA and by similar entities in other countries. 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;

Table of Contents

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.

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 s) proprietary delivery device could revert to pSivida if we (i) fail twice to cure our breach of an obligation to make certain payments to pSivida following receipt of written notice thereof; (ii) fail to cure other breaches of material terms of our agreement with pSivida within 30 days after notice of such breaches or such longer period (up to 90 days) as may be reasonably necessary if the breach cannot be cured within such 30-day period; (iii) file for protection under the bankruptcy laws, make an assignment for the benefit of creditors, appoint or suffer appointment of a receiver or trustee over our property, file a petition under any bankruptcy or insolvency act or have any such petition filed against us and such proceeding remains undismissed or unstayed for a period of more than 60 days; or (iv) notify pSivida in writing of our decision to abandon our license with respect to a certain product using pSivida s proprietary delivery device. If 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 were not in breach of our license agreement with pSivida as of December 31, 2010.

We will rely on a single manufacturer for ILUVIEN, a single manufacturer for the ILUVIEN inserter and a single active pharmaceutical ingredient formulator for ILUVIEN s active pharmaceutical ingredient. Our business would be seriously harmed if 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 inserter (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 finalized a long-term agreement for the manufacture of the ILUVIEN insert (with Alliance), we have not yet finalized long-term agreements for the manufacture of the ILUVIEN inserter (with Flextronics) or for the manufacture of ILUVIEN s active pharmaceutical ingredient (with FARMABIOS), and if any of the third-party manufacturers are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators, enter into favorable agreements with them or get them approved by the FDA 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 inserter 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, if approved, for commercial distribution. Suppliers may not sell these materials to our manufacturers at the times we need them or on commercially

Table of Contents

reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently have not finalized all agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, product testing and potential regulatory approval of ILUVIEN 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 after 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 an agreement for the commercial production of the ILUVIEN insert, we currently have not yet finalized any agreements for the commercial production of the active pharmaceutical ingredient in ILUVIEN or the ILUVIEN inserter. Even if we were able to secure such agreements, the suppliers may be unable or choose not to provide us the ingredients in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain and then supply these ingredients to our contract manufacturer for our clinical trials, potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop our product candidates, which would materially affect our ability to generate revenue from the sale of our product candidates.

The manufacture and packaging of pharmaceutical products such as ILUVIEN are subject to the requirements of the FDA and similar foreign regulatory entities. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be materially harmed.

The manufacture and packaging of pharmaceutical products such as ILUVIEN and our future product candidates are regulated by the FDA and similar foreign regulatory entities and must be conducted in accordance with the FDA s cGMP and comparable requirements of foreign regulatory entities. 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 products, 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. The FDA issued the CRL to communicate its decision that the NDA for ILUVIEN could not be approved in its present form. Additionally, the FDA also indicated that it had observed deficiencies in current good manufacturing practices (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. Our third-party manufacturers are in the process of resolving these deficiencies. One of the manufacturers received confirmation from the FDA in March 2011 that their facility is acceptable. If our third-party manufacturers fail to resolve these deficiencies, the FDA will not grant market approval for ILUVIEN. Additionally, 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. 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 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 may require clinical testing as a way to prove equivalency,

which would result in additional costs and delay.

Table of Contents

Furthermore, in order to obtain approval of our products, including ILUVIEN, 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 ILUVIEN 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 pilot scale batches, some of the steps in the manufacturing processes will need to be revalidated when we begin to manufacture commercial scale batches. If the required testing or process validation is delayed or produces unfavorable results, we may have to launch the product using smaller pilot scale batches, which may impact our ability to fulfill demand for the product.

The FDA and similar foreign regulatory bodies 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.

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 that product candidate. 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;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks;

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 that product candidate, we may not be able to obtain marketing approval or we may obtain approval for indications that is not as broad as intended. Our product

Table of Contents

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.

We may not be successful in executing our sales and marketing strategy for the commercialization of ILUVIEN. We currently have a limited sales and marketing organization and, as part of our sales strategy, we expect to initially depend in large part on a third party contract sales force for the sale of ILUVIEN. If we are unable to successfully execute such strategy, we may not be able to generate significant revenue.

At present, we have no internal sales force and only a limited number of sales and marketing personnel. We began hiring additional sales and marketing personnel in the third quarter of 2010 to establish our own sales and marketing capabilities in the U.S. in time for our previously anticipated commercial launch of ILUVIEN. We have hired three field directors but have determined not to add the personnel and incur the costs of hiring and training an internal sales force at this time. In the fourth quarter of 2010, we entered into a relationship with OnCall LLC, a contract sales force company that will utilize its employees to act as our sales representatives if we receive approval of the ILUVIEN NDA from the FDA.

Pursuant to our agreement with OnCall, following FDA approval, ILUVIEN will be promoted primarily to retinal specialists in the U.S. by OnCall s sales representatives. We will rely in large part on this outside sales force for the sales of ILUVIEN in the U.S. Although we expect to be involved in the hiring, training and management of these sales representatives, they will be employees of OnCall and subject to its ultimate control.

If we determine to establish a direct sales force in the future to sell ILUVIEN or another product candidate following marketing approval, we may not be able to establish such a direct sales force 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, 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 sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of retinal specialists 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 an independent sales and marketing organization.

We have not yet entered into any agreements related to the marketing of ILUVIEN or any of our other product candidates in international markets and we may not be able to enter into any arrangements with respect to international collaborations on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into appropriate marketing arrangements for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize ILUVIEN and our other product candidates in international markets. If we fail to enter into marketing arrangements for our products or are unable to develop an effective international sales force, our ability to generate revenue outside of North America would be limited.

If we are unable to successfully implement our commercialization plans and drive adoption by patients and retinal specialists of ILUVIEN through our sales, marketing and commercialization efforts and the efforts of OnCall, then we will not be able to generate significant revenue, which will have a material adverse effect on our business, results of operations, financial condition and prospects.

Table of Contents

In order to commercialize ILUVIEN, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2010, we had 27 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. 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 private insurers, the Medicare program and other third-party payers which could be affected by the recently enacted U.S. healthcare reform. 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 U.S., we will need to obtain approvals for payment for ILUVIEN from private insurers, including managed care organizations, and from the Medicare program. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. These reforms could significantly reduce payments from Medicare and Medicaid over the next ten years. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling 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.

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.

Table of Contents

Our business could also be adversely affected if private insurers, including managed care organizations, 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.

In some foreign countries, particularly Canada and the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In Canada, each province has a publicly funded drug plan with each having its own formulary citing specific criteria for reimbursement and prior authorization. Each provincial government except Québec considers the clinical and cost-effectiveness recommendations of the Common Drug Review performed by the Canadian Agency for Drugs and Technologies in Health. Québec has a separate drug review process that is performed by its Medication Council. In the European Union, each country has a different reviewing body that evaluates reimbursement dossiers submitted by manufacturers 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 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 products, including ILUVIEN, to other available therapies. 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 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.

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, reimbursement acceptance by 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 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 FA, 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.

There are no ophthalmic drug therapies 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 European Union and in later stage trials in the U.S. 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

Table of Contents

the treatment of DME include Ozurdex, a drug sponsored by Allergan, Inc. and the VEGF Trap, 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 if we receive marketing approval for ILUVIEN, even if ILUVIEN is otherwise viewed as a preferable therapy.

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.

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 entering into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing of ILUVIEN 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.

Table of Contents

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.

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. A number of 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.

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 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

Table of Contents

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.

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, Susan Caballa, our Senior Vice President of Regulatory Affairs, Kenneth Green, Ph.D., our Senior Vice President and Chief Scientific Officer, Richard Eiswirth, our Chief Operating Officer and Chief Financial 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 current Good Laboratory Practices (cGLP) and similar foreign

standards, and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed.

Table of Contents

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 is approved.

Any product for which we obtain marketing approval, 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;

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 foreign jurisdictions would prevent us from marketing our products abroad.

We intend to market our products internationally. 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. In July 2010, we submitted a MAA for ILUVIEN to the U.K. MHRA and to regulatory authorities in Austria, France, Germany, Italy, Portugal and Spain. 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. 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.

Table of Contents

In addition, if any of our product candidates receives marketing approval and 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;
- 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 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.

We may not have rights under some patents or patent applications that may be infringed by our products or potential products. 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.

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

Table of Contents

ILUVIEN. For example, one of our potential competitors holds issued and pending U.S. patents with claims covering devices for injecting an ocular implant into a patient s eye similar to the ILUVIEN inserter. 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 important 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

Table of Contents

or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff were previously employed by other pharmaceutical or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their drug development activities for us.

If our efforts to protect the proprietary nature of the intellectual property related to our products are not adequate, we may not be able to compete effectively in our markets.

The strength of our patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. In addition to the rights we have licensed from pSivida relating to 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, 2010, we owned one pending non-provisional U.S. utility patent application, one issued U.S. design patent and one patent Cooperation Treaty Application, relating to our inserter system 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, 2010, the 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. No patent term extension will be available for any of these U.S. patents or any of our licensed U.S. pending patent applications. After these patents expire in April 2020, 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.

Table of Contents

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.

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

Table of Contents

disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Product liability lawsuits could divert our resources, 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 new legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The new 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.

