ALIMERA SCIENCES INC
Form 424B4
April 23, 2010

Table of Contents

File Pursuant to Rule 424(b)(4)
Registration No. 333-162782

6,550,000 Shares

ALIMERA SCIENCES, INC.

Common Stock

This is an initial public offering of shares of common stock of Alimera Sciences, Inc. All of the shares of common stock are being sold by the company. The initial public offering price is $11.00.

Prior to this offering, there has been no public market for the common stock. Our common stock has been approved for listing on the Nasdaq Global Market under the symbol ALIM.

Investing in the common stock involves risks. See Risk Factors beginning on page 7 to read about factors you should consider before buying shares of the common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$ 11.00	$ 72,050,000
Underwriting discount(1)	$ 0.56	$ 3,654,581
Proceeds, before expenses, to the Issuer	$ 10.44	$ 68,395,419

(1) The underwriters will receive an underwriting discount and commission of 7.00% on the sale of all of the shares of our common stock, except for any shares sold to certain of our existing stockholders and certain specified affiliated entities.

To the extent that the underwriters sell more than 6,550,000 shares of common stock, the underwriters have the option to purchase up to an additional 982,500 shares from the company at the initial public offering price less the underwriting discount.

The underwriters expect to deliver the shares against payment on or about April 27, 2010.

Credit Suisse **Citi**
Cowen and Company **Oppenheimer & Co.**

The date of this prospectus is April 22, 2010.

Table of Contents

Iluvien®
(fluocinolone acetonide intravitreal insert)

Iluvien is currently in clinical development. Iluvien has not been approved by the U.S. Food and Drug Administration and therefore Alimera Sciences, Inc. has not generated any revenues from the commercial sale of Iluvien as of the date of this prospectus.

TABLE OF CONTENTS

	Page
Prospectus Summary	1
The Offering	4
Summary Historical and Pro Forma Financial and Other Data	5
Risk Factors	7
Special Note Regarding Forward-Looking Statements and Projections	31
Use of Proceeds	32
Dividend Policy	32
Capitalization	33
Dilution	35
Selected Financial Data	36
Management s Discussion and Analysis of Financial Condition and Results of Operations	39
Business	60
Management	88
Transactions with Related Persons, Promoters and Certain Control Persons	114
Principal Stockholders	116
Description of Capital Stock	120
Shares Eligible for Future Sale	123
Material United States Federal Tax Consequences for Non-U.S. Stockholders	125
Underwriting	128
Selling Restrictions	131
Industry and Market Data	134
Legal Matters	135
Experts	135
Where You Can Find More Information	135
Index to Financial Statements	F-1

Through and including May 17, 2010 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This obligation is in addition to a dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights the most important features of this offering and the information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under the heading Risk Factors and our financial statements and related notes included in this prospectus.

Our Company

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, an intravitreal insert containing fluocinolone acetonide (FA), 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. We are developing Iluvien to provide a sustained therapeutic effect for up to 36 months in 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. There are no ophthalmic drug therapies approved by the U.S. Food and Drug Administration (FDA) for the treatment of DME. We believe that Iluvien will be the first ophthalmic drug therapy approved by the FDA for the treatment of DME.

We are currently conducting two Phase 3 pivotal clinical trials for Iluvien (collectively, our FAME Study) involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of Iluvien in the treatment of DME. The primary efficacy endpoint for our FAME Study is the difference in the percentage of patients with improved visual acuity of 15 or more letters on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart at month 24 between the treatment and control groups. In December 2009 we received the month 24 clinical readout from our FAME Study. Based on our analysis of this readout, Iluvien demonstrated efficacy in the treatment of DME. In addition, based on this readout, we believe that the adverse events associated with the use of Iluvien, which are typical of the side effects associated with the use of intravitreal corticosteroids, are within the acceptable limits of a drug for the treatment of DME.

Based upon our analysis of the month 24 clinical readout from our FAME Study, we plan to file a New Drug Application (NDA) in the United States for the low dose of Iluvien in the second quarter of 2010, followed by registration filings in certain European countries and Canada. We intend to request Priority Review of our NDA from the FDA. If Priority Review is granted, we can expect a response to our NDA from the FDA in the fourth quarter of 2010. If our NDA is approved, we plan to commercialize Iluvien in the United States by marketing and selling Iluvien to retinal specialists as early as the first quarter of 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).

In 2007, according to the U.S. Department of Health and Human Services Centers for Disease Control and Prevention, there were approximately 17.9 million diagnosed diabetics in the United States. Additionally, per the International Diabetes Federation s Diabetes Atlas, the estimated prevalence of people diagnosed with diabetes for 2010 has increased to 285 million people worldwide. All patients with diabetes are at risk of developing some form of diabetic retinopathy, an ophthalmic condition that includes the swelling and leakage of blood vessels within the retina or the abnormal growth of new blood vessels on the surface of the retina. When the blood vessel leakage of diabetic

retinopathy causes swelling in the macula, the part of the eye responsible for central vision, the condition is called DME. We estimate the incidence of DME in the United States to be approximately 340,000 cases annually.

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. Corticosteroids have shown improved visual acuity in DME patients in non-pivotal clinical trials, but they are associated with the side effects of increased intraocular pressure (IOP), which may increase the risk of glaucoma, and cataract formation. Both of these alternate therapies are limited by a need for multiple injections to maintain a therapeutic effect.

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. Iluvien is inserted with a device that employs a 25-gauge needle which allows for a self-sealing wound. Iluvien is designed to provide a therapeutic effect for up to 36 months by delivering sustained sub-microgram levels of FA. The sustained sub-microgram dosage level of Iluvien provides lower exposure to corticosteroids than other intraocular dosage forms currently available. 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, which are typical of the side effects associated with the use of corticosteroids, are within the acceptable limits of a drug for the treatment of DME.

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 intend to capitalize on our management s 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 United States and Canada. We intend to seek a commercialization partner for sales and marketing activities outside North America. Our commercialization strategy is subject to and dependent upon regulatory approval of Iluvien for the treatment of DME.

In addition to our activities related to Iluvien, we are pursuing 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. We have executed agreements with Emory University, whereby we acquired exclusive, worldwide licenses of rights under patent applications covering two classes of nicotinamide adenine dinucleotide phosphate (NADPH) oxidase inhibitors. 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.

Our 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 December 2009 we received the month 24 clinical readout from our FAME Study. Based upon our analysis of this data, we plan to file an NDA in the United States for the low dose of Iluvien in the second quarter of 2010, followed by registration filings in certain European countries and Canada.

Maximize the Commercial Success of Iluvien. If approved by the FDA, we intend to market and sell Iluvien to the approximately 1,600 retinal specialists practicing in the approximately 900 retina centers in the United States and Canada and to seek a commercialization partner for sales and marketing activities outside North America.

Assess the Effectiveness of Iluvien for Additional Retinal Diseases. Iluvien is being studied in three Phase 2 clinical trials with retinal specialists to assess its safety and efficacy in the treatment of dry AMD, wet AMD and RVO.

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 and are evaluating the use of these compounds in the treatment of dry AMD. We plan to evaluate the

Table of Contents

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 needs in the treatment of ophthalmic diseases. Toward that end, we intend to leverage 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.

Risks That We Face

Our business is subject to numerous risks that could prevent us from successfully implementing our business strategy. You should carefully consider these risks and other risks described under Risk Factors and elsewhere in this prospectus, which include the following:

We are dependent on the success of our product candidates and specifically on the success of Iluvien, our only product candidate currently in clinical development, and if we are not successful in commercializing Iluvien, or are significantly delayed in doing so, our business will be materially harmed and we may need to curtail or cease 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, in particular the FDA may have a different interpretation of our clinical data than that presented in our NDA, which could result in the FDA not granting marketing approval for Iluvien;

Even if approved, the demonstration of Iluvien s safety and efficacy, its cost-effectiveness, its potential advantages over other therapies, the reimbursement policies of government and third-party payors with respect to Iluvien, and the effectiveness of our marketing and distribution capabilities may impact the degree of Iluvien s acceptance in the market;

We are dependent upon our ability, and the ability of our licensors, to obtain and maintain protection for the intellectual property incorporated into our products and the value of our technology and products will be adversely affected if we or our licensors are unable to obtain or maintain such protection; and

We do not expect to generate revenues from our product candidates until the first quarter of 2011 and although we anticipate that the proceeds from this offering will fund our operations through the projected commercialization of Iluvien as early as the first quarter of 2011, we cannot be sure that this offering will be completed, that Iluvien will be approved by the FDA in the fourth quarter of 2010 or that, if approved, future sales of Iluvien will generate revenues sufficient to fund our operations beyond the first quarter of 2011, or ever.