Table of Contents

The full effects of the U.S. healthcare reform legislation cannot be known until the new law is implemented through regulations or guidance issued by the Centers for Medicare & Medicaid Services and other federal and state healthcare agencies. The financial impact of the U.S. healthcare reform legislation over the next few years will depend on a number of factors, including but not limited, to the policies reflected in implementing regulations and guidance, and changes in sales volumes for products affected by the new system of rebates, discounts and fees. The new 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.

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 European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 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, 2010, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $97.8 million and $81.0 million, respectively, which expire at various dates beginning in 2020 through 2030.

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 are currently evaluating the impact of our IPO on our NOL carry-forwards and whether certain changes in ownership have occurred that

Table of Contents

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 Section 382 (or comparable provisions of state law).

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, as well as rules subsequently implemented by the SEC and Nasdaq, have 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 may be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report, commencing in our annual report on Form 10-K for the year ending December 31, 2011, on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 would require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will 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;
- 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.

Table of Contents

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.

We may need additional financing in the event that we do not receive regulatory approval for ILUVIEN or the approval is delayed or, if approved, the future sales of ILUVIEN 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 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, 2010, we had approximately $28.5 million in cash and cash equivalents and $26.3 million in investments which, together with the Credit Facility described below, we believe is sufficient to fund our operations through the projected commercialization of ILUVIEN and the expected generation of revenue in late 2011. 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 consists of a $20 million revolving line of credit and a $12.5 million term loan. The lenders have advanced $6.25 million under the term loan and may advance the remaining $6.25 million following FDA approval of ILUVIEN, but no later than July 31, 2011. Given the status of the FDA s review of the NDA, it is unlikely that FDA approval would occur prior to July 31, 2011. We are in discussions with the lenders to amend the terms of the Credit Facility to, among other things, extend the availability of the term loan. However, there are no assurances that the Credit Facility will be amended. We may draw on the revolving line of credit against eligible, domestic accounts receivable subsequent to the launch of ILUVIEN. The commercialization of ILUVIEN is dependent upon approval by the FDA, however, and we cannot be sure that ILUVIEN will be approved by the FDA in 2011, if at all, or that, if approved, future sales of ILUVIEN will generate enough revenue to fund our operations beyond its commercialization.

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, other than our intellectual property (provided that if we fail to meet certain financial conditions, a curable lien will be imposed on our intellectual property as well), 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 the initial public offering of shares of our common stock in April 2010 at a price of $11.00 per share. Subsequently, our common stock has traded as low as $6.30 per share. The realization of

Table of Contents

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:

- the timing and final outcome of FDA review of our NDA for ILUVIEN;
- results from our clinical trial programs;
- FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- 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 and the submission of regulatory filings. 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 and 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 instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management s attention and resources.

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, 2010, our executive officers, key employees and directors and their affiliates beneficially owned, in the aggregate, approximately 82.6% of our outstanding common stock. As a result,

Table of Contents

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, 2010, there were a total of 2,741,985 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 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, 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.

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.

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, 2011, an additional 1,250,238 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

Table of Contents

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, 2011, an additional 8,246 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.

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 2011. 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.

Table of Contents

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. ***(REMOVED AND RESERVED)***

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 initial public offering 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, 2010	**High**	**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 21, 2011 there were 64 holders of record of our common stock.

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 62. 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, 2010. 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

Table of Contents

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.

Recent Sales of Unregistered Securities

Sales of Unregistered Securities

In October 2010, we issued warrants to purchase an aggregate of up to 39,773 shares of our common stock to Silicon Valley Bank and MidCap Financial LLP, the lenders under our Credit Facility. The warrants were immediately exercisable at a per share exercise price of $11.00 and have a term of 10 years. We issued these warrants in reliance on Section 4(2) of the Securities Act of 1933, as amended, as a transaction not involving a public offering.

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 initial public offering, 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.

Table of Contents

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

The tables below summarize our financial data. The following statements of operations data for fiscal years 2010, 2009 and 2008, and the balance sheet data as of December 31, 2010 and 2009 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 2007 and 2006, and the balance sheet data as of December 31, 2008, 2007 and 2006 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.

Statement of Operations Data

	Years Ended December 31,				
	2010	**2009**	**2008**	**2007**	**2006**
	(In thousands, except per share data)				
Operating expenses					
Research and development	$ 12,581	$ 15,057	$ 43,764	$ 8,363	$ 6,736
General and administrative	4,610	3,407	5,058	3,184	3,028
Marketing	4,880	752	1,259	969	616
Total operating expenses	22,071	19,216	50,081	12,516	10,380
Interest and other income	73	37	585	1,079	596
Interest expense	(848)	(1,897)	(1,514)	(2)	(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	6
Loss from continuing operations	(17,859)	(44,218)	(61,464)	(11,438)	(9,780)
Income (loss) from discontinued operations	4,000			5,733	(3,191)
Net loss	(13,859)	(44,218)	(61,464)	(5,705)	(12,971)
Beneficial conversion feature of preferred stock		(355)			
Preferred stock accretion	(466)	(623)	(718)	(248)	(243)
Preferred stock dividends	(2,638)	(7,225)	(6,573)	(4,685)	(3,548)
Net loss attributable to common stockholders	$ (16,963)	$ (52,421)	$ (68,755)	$ (10,638)	$ (16,762)
Basic and diluted loss per share attributable to common stockholders	$ (0.77)	$ (34.56)	$ (45.50)	$ (7.09)	$ (11.66)

Weighted average number of shares used to compute basic and diluted loss per share attributable to common stockholders	22,168	1,517	1,511	1,500	1,437

Table of Contents

Balance Sheet Data

	Years Ended December 31,				
	2010	2009	2008	2007	2006
	(In thousands)				
Cash and cash equivalents	$ 28,514	$ 4,858	$ 17,875	$ 20,847	$ 27,157
Investments	26,330				
Working capital (deficit)	49,777	(4,428)	14,551	19,862	25,294
Total assets	56,414	6,561	20,264	24,519	31,251
Long-term liabilities	4,785	47,909	28,217	31	60
Preferred stock		113,389	103,017	67,990	63,057
Additional paid-in capital	233,338	4,836	3,474	2,867	2,571
Accumulated deficit	(188,854)	(171,891)	(119,470)	(50,715)	(40,077)
Total stockholders equity (deficit)	45,212	(165,472)	(115,887)	(47,738)	(37,399)

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 Item 1 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 we are developing for the treatment of diabetic macular edema (DME). DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. In September 2010 we completed two Phase 3 pivotal clinical trials (collectively, our FAME Study) for 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. Based on our analysis of the month 24 clinical readout from our FAME Study in December 2009, we filed 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 in July 2010. In December 2010, we received a Complete Response Letter (CRL) from the FDA. The FDA issued the CRL to communicate its decision that the NDA for ILUVIEN could not be approved in its present form. No new clinical studies were requested by the FDA in the CRL. However, the FDA asked us for analyses of the safety and efficacy data through the end of the FAME Study to further assess the relative benefits and risks of ILUVIEN. We are currently preparing the analyses the FDA requested having completed the FAME Study and publicly released data on February 3, 2011. The FDA is also seeking additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN, which

we are currently compiling. We currently anticipate submitting our response to the CRL to the FDA early in the second quarter of 2011. Our submission to the FDA will be considered a Class 2 response, which will provide for a review period of up to an additional six months for our NDA. Based on our discussions with the FDA, we anticipate that the FDA will call an advisory committee during this review. Additionally, we plan to submit the additional safety and efficacy data through the final readout at the end of

Table of Contents

the FAME™ Study to regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the second quarter of 2011. If our NDA for ILUVIEN is approved by the FDA, we plan to commercialize ILUVIEN in the U.S. by marketing and selling it to retinal specialists as early as late 2011. In addition to treating DME, ILUVIEN is 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 are also conducting testing on two classes of nicotinamide adenine dinucleotide phosphate (NADPH) oxidase inhibitors, for which we have acquired exclusive, worldwide licenses from Emory University, in the treatment of dry AMD. We plan to evaluate the use of NADPH oxidase inhibitors in the treatment of other diseases of the eye, including wet AMD and diabetic retinopathy. We intend to seek a collaboration partner for sales and marketing activities outside North America. We currently contract with development partners or outside firms for various operational aspects of our development activities, including the preparation of clinical supplies and have no plans to establish in-house manufacturing capabilities.

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of December 31, 2010, we have accumulated a deficit of $188.9 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

- complete the clinical development and registration of ILUVIEN;
- build our sales and marketing capabilities for the anticipated commercial launch of ILUVIEN in late 2011;
- add the necessary infrastructure to support our growth;
- 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, 2010, we had approximately $28.5 million in cash and cash equivalents and $26.3 million of investments in trading securities. In addition to our net IPO proceeds, our cash and cash equivalents include the January 2010 receipt of $10.0 million in proceeds from the exercise of outstanding Series C-1 warrants, and a $4.0 million option payment from Bausch & Lomb Incorporated (Bausch & Lomb) upon 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.

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 consists 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 and may advance the remaining $6.25 million following FDA approval of ILUVIEN, but no later than July 31, 2011. Given the status of the FDA s review of the NDA for ILUVIEN, we do not currently expect that FDA approval would occur prior to July 31, 2011. We are in

discussions with the lenders to amend the terms of the Credit Facility to, among other things, extend the availability of the term loan. However, there are no assurances that the Credit Facility will be amended. We may draw on the revolving line of credit against eligible, domestic accounts receivable subsequent to the launch of ILUVIEN.

We do not expect to generate revenues from our product, ILUVIEN, until late 2011, if at all, and therefore we do not expect to have positive cash flow from operations before that time. We believe our cash,

Table of Contents

cash equivalents, investments and Credit Facility are sufficient to fund our operations through the projected commercialization of ILUVIEN and the expected generation of revenue in late 2011. The commercialization of ILUVIEN is dependent upon approval by the FDA, however, and we cannot be sure that ILUVIEN will be approved by the FDA or that, if approved, future sales of ILUVIEN will generate enough revenue to fund our operations beyond its commercialization. Due to the uncertainty around FDA approval, management cannot be certain that we will not need additional funds for the commercialization of ILUVIEN. If ILUVIEN is not approved, or if approved, 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 provided 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 accrued interest at 8% per annum, payable quarterly and was payable in full to pSivida upon the earliest of a liquidity event as defined in the agreement,

the occurrence of an event of default under our 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 we were required to begin making principal payments of $500,000 per month. On April 27, 2010, we paid pSivida approximately $15.2 million in principal and interest

Table of Contents

to satisfy the note payable with the proceeds from our IPO. We will owe pSivida an additional milestone payment of $25.0 million upon FDA approval of ILUVIEN.

Our Credit Facility

Term Loan Agreement

On October 14, 2010 (Effective Date), we entered into a Loan and Security Agreement with Silicon Valley Bank and MidCap Financial LLP under (Lenders) which we may borrow up to $12.5 million (Term Loan Agreement). The lenders advanced $6.25 million on the Effective Date (Initial Tranche) and may advance the remaining $6.25 million following FDA approval of ILUVIEN, but no later than July 31, 2011 (Second Tranche). Given the status of the FDA s review of the NDA for ILUVIEN, it is unlikely that FDA approval would occur prior to July 31, 2011. We are in discussions with the Lenders to amend the terms of the Credit Facility to, among other things, extend the availability of the term loan. However, there are no assurances that the Credit Facility will be amended. 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, other than our intellectual property (provided that in the event we fail to meet certain financial conditions, a curable lien will be imposed on our intellectual property). We also agreed not to pledge or otherwise encumber our intellectual property assets.

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.

We will be required to pay interest on borrowings under the Term Loan Agreement at a rate of 11.5% on a monthly basis through July 31, 2011. Thereafter, we will be required to repay the principal, plus interest at such rate if the Second Tranche is advanced to us prior to February 28, 2011 (and plus interest at a rate of 12% if the Second Tranche is advanced to us after February 28, 2011), in 27 equal monthly installments. We paid to the lenders an upfront fee of $62,500, and will pay to the lenders an additional final payment of 3% of the total principal amount. In addition, if we repay the loan prior to maturity, we will pay to the lenders a prepayment penalty of 5% of the total principal amount if the prepayment occurs within one year after the funding date, 3% of the total principal amount if the prepayment occurs between one and two years after the funding date and 1% of the total principal amount of the prepayment occurs thereafter (each a Prepayment Penalty), provided in each case that such Prepayment Penalty will be reduced by 50% in the event we are acquired.

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, other than our intellectual property, provided that, for any date during which the notes are outstanding, our unrestricted balance sheet cash and cash equivalents plus the excess available under the Term Loan Agreement are less than the product of six times the monthly cash burn amount. In the event we fail to meet this financial condition, a curable lien will be imposed on our intellectual property. Should such a lien event take place, the lien would remain in force until such date that the Company s unrestricted cash and cash equivalents plus the excess available under the Term Loan Agreement were equal to or greater than twelve times the monthly cash burn amount. 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.

In connection with entering into this agreement, 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. In addition, the Lenders will have certain registration rights with respect to the shares of common stock issuable upon exercise of the warrants. We estimated the aggregate fair value of the warrants, using the Black-Scholes model, to be $389,000. We 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, we recorded a discount of $366,000 which is being amortized to interest expense using the effective interest method.

Table of Contents

Revolving Loan Agreement

Also on the Effective Date, we and Silicon Valley Bank entered into a Loan and Security Agreement (Revolving Loan Agreement), pursuant to which we obtained a secured revolving line of credit from Silicon Valley Bank with borrowing availability up to $20.0 million.

The Revolving Loan Agreement provides for a working capital-based revolving line of credit (Revolving Line) in an aggregate amount of up to the lesser of (i) $20.0 million, or (ii) 85% of eligible domestic accounts receivable. The Revolving Line matures on October 31, 2013.

Amounts advanced under the Revolving Line 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 Revolving Line is due monthly, with the balance due at the maturity date. We paid to the Silicon Valley Bank an upfront fee of $100,000. In addition, if we terminate the Revolving Line prior to maturity, we will 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 we are acquired.

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, other than our intellectual property, provided that, for any date during which the notes are outstanding, our unrestricted balance sheet cash and cash equivalents plus the excess available under the Term Loan Agreement are less than the product of six times the monthly cash burn amount. In the event we fail to meet this financial condition, a curable lien will be imposed on our intellectual property. Should such a lien event take place, the lien would remain in force until such date that our unrestricted cash and cash equivalents plus the excess available under the Term Loan Agreement were equal to or greater than twelve times the monthly cash burn amount. We also agreed not to pledge or otherwise encumber its intellectual property assets. Additionally, we must seek Silicon Valley Bank s approval prior to the payment of any cash dividends.

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.

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. However, there can be no assurance that Bausch & Lomb will continue the development of this allergy product, that it will receive FDA approval or that we will receive the $8.0 million payment. 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.

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 unless or until we obtain regulatory approval of, and commercialize, our product candidates or in-license additional products that generate revenue. In addition to

Table of Contents

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 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 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;

the number of patients that participate in the trials;

the number of doses that patients receive;

Table of Contents

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 contract research organizations 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.

None of our product candidates has received FDA or foreign regulatory marketing approval. 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 anticipate incurring a significant increase in general and administrative expenses, as we add additional employees and continue to operate as a public company. These increases will include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants, lawyers and accountants. We also expect to continue to incur significant costs to comply with the corporate governance, internal control and similar requirements applicable to public companies.

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. 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. We intend to capitalize on our management s past experience and expertise with eye-care products by marketing and selling ILUVIEN to the approximately 1,600 retinal specialists practicing in the approximately 900 retina centers across the U.S.

Table of Contents

Our plan is to develop our own specialized domestic sales and marketing infrastructure, comprised of approximately 40 people, to market ILUVIEN and other ophthalmic products that we may acquire or develop in the future. We hired regional managers with extensive ophthalmic-based sales experience in the third quarter of 2010 and plan to begin adding sales representatives in the fourth quarter of 2011. We entered into a relationship with OnCall LLC, a contract sales force company, that will utilize its employees to act as our sales representatives if we receive approval of the ILUVIEN NDA from the FDA. We expect that following an FDA approval, the On Call sales force will be able to access and form relationships with retinal specialists in approximately 900 retina centers for to the commercial launch of ILUVIEN, following FDA approval of our NDA. In connection with the commercial launch of ILUVIEN, we expect to hire additional personnel to support the activities of customer service, post-marketing pharmacovigilance, medical affairs, and regulatory compliance.

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 Accounting Standards Codification 815. 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.

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.

Table of Contents

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

We calculated net loss per share in accordance with ASC 260. We have determined that our previously outstanding Series A, Series B, Series C and Series C-1 preferred stock represent participating securities in accordance with ASC 260. However, since we operate at a loss, and losses are not allocated to the preferred stock, the two class method does not affect our calculation of earnings 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 9,131,451, 22,149,592, and 19,741,154 for the years ended December 31, 2010, 2009, and 2008, 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, 2010, 2009, and 2008, 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 contract research organizations, 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 contract research organization and review of contractual terms. However, if we have incomplete or inaccurate information, we may underestimate or overestimate activity levels associated with various clinical trials at a given point in time. In this event, we could record significant research and development expenses in future periods when the actual level of activities becomes known. To date, we have not experienced material changes in these estimates. Additionally, we do not expect material adjustments to research and development expenses to result from changes in the nature and level of clinical trial activity and related expenses that are currently subject to estimation. In the future, as we expand our clinical trial activities, we expect to have increased levels of research and development costs that will be subject to estimation.

Research and Development Costs

Research and development expenditures are expensed as incurred, pursuant to ASC 730. 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

Table of Contents

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 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, 2010, 2009 and 2007, was comprised of the following:

	Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Marketing	$ 127	$ 43	$ 109
Research and development	209	161	269
General and administrative	458	307	372
Total employee stock-based compensation expense	$ 794	$ 511	$ 750

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. 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

Table of Contents

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, 2010 we had federal NOL carry-forwards of approximately $97.8 million and state NOL carry-forwards of approximately $81.0 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 2030 and the state NOL carry-forwards will expire at various dates between 2020 and 2030. 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 Section 382 (or comparable provisions of state law). We have not yet completed a formal evaluation of whether our IPO resulted in certain changes in ownership that would limit our ability to utilize a portion of our NOL carry-forwards.

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 selected financial and operating data are derived from our financial statements and should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements.