These risks and other risks described under Risk Factors and elsewhere in this prospectus could materially and adversely impact our business, financial condition, operating results and future prospects which could cause the trading price of our common stock to decline and could result in a partial or total loss of your investment.

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 prospectus and should not be considered part of this prospectus.

Iluvien® and FAME™ are our trademarks. This prospectus also contains trademarks of other companies including visiongain™, Retisert®, Lucentis®, Ozurdex™, Visudyne®, Macugen®, Avastin®, Trivaris® and TRIESENCE®.

Table of Contents

THE OFFERING

Common stock offered by us	6,550,000 shares
Common stock to be outstanding after this offering	31,051,055 shares
Use of Proceeds	We expect to receive net proceeds from the offering of approximately $66.3 million, based on an initial public offering price of $11.00 per share, and after deducting estimated underwriting discounts and commissions and estimated offering expenses that we must pay. We intend to use the proceeds from this offering primarily to complete the clinical development and registration of Iluvien for DME, to repay indebtedness and make certain milestone payments to pSivida US, Inc., to commence the commercial launch of Iluvien, to continue to develop our product pipeline and for working capital and other general corporate purposes. See Use of Proceeds for additional information.
Risk Factors	You should read the Risk Factors section of this prospectus for a discussion of factors that you should consider carefully before deciding to invest in shares of our common stock.
Directed Share Program	At our request, the underwriters have reserved up to 1,816,491 shares of common stock offered hereby for sale at the initial public offering price to persons who are directors, officers, employees, or who are otherwise associated with us, including certain of our existing shareholders and certain specified affiliates, through a directed share program. The underwriters will receive an underwriting discount and commission of 7.00% on the sale of 12,700 shares reserved under the directed share program. The underwriters will not receive an underwriting discount or commission on the sale of 1,803,791 shares reserved under the directed share program offered to certain of our existing shareholders and certain specified affiliates. See Underwriting.
Nasdaq Global Market symbol	ALIM

The number of shares of our common stock outstanding after this offering is based on 1,637,359 shares of our common stock outstanding as of March 31, 2010 and the automatic conversion of all outstanding shares of our preferred stock into 22,863,696 shares of common stock upon the closing of the offering, including the conversion of certain Series A preferred stock dividends accumulated prior to November 22, 2005 into 380,301 shares of common stock, and excludes:

- 2,225,778 shares of our common stock issuable upon exercise of options outstanding as of March 31, 2010 at a weighted average price per share of $2.14;
- 208,493 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted average price of $3.37 per share, all of which are currently exercisable;

494,422 shares of common stock reserved for issuance under our 2010 Employee Stock Purchase Plan that becomes effective on the effective date of this registration statement; and

1,977,686 shares of common stock reserved for issuance under our 2010 Equity Incentive Plan that becomes effective on the effective date of this registration statement.

Unless otherwise indicated, the information we present in this prospectus assumes and reflects the following:

the automatic conversion of all outstanding shares of our preferred stock into 22,863,696 shares of common stock upon the closing of the offering, including the conversion of certain Series A preferred stock dividends accumulated prior to November 22, 2005 into 380,301 shares of common stock;

the filing of our restated certificate of incorporation and the adoption of our amended and restated bylaws to be effective upon the closing of this offering;

no exercise of the underwriters over-allotment option to purchase additional shares; and

a 3.4-for-one reverse split of our common and preferred stock effected prior to the effective date of this registration statement.

Table of Contents

SUMMARY HISTORICAL AND PRO FORMA FINANCIAL AND OTHER DATA

The tables below summarize our financial data. The following statements of operations data for fiscal years 2007, 2008 and 2009, and the balance sheet data as of December 31, 2008 and 2009 have been derived from our audited financial statements and related notes and are included elsewhere in this prospectus. The statement of operations data for fiscal years 2005 and 2006, and the balance sheet data as of December 31, 2005, 2006 and 2007 are derived from our audited financial statements, but are not included in this prospectus. 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 prospectus.

Statement of Operations Data

	Years Ended December 31,				
	2005	2006	2007	2008	2009
	(In thousands, except per share data)				
Operating expenses					
Research and development(1)	$ 2,926	$ 6,736	$ 8,363	$ 43,764	$ 15,057
General and administrative	2,595	3,028	3,184	5,058	3,407
Marketing	557	616	969	1,259	752
Total operating expenses	6,078	10,380	12,516	50,081	19,216
Interest income	223	596	1,079	585	37
Interest expense	(2)	(2)	(2)	(1,514)	(1,897)
Decrease (increase) in fair value of preferred stock conversion feature	8	6	1	(10,454)	(23,142)
Loss from continuing operations	(5,849)	(9,780)	(11,438)	(61,464)	(44,218)
Income (loss) from discontinued operations(2)	(7,790)	(3,191)	5,733		
Net loss	(13,639)	(12,971)	(5,705)	(61,464)	(44,218)
Beneficial conversion feature of preferred stock (see Note 9)					(355)
Preferred stock accretion	(164)	(243)	(248)	(718)	(623)
Preferred stock dividends	(1,546)	(3,548)	(4,685)	(6,573)	(7,225)
Net loss attributable to common stockholders	$ (15,349)	$ (16,762)	$ (10,638)	$ (68,755)	$ (52,421)
Net loss per share attributable to common stockholders basic and diluted	$ (10.68)	$ (11.66)	$ (7.09)	$ (45.50)	$ (34.56)
Weighted average common shares outstanding basic and diluted	1,437	1,437	1,500	1,511	1,517

Pro forma net loss per share attributable to common stockholders basic and diluted(3)	$ (0.94)
Pro forma weighted average common shares outstanding basic and diluted(3)	22,496

(1) Includes $29.8 million of research and development expenses incurred in connection with an amendment to the pSivida license agreement in the year ended December 31, 2008. See Note 7 to the financial statements for a more detailed description of the pSivida agreement and the amendment.

(2) Includes gains on disposal of $9.7 million and $6.0 million for the years ended December 31, 2006 and 2007, respectively. See Note 3 to the financial statements for a more detailed description of the discontinued operations.

(3) The pro forma basic and diluted net loss per common share data for the year ended December 31, 2009 reflect the conversion, upon the closing of this offering, of our Series A, Series B, Series C and Series C-1 preferred stock (including shares of Series C-1 preferred stock issued upon the exercise of warrants in January 2010) at their respective conversion rates into our common stock, as if the conversion had occurred at the later of the beginning of the period presented or the date of issuance of such shares of preferred stock and excludes the effect of the change in fair value of the preferred stock conversion feature, preferred stock accretion and preferred stock dividends. The pro forma data does not give effect to the consummation of this offering.

Table of Contents

Balance Sheet Data

	As of December 31,					
	2005	2006	2007	2008	2009	2009 Pro Forma(1)
			(In thousands)			
Cash and cash equivalents	$ 22,815	$ 27,157	$ 20,847	$ 17,875	$ 4,858	$ 14,858(2)
Working capital	21,846	25,294	19,862	14,551	(4,428)	5,572
Total assets	25,081	31,251	24,519	20,264	6,561	16,561
Long-term liabilities	57	60	31	28,217	47,909	11,208
Preferred stock	43,373	63,057	67,990	103,017	113,389	
Additional paid-in capital	2,193	2,571	2,867	3,474	4,836	164,560
Accumulated deficit	(23,315)	(40,077)	(50,715)	(119,470)	(171,891)	(170,282)
Total stockholders deficit	(21,015)	(37,399)	(47,738)	(115,887)	(165,472)	(5,382)

(1) Assumes and gives effect to the conversion of all outstanding shares of preferred stock into common stock upon the completion of this offering, including the conversion of certain Series A preferred stock dividends accumulated prior to November 22, 2005 into 380,301 shares of common stock and the conversion of 1,935,700 shares of our Series C-1 preferred stock issued upon the exercise of warrants in January 2010, the receipt of $10.0 million in proceeds in January 2010 as a result of the exercise of Series C-1 warrants, and an incremental gain of $1.6 million on the revaluation of the embedded conversion feature based on the initial public offering price of $11.00 per share immediately prior to the conversion of our Series A, Series B, Series C and Series C-1 preferred stock.

(2) This amount does not include a $4.0 million option payment that we received in January 2010 from Bausch & Lomb Incorporated (Bausch & Lomb) upon the exercise by Bausch & Lomb of its option to extend the period during which it may continue to develop an allergy product acquired from us in 2006 by two years.