	Years Ended December 31,		
	2010	**2009**	**2008**
	(In thousands except share and per share data)		
RESEARCH AND DEVELOPMENT EXPENSES	$ 12,581	$ 15,057	$ 43,764
GENERAL AND ADMINISTRATIVE EXPENSES	4,610	3,407	5,058
MARKETING EXPENSES	4,880	752	1,259
OPERATING EXPENSES	22,071	19,216	50,081
INTEREST AND OTHER INCOME	73	37	585
INTEREST EXPENSE	(848)	(1,897)	(1,514)
GAIN ON EARLY EXTINGUISHMENT OF DEBT	1,343		
DECREASE (INCREASE) IN FAIR VALUE OF PREFERRED STOCK CONVERSION FEATURE	3,644	(23,142)	(10,454)
LOSS FROM CONTINUING OPERATIONS	$ (17,859)	$ (44,218)	$ (61,464)

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

Table of Contents

for ILUVIEN in Austria, France, Germany, Italy, Portugal, Spain, and the U.K., $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 Europe, 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.

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.

Year ended December 31, 2009 compared to the year ended December 31, 2008

Research and development expenses. Research and development expenses decreased by approximately $28.7 million, or 66%, to approximately $15.1 million for the year ended December 31, 2009 compared to approximately $43.8 million for the year ended December 31, 2008. The decrease was principally attributable

Table of Contents

to the restructuring of our agreement with pSivida Inc., which resulted in incremental expenses of $29.8 million in the year ended December 31, 2008 that were not incurred in the year ended December 31, 2009. The $29.8 million cost in 2008 was comprised of a $12.0 million cash payment, a $15.0 million promissory note issued to pSivida, and the forgiveness of $2.8 million of net outstanding receivables due from pSivida related to the agreement. We continued to incur costs in 2009 with respect to our FAME Study, which completed enrollment in October 2007, and preparations for its anticipated registration with the FDA. We incurred increased costs in 2009 related to our FAME Study of $620,000 for our CRO costs as we prepared for and completed the lock of our FAME Study database and month 24 readout in the fourth quarter of 2009 and $490,000 in technology transfer costs associated with establishing manufacturing capabilities with a third-party manufacturer for ILUVIEN. These amounts were offset by decreases of $1.2 million in FAME Study trial site costs, $310,000 for our reading center to evaluate pictures of each enrollee s retina, and $240,000 for our PK Study due to the completion of enrollment and fewer patient visits per month as the trial progressed. Additionally, total development costs related to ILUVIEN increased by $1.3 million due to the absence of cost sharing reimbursements from pSivida as a result of the restructuring of our agreement in March 2008. We also decreased spending on the evaluation of the NADPH oxidase inhibitors obtained from Emory University and other development pipeline candidates by $270,000 due to the restricted capital markets in 2009 and in order to focus our resources on completing the development of ILUVIEN, but incurred $300,000 in initial license fees in 2009 to enter into these agreements with Emory University.

General and administrative expenses. General and administrative expenses decreased by approximately $1.7 million, or 33%, to approximately $3.4 million for the year ended December 31, 2009 compared to approximately $5.1 million for the year ended December 31, 2008. The decrease was primarily attributable to $1.3 million incurred in preparation for the anticipated 2008 initial public offering of our common stock that was expensed in the year ended December 31, 2008 when we determined that an initial public offering was unlikely in the then near term and $380,000 in legal fees associated with the restructuring of our agreement with pSivida, the evaluation of intellectual property regarding our ILUVIEN inserter system and the evaluation of certain strategic options.

Marketing expenses. Marketing expenses decreased by approximately $510,000, or 40%, to approximately $750,000 for the year ended December 31, 2009 compared to approximately $1.3 million for the year ended December 31, 2008. The decrease was primarily attributable to $230,000 in decreased spending on travel and general corporate awareness due to the restricted capital markets in 2009 and in order to focus our resources on completing the development of ILUVIEN, and $210,000 incurred for the initiation of pricing studies of the U.S. and European markets for ILUVIEN during the year ended December 31, 2008 that were not incurred in the year ended December 31, 2009.

Interest and other income. Interest income decreased by approximately $550,000, or 94%, to approximately $40,000 for the year ended December 31, 2009 compared to approximately $590,000 for the year ended December 31, 2008. The decrease in interest income is primarily attributable to a decrease in our average cash balance from $25.5 million during the year ended December 31, 2008 to $11.1 million for the year ended December 31, 2009, combined with a substantial drop in the rates of return available on our money market accounts from approximately 2.3% during the year ended December 31, 2008 to 0.3% for the year ended December 31, 2009.

Interest expense. Interest expense increased by approximately $380,000, or 25%, to approximately $1.9 million for the year ended December 31, 2009 compared to approximately $1.5 million for the year ended December 31, 2008. Our interest expense is associated with our $15.0 million note payable to pSivida issued in March 2008, and the increase is due to the note payable being outstanding for the full year ended December 31, 2009 as opposed to being outstanding for nine months in 2008.

Decrease (increase) in fair value of preferred stock conversion feature. For the year ended December 31, 2009 we recognized an expense of approximately $23.1 million related to the increase in the fair value of the conversion

feature of our preferred stock. The increase was attributable to an increase in the estimated fair value of our common stock from $3.71 at December 31, 2008 to $8.53 at December 31, 2009 and increased volatility in the market values of our peer group.

Table of Contents

Income from discontinued operations. We did not have any income (loss) from discontinued operations for either of the year ended December 31, 2008 or December 31, 2009 due to the sale of our dry eye product to Bausch & Lomb in July 2007.

Liquidity and Capital Resources

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of $188.9 million from our inception through December 31, 2010. 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 consists 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 and may advance the remaining $6.25 million following FDA approval of ILUVIEN, but no later than July 31, 2011. Given the status of the FDA s review of the ILUVIEN NDA, it is unlikely that FDA approval would occur prior to July 31, 2011. We are in discussions with the lenders to amend the terms of the Credit Facility to, among other things, extend the availability of the term loan. However, there are no assurances that the Credit Facility will be amended. We may draw on the revolving line of credit against eligible, domestic accounts receivable, as defined, subsequent to the launch of ILUVIEN. 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, other than our intellectual property, provided that, for any date during which the notes are outstanding, our unrestricted balance sheet cash and cash equivalents plus the excess available under the Term Loan Agreement is less than the product of six times the monthly cash burn amount. In the event we fail to meet this financial condition, a curable lien will be imposed on our intellectual property. Should such a lien event take place, the lien would remain in force until such date that the Company s unrestricted cash and cash equivalents plus the excess available under the Term Loan Agreement was equal to or greater than twelve times the monthly cash burn amount. 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. As of December 31, 2010, we had approximately $28.5 million in cash and cash equivalents and $26.3 million of investments. We believe that we have sufficient funds available to fund our operations through the projected commercialization of ILUVIEN and the expected generation of revenue in late 2011. The commercialization of ILUVIEN is dependent upon approval by the FDA, however, and we cannot be sure that ILUVIEN will be approved by the FDA or that, if approved, future sales of ILUVIEN will generate enough revenue to fund the Company s operations beyond its commercialization. Due to the uncertainty around FDA approval, management cannot be certain that we will not need additional funds for the commercialization of ILUVIEN. If ILUVIEN is not approved, or if approved, does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

In the event additional financing is needed or desired, we may seek to fund our operations through the sale of equity securities, strategic collaboration agreements and debt financing. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders especially in light of the current difficult financial environment. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result and the terms of any new equity securities may have a preference over our common stock. If we attempt to raise additional funds through strategic collaboration agreements and debt financing, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the

debt may involve

Table of Contents

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, 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.

For the year ended December 31, 2008, our cash used in continuing operations of $32.2 million was primarily due to our net loss from continuing operations of $61.5 million offset by non-cash charges including a promissory note payable of $15.0 million issued to pSivida and the forgiveness of $2.8 million of net receivables due from pSivida in connection with the amendment of our agreement, $10.5 million related to the change in fair value of our preferred stock conversion feature, $750,000 in stock compensation and other expense, and $240,000 in depreciation and amortization. An increase of $1.2 million in prepaid and other current assets was offset by increases of $700,000 accounts payable, accrued expenses and other current liabilities and $540,000 in other long-term liabilities. The increase in prepaid expenses and other current assets was due primarily to $1.1 million in advances to our third party manufacturers for the technology transfer of ILUVIEN and an $880,000 increase in our receivable due from pSivida prior to the renegotiation of our agreement, offset by decreases in prepayments of $460,000 to certain clinical trial sites and $360,000 to our contract research organizations as our FAME Study progressed. Accounts payable, accrued expenses and other current liabilities increased primarily due to $440,000 to our CROs as our FAME Study continued, $400,000 related to the technology transfer of ILUVIEN and $380,000 associated with preparation for an initial public offering of our common stock, offset by decreases of $440,000 in amounts payable to our clinical trial sites and

$150,000 for our animal toxicology and degradation studies. The increase in other long term liabilities is due to interest being accrued on our promissory note to pSivida.

Table of Contents

Net cash used in the investing activities of our continuing and discontinued operations in the years ended December 31, 2010, 2009 and 2008 as follows:

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Continuing Operations	$ (26,460)	$ (65)	$ (640)
Discontinued Operations	4,000		
Total	$ (22,460)	$ (65)	$ (640)

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 years ended December 31, 2009, and 2008 net cash used in the investing activities of our continuing operations was attributable to purchases of property and equipment.

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 were 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.