Table of Contents

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors described below, together with the other information in this prospectus (including our financial statements and the related notes appearing at the end of this prospectus) before deciding to invest in shares of our common stock. If any of the events contemplated by the following discussion of risks should occur, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. As a result, 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 have invested a significant portion of our time and financial resources in the development of Iluvien, our only product candidate in clinical development. We anticipate that in the near term our ability to generate revenues will depend solely on the successful development and commercialization of Iluvien. 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), we plan to file a New Drug Application (NDA) for the low dose of Iluvien in the United States in the second quarter of 2010, followed by registration filings in certain European countries and Canada. However, we may not complete our registration filings in our anticipated time frame. Even after we complete our NDA filing, the U.S. Food and Drug Administration (FDA) may not accept our submission, may request additional information from us, including data from additional clinical trials, and, ultimately, may not grant marketing approval for Iluvien. In addition, although we believe the month 24 clinical readout from our FAME Study demonstrates that Iluvien is 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.

If we are not successful in commercializing Iluvien, or are significantly delayed in doing so, our 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:

- successfully complete our clinical trials;
- produce, through a validated process, 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 payors.

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.

Table of Contents

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 United States, 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.

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 United States. For example, the FDA may object to the use of a sham injection in our control arm or 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 United States 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 plan to submit an NDA in the United States for the low dose of Iluvien in the second quarter of 2010 with 24 months of clinical data from our FAME Study, followed by registration filings in certain European countries and Canada. 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 Principals for Clinical Trials, we believe that the FDA will consider 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 intend to submit 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. 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, which could result in the FDA not granting marketing approval for Iluvien.

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

Table of Contents

fluocinolone acetonide (FA) in patients being treated with Iluvien, we expect to obtain a waiver from these regulatory agencies from the requirement to perform carcinogenicity studies. However, we may not be able to demonstrate negligible systemic absorption of FA in our PK Study beyond 18 months or may not obtain a waiver from regulatory agencies for the requirement to perform carcinogenicity studies in animals. If we are required to perform carcinogenicity studies in animals, the approval of Iluvien could be delayed by up to 36 months.

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 FA, 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 intraocular pressure (IOP), which may increase the risk of glaucoma, and cataract formation. We have received only the month 24 clinical readout from our FAME Study and the extent of Iluvien s long-term side effect profile 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 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 United States 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.

Iluvien may not be granted Priority Review by the FDA and, even if Iluvien receives Priority Review, Iluvien may not receive approval within the six-month review/approval cycle.

We believe that Iluvien may be eligible for Priority Review under FDA procedures. We will request Priority Review for Iluvien at the time we submit our NDA. Although the FDA has granted Priority Review to other products that treat retinal disease (including Visudyne, Retisert, Macugen, Lucentis and Ozurdex), Iluvien may not receive similar consideration. However, even in the event that Iluvien is designated for Priority Review, such a designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval

compared to conventional FDA procedures. Receiving Priority Review from the FDA does not guarantee approval within the six-month review/approval cycle.

Table of Contents

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 payors 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 the demonstration of its safety and efficacy, its cost-effectiveness, its potential advantages over other therapies, the reimbursement policies of government and third-party payors 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 payors 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 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 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 S.R.L./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, 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. Any inability to acquire information necessary to file for regulatory approval from such third-parties could also prevent us from obtaining regulatory approval for Iluvien in a timely manner. In addition, all our third-party manufacturers are subject to cGMP and comparable requirements of foreign regulatory bodies, and certain of our manufacturers utilize

production facilities outside the U.S. that are subject to local regulations with respect to those operations, and we do not have control over compliance with these regulations by our manufacturer. If our manufacturer fails to maintain compliance, the production of Iluvien could be interrupted, resulting in delays

and additional costs. In addition, if the facilities of our manufacturer do not pass a pre-approval plant inspection, the FDA will not grant market approval 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. Suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently have not finalized any 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.

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.

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.

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.

Table of Contents

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.

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 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 currently have no sales or marketing organization. If we are unable to establish satisfactory sales and marketing capabilities, we may not succeed in commercializing Iluvien.

At present, we have no sales personnel and a limited number of marketing personnel. In anticipation of receiving FDA approval for the commercial launch of Iluvien, we plan to begin hiring additional sales and marketing personnel to establish our own sales and marketing capabilities in the United States in time for our anticipated commercial launch of Iluvien. We plan to add our first sales representatives in the fourth quarter of 2010. Therefore, at the time of our

commercial launch of Iluvien, assuming regulatory approval by the FDA, our sales and marketing team will have worked together for only a limited period of time.

We may not be able to establish 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, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective 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.

If appropriate regulatory approvals are obtained, we intend to commercialize Iluvien and our other product candidates in international markets through collaboration arrangements with third-parties. 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 and are unable to develop an effective international sales force, our ability to generate revenue outside of North America would be limited.

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

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

As of March 31, 2010, we had 21 employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize Iluvien and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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 payors 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 payors affect the market for products such as Iluvien and others that we may develop. These third-party payors continually attempt to contain or

reduce the costs of health care by challenging the prices charged for medical products and services. In the United States, 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 payors 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.

Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors 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 FA. 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. 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 include Lucentis, a drug sponsored by Genentech, Inc., a wholly-owned member of the Roche Group and Ozurdex, a drug sponsored by Allergan, Inc. 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 collaborations 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 collaborations 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;

Table of Contents

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

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

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

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

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

A key element of our strategy is to commercialize a portfolio of new ophthalmic drugs in addition to Iluvien. We are seeking to do so through our internal research programs and through licensing or otherwise acquiring the rights to potential new drugs and drug targets for the treatment of ophthalmic disease.

A significant portion of the research that we are conducting involves new and unproven technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

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

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

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.

Table of Contents

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 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 on 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, and Kenneth Green, Ph.D., our Senior Vice President and Chief Scientific Officer. These executives each have significant ophthalmic and regulatory industry 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 Iluvien or any of our other 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 Iluvien or any of our other 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.

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 outside North America with one or more commercial partners. In order to market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. 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

Table of Contents

able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could harm our business materially.

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

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

In addition, if 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 United States 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, FA 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.

Table of Contents

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 United States 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 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 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 April 22, 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 April 22, 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 FA 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 and, 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 United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

Third-party claims of intellectual property infringement may prevent or delay our discovery, development and commercialization efforts with respect to Iluvien and our other product candidates.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third-parties. Third-parties may assert that we are employing their proprietary technology without authorization. In addition, at least several issued and pending U.S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of Iluvien.

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 United States.

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

Product liability lawsuits could divert our resources, 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 United States and foreign jurisdictions may affect our ability to sell our products profitably.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the United States and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue. The pricing and reimbursement environment may change in the future and

become more challenging due to several reasons, including policies advanced by the current executive administration in the U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the U.S., changes in federal health care policy are

Table of Contents

being considered by Congress this year. Some of these proposed reforms could result in reduced reimbursement rates for Iluvien and our other potential products, which would adversely affect our business strategy, operations and financial results.

In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reforms the way Medicare will cover and reimburse for pharmaceutical products. This legislation could decrease the coverage and price that we may receive for our products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

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.

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.

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 United States 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.

Table of Contents

Risks Relating to Our Financial Results and Need for Financing

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 anticipated commercial launch of Iluvien as early as the first quarter of 2011, particularly as we increase our research, clinical development, administrative and sales and marketing activities. 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, 2009, we have accumulated a net deficit of $171.9 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.

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,

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.

Since the inception of our company, we have 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, 2009, we had $4.9 million in cash and cash equivalents. Including 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 upon the exercise by Bausch & Lomb Incorporated of its option to extend the period during which it may continue to develop an allergy product acquired from us in 2006 by two years; we had $18.9 million in cash and cash equivalents which we believe is sufficient to fund our operations into September 2010, but not beyond. Our need for additional financing, and current lack of a commercial product raise substantial doubt about our ability to continue as a going concern. On a pro forma as adjusted basis (based on the initial public offering price of $11.00 per share) as of December 31, 2009 we expect to have approximately $66.2 million in

Table of Contents

cash and cash equivalents which we believe is sufficient to fund our operations through the projected commercialization of Iluvien as early as the first quarter of 2011. However, we cannot be sure that this offering will be completed, that Iluvien will be approved by the FDA in the fourth quarter of 2010 or that, if approved, future sales of Iluvien will generate revenues sufficient to fund our operations beyond the first quarter of 2011, or ever. In the event additional financing is needed, 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. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result and the terms of any new equity securities may have a preference over our common stock. If we attempt to raise additional funds through strategic collaboration agreements and debt financing, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize our product candidates or operate as a business.

Risks Related to this Offering

Our existing stockholders will 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.

After this offering, our existing stockholders, which will include certain executive officers, key employees and directors and their affiliates, will beneficially own approximately 84.71% of our outstanding common stock (approximately 82.12% if the underwriters option to purchase additional shares is exercised in full) and will have the ability to control all matters requiring stockholder approval, including the election of directors. As a result, our existing stockholders would have the power to prevent a change of control in our company. The interests of our existing stockholders may differ from the interests of our stockholders who purchased their shares of our common stock in this offering, and this concentration of voting power may have the affect of delaying or impeding actions that could be beneficial to you, including actions that may be supported by our board of directors. See Principal Stockholders for additional information regarding the ownership of our outstanding stock by our executive officers, directors and their affiliates.

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. Although we anticipate that our common stock will be approved for listing on the Nasdaq Global Market (Nasdaq), an active trading market for our shares may never develop or be sustained following this offering. If the market does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at a price that is attractive to you or at all. In addition, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration, which, in turn, could materially adversely affect our business.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for investors purchasing shares in this offering.

The initial public offering price for the shares of our common stock sold in this offering will be determined by negotiation between the representatives of the underwriters and us. This price may not reflect the market price of our common stock following this offering. Investors may not be able to sell their common stock at or above the initial public offering price. In addition, the market price of our common stock is likely to be highly volatile and may fluctuate substantially due to factors including the following (in addition to the other risk factors described in this section):

actual or anticipated fluctuations in our results of operations;

changes in, or our failure to meet, securities analysts expectations;

conditions and trends in the markets we serve;

Table of Contents

announcements of significant new services or solutions by us or our competitors, including technological innovations;

additions to or changes in key personnel;

the commencement or outcome of litigation;

changes in market valuation or earnings of our competitors;

the trading volume of our common stock;

future sales of our equity securities;

changes in the estimation of the future size and growth rate of our markets;

legislation or regulatory policies, practices or actions; and

general economic conditions.

In addition, the stock markets, and in particular Nasdaq, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. These broad market and industry factors may materially harm the market price irrespective of our operating performance. As a result of these factors, after this offering you might be unable to resell your shares at or above the initial public offering price. In the past, following periods of volatility in the overall market and the market price of a 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.

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.

Following the completion of this offering, 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, if you purchase shares in this offering, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur. Investors seeking cash dividends in the foreseeable future should not purchase our common stock. See Dividend Policy for additional information.

The actual or possible sale of our shares by our existing stockholders, who will beneficially own approximately 84.71% of our outstanding common stock following this offering, or by others 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.

The market price of our common stock could drop as a result of sales in the market by our existing stockholders of substantial amounts of our common stock after this offering or the perception that these sales could occur. These factors also could make it more difficult for us to raise funds through future offerings of our common stock.

In conjunction with this offering, our officers, directors and holders of substantially all of our common stock have entered into lock-up agreements with the underwriters under which they will agree not to sell or otherwise dispose of any shares of our common stock for 180 days after the completion of this offering, subject to certain exceptions, without the written consent of Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. After these lock-up agreements expire, the shares subject to these lock-up agreements and not sold in this offering will be eligible for sale in the public market, subject in some cases to volume limitations and manner of sale requirements. These factors could also make it difficult for us to raise additional capital by selling stock. See Shares Eligible for Future Sale for additional information.

Table of Contents

If you purchase shares of common stock sold in this offering, you will experience immediate and substantial dilution.

If you purchase shares of our common stock in this offering, you will experience immediate and substantial dilution of $9.04 per share, based on the initial public offering price of $11.00 per share, because the price that you pay will be substantially greater than the net tangible book value per share of the shares you acquire based on the net tangible book deficit per share as of December 31, 2009. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares. You will experience additional dilution upon the exercise of stock options by employees or directors to purchase common stock under our equity incentive plans. As of December 31, 2009, we had options outstanding to purchase 2,225,778 shares of our common stock with a weighted average exercise price of $2.14 per share. In addition, as of December 31, 2009 there were warrants outstanding to purchase 248,181 shares of our common stock with a weighted average exercise price of $3.48 per share. See Dilution for additional information.

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 additional 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 further 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 as determined by our board of directors.

All of the shares of common stock sold in our initial public offering will be freely tradable without restrictions or further registration under the Securities Act, as amended, except for any shares purchased by our affiliates as defined in Rule 144 under the Securities Act. Rule 144 defines an affiliate as a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, us and would include persons such as our directors and executive officers.

Our management will have broad discretion over the use of the net proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.

Our management will have broad discretion to use the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. They might not apply the net proceeds of this offering in ways that increase the value of your investment. We expect to use the net proceeds from this offering primarily to complete the development and registration of Iluvien for DME, to repay indebtedness and make certain milestone payments to pSivida, to commence the commercial launch of Iluvien, to continue to develop our product pipeline and for working capital and other general corporate purposes. Our management might not be able to yield any return on the investment and use of these net proceeds. You will not have the opportunity to influence our decisions on how to use the proceeds.

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. See Description of

Table of Contents

Capital Stock Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Bylaws and Delaware Law for additional information. 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, which will be in effect as of the closing of this offering:

- 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.

See Description of Capital Stock for additional information regarding these and other provisions.

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 will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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.

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

At December 31, 2009, we had U.S. federal and state net operating loss carry-forwards (NOLs) of approximately $79.5 million and $62.7 million, respectively, which expire at various dates beginning in 2018 through 2029. Section 382 of the Internal Revenue Code limits the annual utilization of NOLs and tax credit carry-forwards following an ownership change in our company. If it is determined that significant ownership changes have occurred since we generated these NOLs, 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).

Table of Contents

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

As a public company, we will 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 Securities and Exchange Commission 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 will need to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. We expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we will 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 will 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 Securities and Exchange Commission or other regulatory authorities, which would require additional financial and management resources.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND PROJECTIONS

This prospectus contains forward-looking statements. All statements other than statements of historical fact contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, we identify forward-looking statements by terms such as may, will, should, expects, plans, anti could, intends, target, projects, contemplates, believes, estimates, predicts, potential or continue o these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the Risk Factors section and elsewhere in this prospectus. All forward-looking statements involve risks, assumptions and uncertainties. You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. 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.

Table of Contents

USE OF PROCEEDS

We estimate that the net proceeds to us of the sale of the common stock that we are offering will be approximately $66.3 million, assuming an initial public offering price of $11.00 per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses that we must pay.

We anticipate using the net proceeds from this offering as follows:

approximately $13.4 million to complete the clinical development and registration of Iluvien for DME;

$15.0 million to repay indebtedness to pSivida US, Inc. (pSivida) pursuant to a promissory note issued in connection with the amendment and restatement of our agreement with pSivida (this promissory note is currently accruing interest at the rate of 8% per annum, adjusting to 20% per annum effective April 1, 2010, and is payable in full upon the earlier of certain liquidity events (including related and unrelated offerings of our capital stock greater than $75.0 million in the aggregate), the occurrence of an event of default under our agreement with pSivida or on September 30, 2012);

$183,333 to repay interest accrued on the indebtedness to pSivida as of April 22, 2010;

$25.0 million to pay a milestone payment to pSivida US, Inc. (pSivida) upon the FDA approval of Iluvien pursuant to our agreement with pSivida; and

the balance of $12.7 million to commence the commercial launch of Iluvien, to continue to develop our product pipeline and for working capital and other general corporate purposes.

Pending use of proceeds from this offering, we intend to invest the proceeds in a variety of capital preservation investments, including short-term, investment-grade and interest-bearing instruments.

DIVIDEND POLICY

We have never declared or paid any cash dividends on capital stock. We currently intend to retain all available funds and any future earnings for use in financing the growth of our business and do not anticipate paying any cash dividends after the offering and for the foreseeable future. Any future determination relating to dividend policy will be made at the discretion of our board of directors and will depend on our future earnings, financial condition, results of operations, capital requirements, general business conditions, future prospects, applicable Delaware law, which provides that dividends are only payable out of surplus or current net profits, and other factors that our board of directors may deem relevant.

Table of Contents

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2009 (in thousands, except share data):

- our actual capitalization as of December 31, 2009, assuming and giving effect to a 3.4-for-one reverse split of our common and preferred stock to be effected prior to the effective date of this registration statement;

- our pro forma capitalization assuming and giving effect to the conversion of all outstanding shares of preferred stock into common stock upon the completion of this offering, including the conversion of certain Series A preferred stock dividends accumulated prior to November 22, 2005 into 380,301 shares of common stock and the conversion of 1,935,700 shares of our Series C-1 preferred stock issued upon the exercise of warrants in January 2010, the receipt of $10.0 million in proceeds in January 2010 as a result of the exercise of Series C-1 warrants, and an incremental gain of $1.6 million on the revaluation of the embedded conversion feature based on the initial public offering price of $11.00 per share immediately prior to the conversion of our Series A, Series B, Series C and Series C-1 preferred stock; and

- our pro forma capitalization as adjusted to reflect the receipt of the estimated net proceeds from our sale of 6,550,000 shares of common stock in this offering based on the initial public offering price of $11.00 per share after deducting the underwriting discounts and commissions and estimated offering expenses and after deducting the amount necessary to repay the note due to pSivida, and the filing of a restated certificate of incorporation after the closing of this offering.