For the year ended December 31, 2008 net cash provided by our financing activities was $29.8 million which was provided primarily by net proceeds from the issuance of our Series C preferred stock.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2010:

	Payments Due by Future Period				
	Total	Less than 1 Year	1 3 Years	3 5 Years	5+ Years
		(In thousands)			

Note payables	$ 6,250	$ 1,157	5,093	$	$
Operating lease	262	262			
Capital leases	29	11	18		
Total	$ 6,541	$ 1,430	5,111	$	$

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 July 2009 license and option agreement with Emory University for the fulvene class of NADPH oxidase inhibitors, we are required to make annual minimum royalty payments in the first through the fourth calendar years following regulatory approval of the product in a major market

Table of Contents

country (i.e., the U.S., Japan, China, India or any European country) in the amount of $250,000, $500,000, $1.0 million and $2.5 million, respectively, and $2.5 million for each subsequent year during the term of our agreement. We will also be required to make payments of up to $5.8 million depending upon which regulatory milestones we achieve. If we do not make any milestone payments to Emory University under our agreement prior to the third anniversary of the effective date of the agreement, then we will be required to pay Emory University annual license maintenance fees ranging from $500,000 to $2.0 million (depending upon when such payment is made) until a milestone payment is made under the agreement. As an upfront license fee for the license granted by Emory University to us, we issued to Emory University (and its inventors) that number of shares of our common stock with a fair market value equal to $150,000 on the date of issuance. To date, no other payments have been made to Emory University in connection with this license agreement.

In connection with our August 2009 license and option agreement with Emory University for the triphenylmethane class of NADPH oxidase inhibitors, we are required to make annual minimum royalty payments in the first through the fourth calendar years following regulatory approval of the product in a major market country (i.e., the U.S., Japan, China, India or any European country) in the amount of $250,000, $500,000, $1.0 million and $2.5 million, respectively, and an annual minimum royalty payment of $2.5 million for each subsequent year during the term of our agreement. We will also be required to make payments of up to $5.9 million depending upon which regulatory milestones we achieve. If we do not make any milestone payments to Emory University under our agreement prior to the third anniversary of the effective date of the agreement, then we will be required to pay Emory University annual license maintenance fees ranging from $500,000 to $2.0 million (depending upon when such payment is made) until a milestone payment is made under the agreement. As an upfront license fee for the license granted by Emory University to us, in the fourth quarter of 2009 we issued to Emory University (and its inventors) that number of shares of our common stock with a fair market value equal to $150,000 on the date of issuance. To date, no other payments have been made to Emory University in connection with this license agreement.

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 contract research organization for clinical and data management services to be performed in connection with our FAME Study clinical sites in the U.S., Canada, and Europe. In accordance with the terms of the agreement, we will incur approximately $16.9 million of expenses with the contract research organization through 2011. Through December 31, 2010 we incurred $16.2 million of expense associated with this agreement.

In July 2006, we entered into an agreement with a contract research organization for clinical services to be performed in connection with our FAME Study clinical sites in India. In accordance with the terms of the agreement, we will incur approximately $1.8 million of expenses with the contract research organization through 2011. Through December 31, 2010 we incurred $1.3 million of expense associated with this agreement.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business

related to the guarantee of our own performance and the performance of our subsidiaries.

Table of Contents

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.

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, 2010, we had approximately $28.5 million in cash and cash equivalents and $26.3 million in investments. 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, 2010, 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 contract research organizations 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 81 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, 2010. 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, 2010, our Chief Executive Officer and Chief Financial

Table of Contents

Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management s Report on Internal Control over Financial Reporting

The SEC, as required by Section 404 of the Sarbanes-Oxley Act, adopted rules requiring companies that file reports with the SEC to include a management report on such company s internal control over financial reporting in its annual report. In addition, our independent registered public accounting firm may be required to attest to our internal control over financial reporting. This report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by SEC rules applicable to newly public companies. Management will be required to provide an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2011. We believe we will have adequate resources and expertise, both internal and external, in place to meet this requirement. However, there is no guarantee that our efforts will result in management s ability to conclude, or, if required, our independent registered public accounting firm to attest, that our internal control over financial reporting is effective as of December 31, 2011.

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 2010 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.

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, 2010, 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, 2010, 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

Table of Contents

deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that we specifically incorporate it by reference into such filing.

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

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, 2010, 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, 2010, 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	A Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights	B Weighted-Average Exercise Price of Outstanding Options, Warrants, and Rights	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	2,829,405(1)	$ 3.90	1,888,712(2)
Equity compensation plans not approved by security holders			
Total	2,829,405	$ 3.90	1,888,712

(1) Of these shares, 570,150 were subject to options then outstanding under the 2010 Plan, 1,802,080 were subject to options then outstanding under the 2005 Plan and 369,755 were subject to options then outstanding under the 2004 Plan.

(2) Represents 1,402,536 shares of common stock available for issuance under our 2010 Plan and 486,176 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, 2011, an additional 1,250,238 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, 2011, an additional 8,246 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.

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

Table of Contents

December 31, 2010, 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, 2010, 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 81. Certain schedules are omitted because they are not applicable, or not required, or because the required information is included in the consolidated financial statements or notes thereto.

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

Table of Contents

Signatures

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in Alpharetta, Georgia, on March 25, 2011.

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 25, 2011
/s/ Richard S. Eiswirth, Jr. Richard S. Eiswirth, Jr.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 25, 2011
/s/ Philip R. Tracy Philip R. Tracy	Chairman of the Board of Directors	March 25, 2011
/s/ Mark J. Brooks Mark J. Brooks	Director	March 25, 2011
/s/ Brian K. Halak, Ph.D Brian K. Halak, Ph.D	Director	March 25, 2011
/s/ Anders D. Hove, M.D. Anders D. Hove, M.D.	Director	March 25, 2011
/s/ Peter J. Pizzo, III Peter J. Pizzo, III	Director	March 25, 2011
/s/ Calvin W. Roberts, M.D.	Director	March 25, 2011

Calvin W. Roberts, M.D.		
/s/ Bryce Youngren	Director	March 25, 2011
Bryce Youngren		

Table of Contents

ALIMERA SCIENCES, INC.

INDEX TO FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm	82
Financial Statements as of December 31, 2010 and 2009 and for the years ended December 31, 2010, 2009, and 2008:	
Balance Sheets	83
Statements of Operations	84
Statements of Changes in Stockholders Equity (Deficit)	85
Statements of Cash Flows	86
Notes to Financial Statements	87

Table of Contents

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, 2010 and 2009, 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, 2010. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010 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 25, 2011

Table of Contents

ALIMERA SCIENCES, INC.

BALANCE SHEETS
AS OF DECEMBER 31, 2010 AND 2009

	December 31, 2010	2009
	(In thousands, except per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 28,514	$ 4,858
Investments	26,330	
Prepaid expenses and other current assets	1,078	634
Deferred financing costs	272	815
Total current assets	56,194	6,307
PROPERTY AND EQUIPMENT at cost less accumulated depreciation	220	254
TOTAL ASSETS	$ 56,414	$ 6,561
CURRENT LIABILITIES:		
Accounts payable	$ 1,677	$ 1,758
Accrued expenses (Note 6)	2,731	3,314
Outsourced services payable	841	1,157
Notes payable (Note 9)	1,157	4,500
Capital lease obligations	11	6
Total current liabilities	6,417	10,735
LONG-TERM LIABILITIES:		
Notes payable, net of discount less current portion (Note 9)	4,767	10,500
Fair value of preferred stock conversion feature		36,701
Other long-term liabilities	18	708
COMMITMENTS AND CONTINGENCIES (Note 10)		
PREFERRED STOCK:		
Series A preferred stock, $.01 par value no shares authorized, issued, and outstanding at December 31, 2010 and 6,624,866 shares authorized and 6,624,844 shares issued, and outstanding at December 31, 2009; liquidation preference of $37,019 at December 31, 2009		36,467
Series B preferred stock, $.01 par value no shares authorized, issued, and outstanding at December 31, 2010 and 7,147,912 shares authorized and 7,147,894 shares issued, and outstanding at December 31, 2009; liquidation preference of $41,057 at December 31, 2009		40,617
Series C preferred stock, $.01 par value no shares authorized, issued, and outstanding at December 31, 2010 and 5,807,131 shares authorized and 5,807,112 shares issued and outstanding at December 31, 2009; liquidation preference of $34,281 at December 31, 2009		33,452
Series C-1 preferred stock, $.01 par value no shares authorized, issued, and outstanding at December 31, 2010 and 2,903,565 shares authorized and		2,853

967,845 shares issued and outstanding at December 31, 2009; liquidation preference of $5,140 at December 31, 2009		
Preferred stock, $.01 par value 10,000,000 shares authorized and no shares issued and outstanding at December 31, 2010 and 2009		
STOCKHOLDERS DEFICIT:		
Common stock, $.01 par value 100,000,000 shares authorized and 31,255,953 shares issued and outstanding at December 31, 2010 and 29,411,764 shares authorized and 1,598,571 shares issued and outstanding at December 31, 2009	313	54
Additional paid-in capital	233,338	4,836
Series C-1 preferred stock warrants		1,472
Common stock warrants	415	57
Accumulated deficit	(188,854)	(171,891)
TOTAL STOCKHOLDERS EQUITY (DEFICIT)	45,212	(165,472)
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)	$ 56,414	$ 6,561

See Notes to Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2010, 2009, AND 2008