The following table does not include a $4.0 million option payment that we received in January 2010 from Bausch & Lomb Incorporated (Bausch & Lomb) upon the exercise by Bausch & Lomb of its option to extend the period during which it may continue to develop an allergy product acquired from us in 2006 by two years.

Table of Contents

	As of December 31, 2009		
	Actual	Pro Forma	Pro Forma As Adjusted
	(In thousands, except per share data)		
Cash and cash equivalents	$ 4,858	$ 14,858	$ 66,157
Note payable to pSivida	$ 15,000	$ 15,000	$
Fair value of preferred stock conversion features	36,701		
Preferred stock			
Series A preferred stock, $.01 par value; 6,624,866 shares authorized and 6,624,844 shares issued and outstanding on actual basis; 0 shares authorized, issued and outstanding on a pro forma and pro forma as adjusted basis; liquidation preference of $37,019 on an actual basis	36,467		
Series B preferred stock, $.01 par value; 7,147,912 shares authorized and 7,147,894 shares issued and outstanding on actual basis; 0 shares authorized, issued and outstanding on a pro forma and pro forma as adjusted basis; liquidation preference of $41,057 on an actual basis	40,617		
Series C preferred stock, $.01 par value; 5,807,131 shares authorized and 5,807,112 shares issued and outstanding on actual basis; 0 shares authorized, issued and outstanding on a pro forma and pro forma as adjusted basis; liquidation preference of $34,281 on an actual basis	33,452		
Series C-1 preferred stock, $.01 par value; 2,903,565 shares authorized; 967,845 shares issued and outstanding on actual basis; 0 shares authorized, issued and outstanding on a pro forma and pro forma as adjusted basis; liquidation preference of $5,140 on an actual basis	2,853		
Stockholders deficit			
Common stock, $.01 par value; 29,411,764 shares authorized, 1,598,571 shares issued and outstanding on an actual basis; 29,411,764 shares authorized, 24,462,267 shares issued and outstanding on a pro forma basis; 100,000,000 shares authorized, 31,012,267 shares issued and outstanding on a pro forma as adjusted basis	54	283	349
Additional paid-in capital	4,836	164,560	230,793
Series C-1 preferred stock warrants	1,472		
Common stock warrants	57	57	57
Accumulated deficit	(171,891)	(170,282)	(170,282)
Total stockholders deficit	(165,472)	(5,382)	60,917
Total capitalization	$ (382)	$ 9,618	$ 60,917

The number of shares of our common stock outstanding following this offering is based on 1,598,571 shares of our common stock outstanding as of December 31, 2009 and includes:

- the automatic conversion of all outstanding shares of our preferred stock into 22,863,696 shares of common stock upon the closing of the offering, including the conversion of certain Series A preferred stock dividends accumulated prior to November 22, 2005 into 380,301 shares of common stock, the conversion of 1,935,700 shares of Series C-1 preferred stock issued upon the exercise of warrants in January 2010;

and excludes:

- 2,225,778 shares of common stock issuable upon exercise of stock options outstanding at a weighted average exercise price of $2.14 per share;

- 248,181 shares of common stock issuable upon the exercise of outstanding warrants as of December 31, 2009, with a weighted average exercise price of $3.48 per share;

- 494,422 shares of common stock reserved for issuance under our 2010 Employee Stock Purchase Plan that becomes effective on the effective date of this registration statement; and

- 1,977,686 shares of common stock reserved for issuance under our 2010 Equity Incentive Plan that becomes effective on the effective date of this registration statement.

See Management Employee Benefit Plans, and Note 10 of the Notes to the Financial Statements for a description of our equity benefit plans.

Table of Contents

DILUTION

Our pro forma net tangible book value as of December 31, 2009 was approximately $(5.4) million, or approximately $(0.22) per share. Pro forma net tangible book value per share represents the amount of stockholders equity, divided by 24,462,267 shares of common stock outstanding after giving effect to the conversion of all outstanding shares of preferred stock (including shares of Series C-1 preferred stock issued upon the exercise of outstanding warrants in January 2010) into shares of common stock upon completion of this offering.

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of common stock immediately after completion of this offering. After giving effect to our sale of 6,550,000 shares of common stock in this offering at an initial public offering price of $11.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses, the pro forma net tangible book value as of December 31, 2009 would have been approximately $60.9 million or approximately $1.96 per share. This represents an immediate increase in net tangible book value of $2.18 per share to existing stockholders and an immediate dilution in net tangible book value of $9.04 per share to purchasers of common stock in the offering, as illustrated in the following table:

Initial public offering price per share		$ 11.00
Historical net tangible book value per share	$ (103.51)	
Increase attributable to the exercise of the Series C-1 warrants and the conversion of the preferred stock	$ (103.29)	
Pro forma net tangible book value per share before this offering	$ (0.22)	
Increase per share attributable to new investors	$ 2.18	
Pro forma net tangible book value per share after this offering		$ 1.96
Dilution per share to new investors		$ 9.04

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the pro forma net tangible book value per share after the offering would be approximately $2.22 per share, the increase in pro forma net tangible book value per share to existing stockholders would be approximately $2.44 per share and the dilution to new investors purchasing shares in this offering would be approximately $8.78 per share.

The table below presents on a pro forma basis as of December 31, 2009, after giving effect to a 3.4-for-one reverse split of our common and preferred stock to be effected prior to the effective date of this registration statement and the conversion of all outstanding shares of preferred stock (including 1,935,700 shares of Series C-1 preferred stock issued and the receipt of $10.0 million in proceeds in January 2010 as a result of the exercise of Series C-1 warrants) into common stock upon completion of this offering and assuming there are no exercises of stock options or warrants outstanding on December 31, 2009 (as further described below), the differences between the existing stockholders and the purchasers of shares in the offering with respect to the number of shares purchased from us, the total consideration paid and the average price paid per share:

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
	(In thousands, except per share data)				
Existing stockholders	24,462,267	78.9%	$ 105,900	59.5%	$ 4.32
New stockholders	6,550,000	21.1	72,050	40.5	$ 11.00
Totals	31,012,267	100.0%	177,950	100.0%	

As of December 31, 2009, there were options outstanding to purchase a total of 2,225,778 shares of common stock at a weighted average exercise price of $2.14 per share. In addition, as of December 31, 2009, there were warrants outstanding to purchase 248,181 shares of common stock with a weighted average exercise price of $3.48 per share. To the extent outstanding options or warrants are exercised, there will be further dilution to new investors. See Management Employee Benefit Plans and Note 10 of the Notes to the Financial Statements for a description of our equity benefit plans.

Table of Contents

SELECTED FINANCIAL DATA

The following statements of operations data for fiscal years 2007, 2008 and 2009, and the balance sheet data as of December 31, 2008 and 2009, have been derived from our audited financial statements and related notes and are included elsewhere in this prospectus. The statement of operations data for fiscal years 2005 and 2006, and the balance sheet data as of December 31, 2005, 2006 and 2007 are derived from our audited financial statements, but are not included in this prospectus. The following selected 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 prospectus.

Table of Contents

Statement of Operations Data

	Years Ended December 31,				
	2005	2006	2007	2008	2009
	(In thousands, except per share data)				
Operating expenses					
Research and development(1)	$ 2,926	$ 6,736	$ 8,363	$ 43,764	$ 15,057
General and administrative	2,595	3,028	3,184	5,058	3,407
Marketing	557	616	969	1,259	752
Total operating expenses	6,078	10,380	12,516	50,081	19,216
Interest income	223	596	1,079	585	37
Interest expense	(2)	(2)	(2)	(1,514)	(1,897)
Decrease (increase) in fair value of preferred stock conversion feature	8	6	1	(10,454)	(23,142)
Loss from continuing operations	(5,849)	(9,780)	(11,438)	(61,464)	(44,218)
Income (loss) from discontinued operations(2)	(7,790)	(3,191)	5,733		
Net loss	(13,639)	(12,971)	(5,705)	(61,464)	(44,218)
Beneficial conversion feature of preferred stock (see Note 9)					(355)
Preferred stock accretion	(164)	(243)	(248)	(718)	(623)
Preferred stock dividends	(1,546)	(3,548)	(4,685)	(6,573)	(7,225)
Net loss attributable to common stockholders	$ (15,349)	$ (16,762)	$ (10,638)	$ (68,755)	$ (52,421)
Net loss per share attributable to common stockholders basic and diluted	$ (10.68)	$ (11.66)	$ (7.09)	$ (45.50)	$ (34.56)
Weighted average common shares outstanding basic and diluted	1,437	1,437	1,500	1,511	1,517
Pro forma net loss per share attributable to common stockholders basic and diluted(3)					$ (0.94)
Pro forma weighted average common shares outstanding basic and diluted(3)					22,496

(1) Includes $29.8 million of research and development expenses incurred in connection with an amendment to the pSivida license agreement in the year ended December 31, 2008. See Note 8 to the financial statements for a more detailed description of the pSivida agreement and the amendment.

(2) Includes gains on disposal of $9.7 million and $6.0 million for the years ended December 31, 2006 and 2007, respectively. See Note 3 to the financial statements for a more detailed description of the discontinued operations.

(3) The pro forma basic and diluted net loss per common share data for the year ended December 31, 2009 reflect the conversion, upon the closing of this offering, of our Series A, Series B, Series C and Series C-1 preferred stock (including shares of Series C-1 preferred stock issued upon the exercise of warrants in January 2010) at their respective conversion rates into our common stock, as if the conversion had occurred at the later of the beginning of the period presented or the date of issuance of such shares of preferred stock and excludes the effect of the change in fair value of the preferred stock conversion feature, preferred stock accretion, and preferred stock dividends. The pro forma data does not give effect to the consummation of this offering.

Table of Contents

Balance Sheet Data

	As of December 31,					
	2005	2006	2007	2008	2009	2009 Pro Forma(1)
	(In thousands)					
Cash and cash equivalents	$ 22,815	$ 27,157	$ 20,847	$ 17,875	$ 4,858	$ 14,858(2)
Working capital	21,846	25,294	19,862	14,551	(4,428)	5,572
Total assets	25,081	31,251	24,519	20,264	6,561	16,561
Long-term liabilities	57	60	31	28,217	47,909	11,208
Preferred stock	43,373	63,057	67,990	103,017	113,389	
Additional paid-in capital	2,193	2,571	2,867	3,474	4,836	164,560
Accumulated deficit	(23,315)	(40,077)	(50,715)	(119,470)	(171,891)	(170,282)
Total stockholders deficit	(21,015)	(37,399)	(47,738)	(115,887)	(165,472)	(5,382)

(1) Assumes and gives effect to the conversion of all outstanding shares of preferred stock into common stock upon the completion of this offering, including the conversion of certain Series A preferred stock dividends accumulated prior to November 22, 2005 into 380,301 shares of common stock and the conversion of 1,935,700 shares of our Series C-1 preferred stock issued upon the exercise of warrants in January 2010, the receipt of $10.0 million in proceeds in January 2010 as a result of the exercise of Series C-1 warrants, and an incremental gain of $1.6 million on the revaluation of the embedded conversion feature based on the initial public offering price of $11.00 per share immediately prior to the conversion of our Series A, Series B, Series C and Series C-1 preferred stock.

(2) This amount does not include a $4.0 million option payment that we received in January 2010 from Bausch & Lomb Incorporated (Bausch & Lomb) upon the exercise by Bausch & Lomb of its option to extend the period during which it may continue to develop an allergy product acquired from us in 2006 by two years.

Table of Contents

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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. We are currently conducting two Phase 3 pivotal clinical trials (collectively, our FAME Study) for Iluvien involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of Iluvien in the treatment of DME. In December 2009 we received the month 24 clinical readout from our FAME Study. Based upon our analysis of this data, we plan to file a New Drug Application (NDA) in the United States for the low dose of Iluvien in the second quarter of 2010, followed by registration filings in certain European countries and Canada. We intend to request Priority Review of our NDA from the U.S. Food and Drug Administration (FDA). If Priority Review is granted, we can expect a response to our NDA from the FDA in the fourth quarter of 2010. If our NDA is approved, we plan to commercialize Iluvien in the United States by marketing and selling Iluvien to retinal specialists as early as the first quarter of 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 eye 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, 2009 we have accumulated a deficit of $171.9 million. We expect to incur substantial losses through the projected commercialization of Iluvien through at least the first quarter of 2011 as we:

- complete the clinical development and registration of Iluvien;
- build our sales and marketing capabilities for the anticipated commercial launch of Iluvien as early as the first quarter of 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.

To date we have 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, 2009, we had $4.9 million in cash and cash equivalents. Including 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 the period during which it may continue to develop an allergy product acquired from us in 2006 by two years, we had $18.9 million in cash and cash equivalents which we believe is sufficient to fund our operations into September 2010, but not beyond. We anticipate that the proceeds of this offering will be sufficient to fund our operations through the projected commercialization of Iluvien as early as the first quarter of 2011. However, we may need additional financing in the event that we do not receive regulatory approval for Iluvien in the fourth quarter of 2010 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.

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 (FA) 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 FA 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.

We made initial license fee payments totaling $750,000 to pSivida in 2004 and additional license fee payments of $750,000 in 2005 upon the initiation of our FAME Study. 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. For financial reporting purposes we fully reserved the $2.0 million in past due development payments and all penalties and interest due with respect to such past due payment, due to the uncertainty of future collection.

The February 2005 agreement provided that after commercialization of Iluvien, profits, as defined in our 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 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 accrues interest at 8% per annum, payable quarterly and is payable in full to pSivida upon the earlier of a liquidity event as defined in the agreement (including related and unrelated offerings of our capital stock greater than $75.0 million in the aggregate), the occurrence of an event of default under our agreement with pSivida, or September 30, 2012. If the note is not paid in full by March 31, 2010, the interest rate will increase to the lesser of 20% and the highest rate permitted by applicable law per annum

effective April 1, 2010, and we will be required to begin making principal payments of $500,000 per month. The outstanding receivables forgiven represented all outstanding development payments, penalties and interest totaling $6.8 million, of which $4.0 million was reserved for financial reporting purposes prior to the date of the amendment. The

Table of Contents

remaining $2.8 million represented a receivable for current and unbilled development payments as of the effective date of the March 2008 agreement. In connection with this transaction we recognized incremental research and development expenses of $29.8 million in March 2008 and we prospectively assumed all financial responsibility for the remaining development of Iluvien. We will owe pSivida an additional milestone payment of $25.0 million upon FDA approval of Iluvien. As a result of the amended profit sharing percentages we will only be able to recover 20% of the commercialization costs of Iluvien incurred prior to profitability, reduced from the 50% established in the February 2005 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 an allergy product acquired from us in 2006 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 income (loss) from discontinued operations in the accompanying statements of operations.

Financial 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 which are included in the income (loss) from discontinued operations in the accompanying financial statements. 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 generating revenue from product sales, we intend to seek to generate revenue from other sources such as up-front 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. We anticipate that we will incur expenses of approximately $11.6 million and $1.8 million in 2010 and 2011, respectively, to complete the clinical development and registration of Iluvien for DME. Upon the approval of Iluvien by the FDA, 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;

Table of Contents

fees paid to consultants and contract research organizations 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 for Iluvien 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;

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 have 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 submission is reviewed by a health authority, 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. After completion of this offering, we anticipate incurring a significant increase in general and administrative expenses, as we operate as a public company. These increases will likely 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 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 United States and Canada. We intend to seek a commercialization partner for sales and marketing activities outside North America.

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 acquire or develop in the future. We will begin recruiting sales representatives and regional managers with extensive ophthalmic-based-sales experience in 2010 in advance of an expected commercial launch of Iluvien as early as the first quarter of 2011. We expect that our domestic sales force will be able to access and form relationships with retinal specialists in the approximately 900 retina centers prior to the commercial launch of Iluvien.

Interest Income

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

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 is currently accruing interest at the rate of 8% per annum and will increase to 20% per annum effective April 1, 2010). Accrued interest in excess of amounts payable currently at the stated rate are included in accrued expenses and in other long-term liabilities in the accompanying balance sheets. Interest expense also includes interest on our capital leases.

Table of Contents

Change in Fair Value of Preferred Stock Conversion Feature

Our Series A, Series B, Series C and Series C-1 preferred stock contain certain conversion features which are considered embedded derivatives. We account for such embedded derivative financial instruments in accordance with the Financial Accounting Standards Board s (FASB) Statement of Financial Accounting Standards (SFAS) No. 133, *Accounting for Derivative Instruments and Hedging Activities* (ASC 815). We record derivative financial instruments as assets or liabilities in our balance sheet measured at their fair value. We record the changes in fair value of such instruments as non-cash gains or losses in the statement of operations. Based upon the initial public offering price of $11.00 per share, we anticipate recognizing a gain on the revaluation of the embedded conversion feature of $1.6 million immediately prior to the conversion of our Series A, Series B, Series C and Series C-1 preferred stock at their respective conversion rates (including shares of Series C-1 preferred stock issued upon the exercise of warrants in January 2010) into 22,863,696 shares of our common stock.