	Years Ended December 31,		
	2010	2009	2008
	(In thousands except share and per share data)		
RESEARCH AND DEVELOPMENT EXPENSES	$ 12,581	$ 15,057	$ 43,764
GENERAL AND ADMINISTRATIVE EXPENSES	4,610	3,407	5,058
MARKETING EXPENSES	4,880	752	1,259
OPERATING EXPENSES	22,071	19,216	50,081
INTEREST AND OTHER INCOME	73	37	585
INTEREST EXPENSE	(848)	(1,897)	(1,514)
GAIN ON EARLY EXTINGUISHMENT OF DEBT (NOTE 7)	1,343		
DECREASE (INCREASE) IN FAIR VALUE OF PREFERRED STOCK CONVERSION FEATURE	3,644	(23,142)	(10,454)
LOSS FROM CONTINUING OPERATIONS	(17,859)	(44,218)	(61,464)
INCOME FROM DISCONTINUED OPERATIONS (NOTE 3)	4,000		
NET LOSS	(13,859)	(44,218)	(61,464)
BENEFICIAL CONVERSION FEATURE OF PREFERRED STOCK (NOTE 11)		(355)	
PREFERRED STOCK ACCRETION	(466)	(623)	(718)
PREFERRED STOCK DIVIDENDS	(2,638)	(7,225)	(6,573)
NET LOSS APPLICABLE TO COMMON SHAREHOLDERS	$ (16,963)	$ (52,421)	$ (68,755)
NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS Basic and diluted	$ (0.77)	$ (34.55)	$ (45.52)
WEIGHTED AVERAGE SHARES OUTSTANDING Basic and diluted	22,167,873	1,517,365	1,510,496

See Notes to Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)
FOR THE YEARS ENDED DECEMBER 31, 2010, 2009, AND 2008

	Common Stock Shares	Amount	Additional Paid-In Capital	Series C-1 Preferred Warrants	Common Warrants	Accumulated Deficit	Total
			(In thousands except share data)				
BALANCE December 31, 2007	1,516,389	$ 52	$ 2,867	$	$ 58	$ (50,715)	$ (47,738)
Preferred stock accretion and dividends						(7,291)	(7,291)
Repurchase and retirement of common stock	(27,746)	(1)	(149)				(150)
Stock compensation expense			750				750
Exercise of warrants	1,470		6				6
Net loss						(61,464)	(61,464)
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 upon conversion of preferred stock to common stock (Note 11)			36,528				36,528
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

See Notes to Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2010, 2009, AND 2008

	Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (13,859)	$ (44,218)	$ (61,464)
Income from discontinued operations (Note 3)	(4,000)		
Change in fair value of preferred stock conversion feature	(3,644)	23,142	10,454
Gain from early extinguishment of debt	(1,343)		
Depreciation and amortization	194	1,098	241
Stock compensation expense and other	957	551	750
Amortization of deferred financing costs	73		
Unrealized investment loss	2		
Noncash research and development expense (Notes 7 and 8)		300	17,809
Changes in assets and liabilities:			
Prepaid expenses and other current assets	(566)	591	(1,213)
Accounts payable	391	183	615
Accrued expenses and other current liabilities	(258)	705	85
Other long-term assets			24
Other long-term liabilities		153	540
Net cash used in operating activities of continuing operations	(22,053)	(17,495)	(32,159)
Net cash (used in) provided by operating activities of discontinued operations		(43)	43
Net cash used in operating activities	(22,053)	(17,538)	(32,116)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of investments	(39,927)		
Proceeds from maturities of investments	13,595		
Purchases of property and equipment	(128)	(65)	(640)
Net cash used in investing activities of continuing operations	(26,460)	(65)	(640)
Net cash provided by investing activities of discontinued operations (Note 3)	4,000		
Net cash used in investing activities	(22,460)	(65)	(640)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from sale of Series C preferred stock net			29,938
Proceeds from sale of Series C-1 preferred stock net	9,997	4,897	
Proceeds from exercise of stock options	94	7	

Repurchase of common stock			(150)
Proceeds from exercise of common stock warrants	613	31	6
Proceeds from sale of common stock	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	(305)		
Repayment of pSivida note payable (Note 7)	(15,000)		
Payments on capital lease obligations	(8)	(10)	(10)
Net cash provided by financing activities	68,169	4,586	29,784
NET INCREASE (DECREASE) IN CASH	23,656	(13,017)	(2,972)
CASH Beginning of period	4,858	17,875	20,847
CASH End of period	$ 28,514	$ 4,858	$ 17,875
SUPPLEMENTAL DISCLOSURES:			
Cash paid for interest	$ 681	$ 1,200	$ 957
Supplemental schedule of noncash investing and financing activities:			
Note payable issued in conjunction with amendment to pSivida agreement (Note 7)	$	$	$ 15,000
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, 2010, 2009, and 2008.

See Notes to Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO 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.

During the year ended December 31, 2006, management and the board of directors approved a plan to discontinue the operations of its non-prescription business (see Note 3). As a result of the completion of the disposal of its non-prescription business in July 2007, the Company no longer has active products and will not have active products until the Company receives U.S. Food and Drug Administration (FDA) approval and launches its initial prescription product (see Note 3).

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. The Company has completed its two Phase 3 pivotal clinical trials (collectively referred to as the Company s FAME Study) for 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.

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 June 2010, the Company submitted a New Drug Application (NDA) for ILUVIEN to the FDA. In July 2010, the Company submitted a Marketing Authorization Application for ILUVIEN to the Medicines and Healthcare products Regulatory Agency in the United Kingdom and to regulatory authorities in Austria, France, Germany, Italy, Portugal and Spain. In August 2010, the FDA accepted the Company s NDA for ILUVIEN and granted it priority review status. Priority review status reduces the review time from ten months to six months.

In December 2010, the FDA issued a Complete Response Letter (CLR) in response to the Company s NDA. In the CLR, the FDA communicated its decision that the NDA could not be approved in its present form. No new clinical studies were requested in the CRL. However, the FDA asked for analyses of the safety and efficacy data through month 36 of the FAME Study, including exploratory analyses in addition to those previously submitted to the FDA, to further assess the relative benefits and risks of ILUVIEN. The NDA included data through month 24. The Company has completed month 36 of the study and is preparing the analyses the FDA requested. The FDA is also seeking additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN, which the Company is in the process of compiling.

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 U.S. of America and, as such, include amounts based on informed estimates and judgments of management. Actual results could differ from those estimates.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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 are 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 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

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

value in accordance with the provisions of ASC 718, *Compensation Stock Compensation*. The fair values for the options are estimated at the dates of grant using a Black-Scholes option-pricing model.

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

Derivative Financial Instruments The Company s previously outstanding preferred stock (see Note 11) contained certain features which are 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 (see Note 14). The Company recorded the changes in fair value of such instruments as noncash gains or losses in the consolidated statement of operations. 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, investments, receivables, and current liabilities approximate their fair value because of their short maturities.

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,		
	2010	2009	2008
Series A preferred stock and convertible accrued dividends	2,245,484	7,005,145	7,005,145
Series B preferred stock	2,291,242	7,147,894	7,147,894
Series C preferred stock	1,861,457	5,807,112	4,570,674
Series C-1 preferred stock	888,298	339,408	
Series C-1 preferred stock warrants	42,426	678,820	
Common stock warrants	97,757	45,297	30,271
Stock options	1,704,787	1,125,916	987,170
Total	9,131,451	22,149,592	19,741,154

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

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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.

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. There were no revenues or expenses from discontinued operations during the years ended December 31, 2009 and 2008. 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):

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

4. FACTORS AFFECTING OPERATIONS

To date the Company has incurred recurring losses, negative cash flow from operations, and has accumulated a deficit of $188,854,000 from the Company s inception through December 31, 2010. The Company does not expect to generate revenues from its product, ILUVIEN, until late 2011, if at all, and therefore does not expect to have cash flow from operations until 2012, if at all. As of December 31, 2010 the Company had approximately $54,844,000 in cash, cash equivalents, and investments. In October 2010, the Company obtained a $32,500,000 senior secured credit facility (Credit Facility) to help fund its working capital requirements (see Note 9). The Credit Facility consists of a $20,000,000 revolving line of credit and a $12,500,000 term loan. The lenders have advanced $6,250,000 under the term loan and may advance the remaining $6,250,000 following FDA approval of Iluvien, but no later than July 31, 2011. Given the status of the FDA s review of the ILUVIEN NDA, it is unlikely that the FDA approval would occur prior to July 31, 2011. The Company is currently in discussions with the lenders to amend the terms of the Credit Facility to, among other things, extend the availability of the term loan. However, there are no assurances that the Credit Facility will be amended. The Company may draw on the revolving line of credit against eligible, domestic accounts receivable subsequent to the launch of ILUVIEN. Management believes it has sufficient funds available to fund its operations through the projected commercialization of ILUVIEN and the expected generation of revenue in late 2011. The commercialization of Iluvien is dependent upon approval by the FDA, however, and management cannot be sure that ILUVIEN will be approved by the FDA or that, if approved, future sales of ILUVIEN will generate enough revenue to fund the Company s operations beyond its commercialization (see Note 1). Due to the uncertainty around FDA approval, management also cannot be certain that the Company will not need additional funds for the commercialization of ILUVIEN. If ILUVIEN is not approved, or if approved, 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.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31, 2010	2009
	(In thousands)	
Furniture and fixtures	$ 292	$ 290
Office equipment	415	290
Software	489	470
Leasehold improvements	12	12
Manufacturing equipment	40	40
Total property and equipment	1,248	1,102
Less accumulated depreciation and amortization	(1,028)	(848)
Property and equipment net	$ 220	$ 254

Depreciation and amortization expense associated with property and equipment of the continuing operations totaled $194,000, $1,098,000 and $241,000 for the years ended December 31, 2010, 2009 and 2008, 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.