Preferred Stock Accretion

Our Series A, Series B, Series C and Series C-1 preferred stock were 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 is accreted on a straight-line basis over a period extending from the date of issuance to the date at which the preferred stock becomes redeemable at the option of the holder.

Preferred Stock Dividends

Our Series A, Series B, Series C and Series C-1 preferred stock accrue dividends at 8% per annum which are recorded as an increase in the carrying amount of the respective preferred stock. Upon conversion of our preferred stock immediately prior to this initial public offering, $1.5 million of dividends accrued on our Series A preferred stock prior to November 17, 2005 will convert into 380,301 shares of our common stock. All other preferred dividends will be eliminated upon conversion of the underlying preferred stock. We also recognized a dividend of $355,000 to holders of our Series C-1 preferred stock during the year ended December 31, 2009 for a beneficial conversion feature associated with the Series C-1 preferred stock at issuance.

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

We calculated net loss per share in accordance with SFAS No. 128, *Earnings Per Share* (ASC 260). We have determined that the 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 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 14,378,628, 19,741,154 and 22,149,592 for the years ended December 31, 2007, 2008 and 2009, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect. Therefore, the weighted average shares used to calculate both basic and diluted earnings 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 United States (GAAP). 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,

Table of Contents

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.

While our significant accounting policies are more fully described in Note 1 to our financial statements included within this prospectus, 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 SFAS No. 2, *Research and Development* (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 incurred. Payments to licensors that relate to the achievement of pre-approval development milestones are recorded as research and development expense when incurred.

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 SFAS No. 109, *Accounting for Income Taxes* (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 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, 2007, 2008 and 2009 we had federal NOL carry-forwards of approximately $33.9 million, $57.5 million and $79.5 million, respectively, and state NOL carry-forwards of approximately

Table of Contents

$24.7 million, $40.7 million and $62.7 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 2029 and the state NOL carry-forwards will expire at various dates between 2018 and 2029. 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).

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. Our adoption of ASC 740 did not result in a cumulative effect adjustment to retained earnings. We will 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.

The Valuation of Our Common Stock

In the absence of a public trading market for our common stock, we determined a reasonable estimate of the then current fair value of our common stock based upon multiple valuation criteria and contemporaneous analyses (in each case, as adjusted to reflect a 3.4-for-one reverse split of our common and preferred stock effected prior to the effective date of this registration statement). Our board of directors exercised judgment in evaluating and assessing the foregoing based on several factors, including:

- the nature and history of our business;
- our historical operating and financial results;
- the net present value of our expected cash flows;
- the market value of companies that are engaged in a substantially similar business;
- the lack of marketability for our common stock;
- the price at which shares of our common and preferred stock have been sold;
- the liquidation preference and other rights, privileges and preferences associated with our preferred stock;
- our progress in developing and commercializing the non-prescription products owned by our company at the time;
- our progress towards clinical and product development milestones;
- the risks and uncertainties of obtaining FDA approval for Iluvien;

the inherent risks associated with our business at the time stock option grants were approved; and

overall equity market conditions and general economic trends.

We made an initial estimate of the value of our common stock as of December 31, 2005 for the purpose of establishing the exercise price of stock-based awards granted during the year ended December 31, 2006. Our valuation methodology relied upon an application of the income approach and the market approach. The income approach involves applying appropriate risk adjusted discount rates to estimated debt free cash flows, based on forecasted revenues and costs. The projections used to estimate our value were based upon our expected operating performance over the forecast period. There is inherent uncertainty in our forecasts and projections. If different estimates or other assumptions had been used, the valuations would have been different. The market approach assessed the value of our common stock in comparison to a similar transaction,

specifically a recent sale of our preferred stock. Our analysis also included the application of discounts related to (i) the lack of marketability for our common stock, and (ii) the lack of control by our common stockholders due to the rights, privileges and preferences associated with our preferred stock. We selected a lack of marketability discount of 40% and a lack of control discount of 30%. The marketability discount was based upon restricted stock studies, studies of private placements of stock in public companies and studies of initial public offerings that primarily observed discounts ranging from 30% to 40%. We used the higher end of that range in valuing our common stock due to the historical lack of dividends being paid, restrictions on transferability, the high volatility of our peer group, concentration of ownership, and the difficulty in valuing our common stock due to the uncertainty surrounding the future results of our FAME Study. Our lack of control discount was 30%, based on a review of premiums paid in transactions to acquire control of public companies that ranged from 10% to 40%. We used the higher end of that range due to the significant rights, privileges and preferences held by our preferred stockholders.

As of December 31, 2005 the income approach yielded a valuation range of $0.99 to $1.43 per share for our common stock, and the market approach yielded a value of $1.33 per share based upon the sale of our Series B preferred stock in November and December of 2005. We therefore estimated a valuation of $1.33 per share, which was recommended to our board of directors for the strike price of all stock options granted during the year ended December 31, 2006. We also relied on this valuation in determining the fair value of the preferred stock conversion features of our Series A and Series B preferred stock at December 31, 2005, and at the end of each of the first three calendar quarters in the year ended December 31, 2006.

For purposes of valuing the conversion features of our Series A preferred stock at the time of issuance between July 2004 and October 2005, and determining the fair value of stock options granted in each of the years ended December 31, 2004 and 2005, we retrospectively applied the same lack of liquidity and lack of discounts used in our valuation as of December 31, 2005 to the issue price of our Series A preferred stock sold between July 2004 and October 2005. We determined that the fair value of our common stock for purposes of these valuations was $1.22 per share during this period.

We also estimated the value of our common stock on December 31, 2006, utilizing the income and market approaches consistent with its valuation at December 31, 2005. As of December 31, 2006 the income approach yielded a valuation of $1.63 per share for our common stock, and the market approach yielded a value of $1.33 per share based upon the sale of our Series B preferred stock in November 2006. We weighted 25% of its assessment to the income approach and 75% to the market approach, and therefore recommended a valuation of $1.39 per share as of December 31, 2006. We relied on this valuation for our recommendation to the board of directors for the strike price of all stock options granted during the year ended December 31, 2007. We also relied on this valuation in determining the fair value of the conversion features of our Series A and Series B preferred stock at December 31, 2006, and at the end of each of the first three calendar quarters in the year ended December 31, 2007.

Because we began evaluating an initial public offering of our common stock or a sale of our company in 2008, we amended our process to estimate the value of our common stock to utilize a probability-weighted expected return method, as detailed in a practice aid issued by the American Institute of Certified Public Accountants entitled Valuation of Privately Held Company Equity Securities Issued as Compensation as of December 31, 2007 and periodically thereafter. Using this valuation methodology, we estimated the value of our common stock based upon an analysis of future values of the company assuming various liquidity events or the lack of a liquidity event as described below.

At each valuation date, we estimated the value of our common stock under various potential outcomes for the company, including

- the potential of an initial public offering at various market capitalizations;

a sale of us or our assets in a merger or acquisition;

a decision by our board of directors and stockholders to remain an independent private company; or

the liquidation of our company resulting in no value to the holders of common stock.

Table of Contents

The value of our common stock was based upon the impact of the rights, privileges and preferences of the preferred stock on the value of each class of stock in each scenario. We then weighted the values for our common stock determined under each scenario based upon our estimates of the probability of each of the four possible outcomes to determine an estimate of the value of our common stock.

For valuations between December 31, 2007 and May 22, 2008 the significant drivers and weightings for our valuations were: initial public offering 35%; sale of our company/assets 20%, remain private 20%; and liquidation of intellectual property 25%. For valuations between June 25, 2008 and August 27, 2008 the significant drivers and weightings for our valuations were: initial public offering 40%; sale of our company/assets 25%; remain private 20%; and liquidation of intellectual property 15%. For valuations on September 30, 2008 and October 7, 2008 the significant drivers and weightings for our valuations were: initial public offering 35%; sale of our company/assets 35%; remain private 20%; and liquidation of intellectual property 10%. For valuations between December 31, 2008 and December 1, 2009 the significant drivers and weightings for our valuations were: initial public offering 20%; sale of our company/assets 40%; remain private 20%; and liquidation of intellectual property 20%. For the valuations on December 16, 2009 and December 31, 2009 the significant drivers and weightings for our valuations were: initial public offer 25%; sale of our company/assets 45%; remain private 20%; and liquidation of intellectual property 10%. Our estimated valuations on the following dates were as follows:

Valuation Date	Common Stock Valuation
December 31, 2007	$ 2.24
March 17, 2008	2.41
March 31, 2008	2.48
April 23, 2008	2.52
May 22, 2008	3.26
June 25, 2008	3.88
June 30, 2008	3.91
August 27, 2008	5.03
September 30, 2008	5.41
October 7, 2008	5.44
December 31, 2008	3.71
March 31, 2009	3.71
June 30, 2009	3.94
July 17, 2009	4.01
August 25, 2009	4.01
September 30, 2009	4.22
October 27, 2009	4.32
December 1, 2009	6.26
December 16, 2009	8.47
December 31, 2009	8.53

In assessing these valuations, the following factors are significant:

On March 14, 2008, we completed the modification of our agreement with pSivida that resulted in our acquisition of rights to an incremental 30% of the future profits of Iluvien, increasing our total ownership to

80% of the future profits;

On March 17, 2008, we entered into a Series C preferred stock purchase agreement with certain investors. Under the agreement, the investors agreed to purchase up to 5,807,112 shares of our Series C preferred stock at a purchase price of $5.17 per share. The agreement contemplated the purchase of such shares in two tranches. The first sale of shares was completed on March 17, 2008 when we issued

Table of Contents

5,504,542 shares. We completed the second sale of the remaining 302,570 shares on April 23, 2008. The proceeds of this offering have been and will be used primarily to fund the initial payments associated with our amended and restated agreement with pSivida and our incremental development costs associated with our assumption of all financial responsibility for the remaining development of Iluvien.