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31, 2010	2009
	(In thousands)	
Accrued clinical investigator expenses	$ 1,911	$ 3,007
Accrued compensation expenses	730	246
Other accrued expenses	90	61
Total accrued expenses	$ 2,731	$ 3,314

7. PSIVIDA AGREEMENT

In March 2008, in connection with the Company s collaboration agreement with pSivida US, Inc. (pSivida), the licensor of the ILUVIEN technology, the Company 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 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;

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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.

In addition, pSivida is continuing to provide clinical supply materials for the Company s Phase 2 clinical trials being conducted for the use of ILUVIEN for the treatment of dry AMD and wet AMD and perform and maintain stability testing on those supplies.

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. As of December 31, 2009, the Company had accrued and unpaid interest payable to pSivida of $708,000, classified as other long-term liabilities, and $543,000, included in accrued interest in the accompanying balance sheet. On April 27, 2010, the Company paid pSivida approximately $15,200,000 in principal and interest to satisfy the note payable with the proceeds from its initial public offering. 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 year ended December 31, 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. The Company was not in breach of its agreement with pSivida as of December 31, 2010.

Upon commercialization of ILUVIEN, the Company must share 20% of net profits, as defined by the agreement, with pSivida. In connection with this arrangement the Company is entitled to recover 20% of commercialization costs decreased from 50% as a result of the amendment, as defined in the amendment, incurred prior to product profitability out of pSivida s share of net profits. As of December 31, 2010 and 2009, the Company was owed $2,224,000 and $958,000, respectively, in commercialization costs. Due to the uncertainty of FDA approval of the NDA for ILUVIEN, the Company has fully reserved these amounts in the accompanying financial statements.

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.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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 owe Emory University up to $5,775,000 in additional development and regulatory milestones under the terms of the license agreement. If the Company does not make any milestone payments to Emory University under this license agreement prior to the third anniversary of its effective date, and the Company does not elect to terminate this license agreement in accordance with its terms, then the Company will be required to pay Emory University annual license maintenance fees ranging from $500,000 to $2,000,000 (depending on when such payment is made) until a milestone payment is made or this license agreement is terminated in accordance with its terms. Under the terms of the Company s agreement with Emory University, the Company is required to make annual minimum royalty payments in the first through the fourth calendar years following regulatory approval of the product in a major market country (i.e., the U.S., Japan, China, India or any European country) in the amount of $250,000, $500,000, $1,000,000 and $2,500,000, respectively, and an annual minimum royalty payment of $2,500,000 for each subsequent year during the term of the agreement. As part of this license, the Company received an exclusive option for a license of the patent rights for diseases and disorders outside of the eye.

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 owe Emory University up to $5,850,000 in additional development and regulatory milestones under the terms of this license agreement. If the Company does not make any milestone payments to Emory University under this license agreement prior to the third anniversary of its effective date, and the Company does not elect to terminate this license agreement in accordance with its terms, then the Company will be required to pay Emory University annual license maintenance fees ranging from $500,000 to $2,000,000 (depending on when such payment is made) until a milestone payment is made or this license agreement is terminated in accordance with its terms. Under the terms of the Company s agreement with Emory University, the Company is required to make annual minimum royalty payments in the first through the fourth calendar years following regulatory approval of the product in a major market country (i.e., the U.S., Japan, China, India or any European country) in the amount of $250,000, $500,000, $1,000,000 and $2,500,000, respectively, and an annual minimum royalty payment of $2,500,000 for each subsequent year during the term of the agreement. As part of this license, the Company received an exclusive option for a license of the patent rights for diseases and disorders outside of the eye.

9. TERM AND REVOLVING LOAN AGREEMENT

Term Loan Agreement

On October 14, 2010 (Effective Date), the Company entered into a Loan and Security Agreement with Silicon Valley Bank and MidCap Financial LLP under which the Company may borrow up to $12,500,000 (Term Loan Agreement). The lenders advanced the Initial Tranche of $6,250,000 on the Effective Date and may advance the remaining Second

Tranche of $6,250,000 following approval by the FDA of the Company s ILUVIEN product, but no later than July 31, 2011. Given the status of the FDA s review of the Company s NDA, the Company believes it is unlikely that approval of ILUVIEN would occur prior to July 31, 2011. The Company is in discussions with the lenders to amend the terms of the Term Loan Agreement to, among other

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

things, extend its availability. However, there are no assurances that the Term Loan Agreement will be amended.

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.

The Company will be required to pay interest on the First Tranche at a rate of 11.5% on a monthly basis through July 31, 2011, and then will be required to repay the principal in 27 equal monthly installments, beginning August 2011, plus interest at a rate of 11.5%. If the Second Tranche is advanced to the Company, the Company will be required to pay interest on the Second Tranche at a rate of 12.0% on a monthly basis through July 31, 2011, and then will be required to repay the principal in 27 equal monthly installments, plus interest at a rate of 12.0%. The Company paid to the lenders an upfront fee of $62,500, and will pay to the lenders an additional final payment of 3% of the total principal amount. In addition, if the Company repays the loan prior to maturity, it will pay to the lenders a prepayment penalty of 5% of the total principal amount if the prepayment occurs within one year after the funding date, 3% of the total principal amount if the prepayment occurs between one and two years after the funding date and 1% of the total principal amount of the prepayment occurs thereafter (each a Prepayment Penalty), provided in each case that such Prepayment Penalty will be reduced by 50% in the event of an acquisition of the Company. 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.

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, other than its intellectual property, provided that, for any date during which the notes are outstanding, the Company s unrestricted balance sheet cash and cash equivalents plus the excess available under the term loan agreements are less than the product of six times the monthly cash burn amount. In the event the Company fails to meet this financial condition, a curable lien will be imposed on the Company s intellectual property. Should such a lien event take place, the lien would remain in force until such date that the Company s unrestricted cash and cash equivalents plus the excess available under the term loan agreements was equal to or greater than twelve times the monthly cash burn amount. 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.

In connection with entering into this agreement, 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. In addition, the lenders will have certain registration rights with respect to the shares of common stock issuable upon exercise of the warrants. 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.

Revolving Loan Agreement

Also on the Effective Date, the Company and Silicon Valley Bank entered into a Loan and Security Agreement (Revolving Loan Agreement), pursuant to which the Company obtained a secured revolving line of credit from Silicon Valley Bank with borrowing availability up to $20,000,000.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The Revolving Loan Agreement provides for a working capital-based revolving line of credit (Revolving Line) in an aggregate amount of up to the lesser of (i) $20,000,000, or (ii) 85% of eligible domestic accounts receivable. The Revolving Line matures on October 31, 2013. As of December 31, 2010, no amounts under the Revolving Loan Agreement were available to the Company.

Amounts advanced under the Revolving Line 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 Revolving Line is due monthly, with the balance due at the maturity date. The Company paid to Silicon Valley Bank an upfront fee of $100,000. In addition, if the Company terminates the Revolving Line prior to maturity, it will 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, other than its intellectual property, provided that, for any date during which the notes are outstanding, the Company s unrestricted balance sheet cash and cash equivalents plus the excess available under the term loan agreements are less than the product of six times the monthly cash burn amount. In the event the Company fails to meet this financial condition, a curable lien will be imposed on the Company s intellectual property. Should such a lien event take place, the lien would remain in force until such date that the Company s unrestricted cash and cash equivalents plus the excess available under the term loan agreements was equal to or greater than twelve times the monthly cash burn amount. 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.

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.

10. COMMITMENTS

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

Years Ending December 31	
2011	$ 1,157
2012	2,778
2013	2,315
	$ 6,250

The effective interest rate on the Notes Payable is 11.5%. As of December 31, 2010, the Company had no accrued and unpaid interest payables on the Notes 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 July 2010, the Company signed an extension of its lease for office space for a period ended December 31, 2011. The Company s future minimum payments under this operating lease from December 31, 2010 to December 31, 2011 are $262,000.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Rent expense under all operating leases totaled approximately $256,000, $229,000 and $217,000 for the years ended December 31, 2010, 2009, and 2008, 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, 2010, 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	
2011	$ 13
2012	13
2013	6
Total	32
Less amount representing interest	3
Present value of minimum lease payments	29
Less current portion	11
Noncurrent portion	$ 18

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

	December 31,	
	2010	**2009**
	(In thousands)	
Office equipment	$ 60	$ 42
Less accumulated amortization	(32)	(37)
Total	$ 28	$ 5

Depreciation expense associated with office equipment under capital leases was $10,000 for each of the years ended December 31, 2010, 2009, and 2008, respectively.

Significant Agreements In January 2006, the Company entered into an agreement with a contract research organization 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 will incur approximately $16,900,000 in costs with the contract research organization through 2011. For the years ended December 31, 2010, 2009, and 2008, the Company incurred $2,300,000, $3,900,000, and $3,300,000 respectively, of expense associated with this agreement. At December 31, 2010 and 2009, $731,000 and $1,100,000, respectively, are included in outsourced services payable.

In July 2006, the Company entered into an agreement with a contract research organization 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 will incur approximately $1,800,000 in costs with the contract research organization through 2011. For the years ended December 31, 2010, 2009, and 2008, the Company incurred $242,000, $240,000, and $248,000, respectively, of expense associated with this agreement. At December 31, 2010 and 2009, $110,000, and $53,000, 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 inserter and packaging of the completed

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

ILUVIEN commercial product. The Company is responsible for supplying the ILUVIEN inserter 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 European Union from the third party manufacturer for an initial term of six years. The agreement with 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 current term.

Employment Agreements The Company is party to employment agreements with five executives. The agreements generally provide for annual salaries, bonuses, and benefits for a period of three years, and automatically renew for one-year periods after the third year unless terminated by either party. Effective January 1, 2010, the salaries ranged from $227,000 to $368,000. Effective January 1, 2011, the salaries were adjusted to a range of $254,000 to $432,000. If any of the agreements are terminated by the Company without cause, or by the employee for good reason, as defined in the agreements, the Company will be liable for one year of salary and benefits. Certain other employees have general employment contracts which include stipulations regarding confidentiality, Company property, and miscellaneous items.

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

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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. Accumulated, accrued, and unpaid dividends were $23,934,000 at December 31, 2009.

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. The liquidation value plus accumulated, accrued, and unpaid dividends was $117,497,000 at December 31, 2009.

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 December 31, 2009 was $36,701,000. 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, a loss of $23,142,000, and a loss of $10,454,000 associated with the change in fair value for the years ended December 31, 2010, 2009, and 2008 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. At December 31, 2010, no shares of preferred stock were issued or outstanding.

Table of Contents

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, 2010, the Company was authorized to grant under the Company s plans up to 1,402,536 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:

	Years Ended December 31,					
	2010		2009		2008	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options at beginning of period	2,225,778	$ 2.14	1,959,726	$ 1.80	1,419,808	$ 1.50
Grants	575,150	10.17	295,463	4.35	539,918	2.55
Forfeitures	(14,444)	5.11	(25,551)	1.84		
Exercises	(44,499)	2.10	(3,860)	1.70		
Options at end of period	2,741,985	3.81	2,225,778	2.14	1,959,726	1.80
Options exercisable at period end	1,722,281	1.88	1,427,649	1.70	921,055	1.70
Weighted average per share fair value of options granted during the period	$ 7.92		$ 3.74		$ 1.73	

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, 2010:

	Weighted Average Exercise	Weighted Average Contractual	Aggregate Intrinsic

	Shares	Price	Term	Value (In thousands)
Outstanding	2,741,985	$ 3.81	6.99 years	$ 18,338
Exercisable	1,722,281	1.88	5.88 years	14,638
Expected to vest	963,754	7.24	8.92 years	3,334

Table of Contents

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,		
	2010	2009	2008
Risk-free interest rate	1.77%	3.44%	2.87%
Volatility factor	97.32%	112.57%	73.78%
Grant date fair value of common stock	$7.92	$4.35	$2.55
Weighted-average expected life	6.05 years	6.18 years	6.15 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,		
	2010	2009	2008
	(In thousands)		
Marketing	$ 127	$ 43	$ 109
Research and development	209	161	269
General and administrative	458	307	372
Total employee stock-based compensation expense	$ 794	$ 511	$ 750

The total estimated fair value of options granted during the years ended December 31, 2010, 2009, and 2008 was $4,558,000, $1,100,000, and $930,000, respectively, and the total estimated value of options granted prior to 2007 was $1,516,000.

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, 2011, an additional 1,250,238 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.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The following table summarizes outstanding and exercisable options at December 31, 2010:

	Options Outstanding		Options Exercisable	
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable	Weighted Average Remaining Contractual Life
$1.33	693,458	5.36	693,458	5.36
1.39	395,400	6.79	310,696	6.76
2.04	280,770	3.67	280,770	3.67
2.24	4,504	7.17	1,287	7.17
2.41	465,212	7.22	318,906	7.22
3.26	5,882	7.39	3,676	7.39
3.88	33,823	7.09	22,794	7.09
4.01	262,963	8.60	74,695	8.47
5.03	5,146	7.66	2,893	7.66
5.44	2,059	8.67	1,157	8.67
6.74	103,500	9.62		
8.47	22,618	8.96	5,648	8.96
9.87	75,000	9.76		
11.00	65,000	9.33		
11.15	302,650	9.85	6,302	9.85
11.91	24,000	9.93		
	2,741,985		1,722,282	

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 87,420 and 248,181 at December 31, 2010 and 2009, 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 (see Note 9). No warrants to purchase common stock were issued in the years ended December 31, 2009 and 2008, respectively.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

14. INCOME TAXES

The components of the income tax benefit were as follows:

	Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Deferred benefit (expense):			
Federal	$ 5,738	$ 6,649	$ 17,119
State	669	774	2,202
	6,407	7,423	19,321
Valuation allowance	(6,407)	(7,423)	(19,321)
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, 2010 and 2009, the Company had federal net operating loss (NOL) carry-forwards of approximately $97,813,000 and $79,494,000 and state NOL carry-forwards of approximately $80,995,000, and $62,666,000 respectively, that are available to reduce future income unless otherwise taxable. If not utilized, the federal NOL carryforward will expire at various dates between 2023 and 2030 and the state NOL carry-forwards will expire at various dates between 2020 and 2030.

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 has not yet completed a formal evaluation of whether the impact of its IPO (see Note 1) resulted in certain changes in ownership that would limit the Company s ability to utilize a portion of its NOL carry-forwards.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Net deferred tax assets (liabilities) were as follows:

	December 31, 2010	2009
	(In thousands)	
Depreciation and amortization	$ 206	$ 268
Other deferred tax assets	246	338
NOL carry-forwards	36,467	29,512
Research and development costs	9,165	10,039
Collaboration agreement receivable reserves	844	364
Valuation allowance	(46,928)	(40,521)
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:

	Years Ended December 31,					
	2010		2009		2008	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax benefit at statutory rate	$ (4,712)	34.0%	$ (15,035)	34.0%	$ (20,898)	34.0%
State tax net of federal benefit	(549)	4.0	(1,751)	4.0	(2,434)	4.0
Permanent items	(1,166)	8.4	8,938	(20.2)	4,226	(6.9)
Change in state deferred tax rate					(160)	0.3
Other	20		425	(1.0)	(55)	
Increase in valuation allowance	6,407	(46.4)	7,423	(16.8)	19,321	(31.4)
Total tax expense	$	%	$	%	$	%

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.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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:

	December 31, 2010			
	Level 1	Level 2	Level 3	Total
		(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

	December 31, 2009			
	Level 1	Level 2	Level 3	Total
		(In thousands)		
Assets:				
Cash equivalents(1)	$ 4,668	$	$	$ 4,668
Assets measured at fair value	$ 4,668	$	$	$ 4,668
Liabilities:				
Preferred stock conversion feature(3)	$	$	$ 36,701	$ 36,701
Liabilities measured at fair value	$	$	$ 36,701	$ 36,701

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

(3) The fair value of the beneficial conversion feature of preferred stock (see note 11) is established using a probability weighted expected return method (PWERM) and Black Scholes valuation model. Significant inputs to the valuation include:

probability of various scenarios occurring, including the potential for an initial public offering, sale of the Company or its assets, decision to remain a private company or liquidation of the Company;

fair value of common stock as determined under each of the scenarios under the PWERM, adjusted for a lack of control and lack of marketability discount;

volatility estimated as an average of volatilities of publicly traded companies deemed similar to the Company in terms of product composition, stage of lifecycle, capitalization, and scope of operations;

exercise price and weighted-average expected life estimated based on the underlying and the expected remaining life of the underlying instrument;

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

risk-free interest rate estimated as the daily treasury yield for the period that most closely approximates the weighted-average expected life as the valuation date as published by the U.S. Department of Treasury.

The method described above may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. Furthermore, while the Company believes its valuation methods are appropriate, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different fair value measurement at the reporting date.

The following table presents the changes to the fair value of the beneficial conversion feature of preferred stock during the years ended December 31, 2010 and 2009 (in thousands):

Fair value of conversion feature of preferred stock at December 31, 2008	$ 12,656
Issuance of Series C-1 preferred stock (See Note 11)	903
Change in fair value of preferred stock conversion feature	23,142
Fair value of conversion feature of preferred stock at December 31, 2009	36,701
Issuance of Series C-1 preferred stock (Note 11)	3,471
Change in fair value of preferred stock conversion feature	(3,644)
Elimination of the conversion feature of preferred stock (Note 11)	(36,528)
Fair value of conversion feature of preferred stock at December 31, 2010	$

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 $68,000, $70,000 and $61,000 for the years ended December 31, 2010, 2009 and 2008, respectively. The Company may also make an annual discretionary profit-sharing contribution. No such discretionary contributions were made during the years ended December 31, 2010, 2009 and 2008.

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. There are. 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 8,246 shares of the Company s common shares were acquired through the Purchase Plan during the year ended December 31, 2010. As such, on January 1, 2011, an additional 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-

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Scholes valuation model. In connection with the Purchase Plan, the Company recorded $43,000 of compensation expense for the year ended December 31, 2010.

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, 2010 and 2009 are as follows (in thousands except per share data):

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

	Year Ended December 31, 2009			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Selected quarterly financial data:				
Total operating expenses	$ 5,490	$ 4,747	$ 4,634	$ 4,345
Net loss	(10,178)	(6,266)	(5,110)	(22,664)
Net loss attributable to common stockholders	(12,032)	(8,135)	(7,459)	(24,795)
Net loss per common stockholder Basic and diluted(1)	$ (8.07)	$ (5.46)	$ (4.89)	$ (15.85)

(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.

Table of Contents

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)
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)

Table of Contents

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)

Table of Contents

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
10.30	Form of Notice of Stock Option Grant and Stock Option 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
32.2	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.