On April 25, 2008, we had an organizational meeting with a selected group of investment bankers to initiate a process for the initial public offering of our common stock. We filed a registration statement with respect to this offering on July 1, 2008, and subsequently amended that registration statement on August 19, 2008.

In the fall of 2008 the volatility of the public capital markets increased significantly and limited our ability to complete the initial public offering of our common stock contemplated in our July 1, 2008 registration filing, raise additional private capital or complete a sale of our company. We ceased efforts towards an initial public offering in the fourth quarter of 2008.

On August 25, 2009, we entered into a Series C-1 preferred stock and warrant purchase agreement with certain investors. Under the agreement, the investors agreed to purchase up to 967,845 shares of our Series C-1 preferred stock at a purchase price of $5.17 per share and warrants to purchase up to an additional 1,935,700 shares of our Series C-1 preferred stock at an exercise price per share of $5.17. The sale of the shares of Series C-1 preferred stock was completed on August 25, 2009. The proceeds of this offering will be used primarily to fund the continuation of our FAME Study and prepare for filing an NDA for Iluvien.

In June 2008, September 2008 and September 2009, we received interim readouts from our open-label Phase 2 human pharmacokinetic clinical trial (PK Study) that we believe support that the sub-microgram levels of FA delivered by Iluvien will provide visual acuity improvements while reducing the risk of ocular side effects commonly associated with the use of corticosteroids. See Business Iluvien Iluvien is Positioned to Reduce Side Effects for additional information on ocular side effects commonly associated with the use of corticosteroids.

On September 30, 2009, we had an organizational meeting with a selected group of investment bankers to reinitiate a process for the initial public offering of our common stock. We filed a registration statement with respect to this offering on October 30, 2009.

On December 16, 2009, we received the month 24 clinical readout from our FAME Study. Based on our analysis of this readout, Iluvien demonstrated efficacy in the treatment of DME. In addition, based on this readout, 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.

The differences in valuation of our preferred stock and common stock is due to the impact of the rights, privileges and preferences of our preferred stock, including a cumulative preference distribution of approximately $117.5 million at December 31, 2009. We anticipate the per share price of this offering will be in excess of both the most recent issuance price of our preferred stock in August 2009, and the most recent valuations of our common stock. We believe that the increase in value above the issuance price of $5.17 per share for our Series C-1 preferred stock will be due to:

The month 24 clinical readout from our FAME Study in advance of this offering has further reduced the perceived development and regulatory risk associated with Iluvien for a potential investor. In discussions with our underwriters related to the initial public offering of our common stock they have indicated that a higher valuation of our common stock will result from the month 24 readout from our FAME Study.

Our underwriters view of current market conditions and other factors, including the last available financial and market data from which our projections and valuations were derived.

The immediate liquidity available to investors in this offering.

Table of Contents

Our estimated common stock valuation was $8.53 on December 31, 2009. We believe that the impact of the following items will result in additional increases in the value of our common stock up to the issuance price of this offering:

The increased likelihood of consummating this offering.

The assumed conversion of all of our outstanding shares of preferred stock (including shares of Series C-1 preferred stock issued upon the exercise of outstanding warrants in January 2010) into common stock immediately prior to this offering, resulting in the elimination of a cumulative preference distribution of approximately $117.5 million at December 31, 2009 to the holders of our preferred stock.

The immediate liquidity available to investors in this offering.

Stock-Based Compensation

Prior to January 1, 2005 we accounted for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board (APB), Opinion No. 25, *Accounting for Stock Issued to Employees,* FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25*, and related interpretations. For periods prior to January 1, 2005, we have adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* (ASC 718), as amended.

Effective January 1, 2005, we adopted the fair value recognition provisions of ASC 718 using the modified prospective application method. The modified prospective application method requires us to (i) record compensation costs for the unvested portion of previously issued awards that remained outstanding at January 1, 2005 using the fair value amounts measured under ASC 718 and (ii) record compensation costs for any awards issued, modified, repurchased, or cancelled after January 1, 2005.

We recognize the grant date fair value as compensation cost of employee stock-based awards using the straight-line method over the remaining vesting period for awards granted prior to January 1, 2005 and the actual vesting period for all awards issued after January 1, 2005, 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 options granted.

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. As we have been operating as a private company, we are unable to use actual price volatility or option life data as input assumptions within our Black-Scholes valuation model.

For the calculation of expected volatility, because we lack company-specific historical and implied volatility information, we based our estimate of expected volatility on the volatility by utilizing an average of volatilities of publicly traded companies 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 chose to 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.

Table of Contents

Our risk-free interest rates are based on a zero-coupon U.S. treasury instrument, the term of which is consistent with the expected term of the stock options. We have not paid and do not anticipate paying cash dividends on our shares of common stock; therefore, the expected dividend yield is assumed to be zero. We are required to estimate forfeitures at the time of the grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. Stock-based payments are generally amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods.

We believe there is a high degree of subjectivity involved when using option pricing models to estimate stock-based compensation under ASC 718. There is currently not a market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with ASC 718 using an option pricing model, that value may not be indicative of the fair value observed in a market transaction between a willing buyer and a willing seller. If factors change and we employ different assumptions in the application of ASC 718 in future periods than those currently applied under ASC 718, the compensation expense we record in future periods under ASC 718 may differ significantly from what we have historically reported.

The exercise prices of options granted were set by our board of directors, the members of which have extensive experience in the life sciences industry and all but one of whom are non-employee directors. Our board of directors sets the exercise prices of options on its determination of the fair market value of our common stock at the time of the grants, which determination is made in accordance with federal tax rules which require reasonable application of a reasonable valuation method.

We performed valuations of our common stock contemporaneously with the granting of stock options. We believe that all of our stock options have been granted with exercise prices that are equal to or greater than the fair value of our common stock on the date of grant. The following table provides information regarding our stock option grants to our employees and our independent members of our board of directors from our inception:

Periods of Option Grants	Number of Options Granted	Weighted Average Exercise Price	Weighted Average Fair Value at Grant
July 7, 2004 to September 30, 2004	274,219	$ 2.04	$ 1.22
October 1, 2004 to December 31, 2004	86,764	2.04	1.22
January 1, 2005 to March 31, 2005	60,186	2.04	1.22
April 1, 2005 to June 30, 2005	17,647	2.04	1.22
July 1, 2005 to September 30, 2005	29,852	2.04	1.22
October 1, 2005 to December 31, 2005	18,036	2.04	1.22
January 1, 2006 to March 31, 2006	495,198	1.33	1.33
April 1, 2006 to June 30, 2006	36,764	1.33	1.33
July 1, 2006 to September 30, 2006			
October 1, 2006 to December 31, 2006	421,852	1.33	1.33
January 1, 2007 to March 31, 2007	73,530	1.39	1.39
April 1, 2007 to June 30, 2007	2,942	1.39	1.39
July 1, 2007 to September 30, 2007	3,530	1.39	1.39

Table of Contents

Periods of Option Grants	Number of Options Granted	Weighted Average Exercise Price	Weighted Average Fair Value at Grant
October 1, 2007 to December 31, 2007	334,513	1.39	1.39
January 1, 2008 to March 31, 2008	492,272	2.41	2.41
April 1, 2008 to June 30, 2008	39,706	3.77	3.77
July 1, 2008 to September 30, 2008	5,882	5.03	5.03
October 1, 2008 to December 31, 2008	2,058	5.44	5.44
January 1, 2009 to March 31, 2009			
April 1, 2009 to June 30, 2009			
July 1, 2009 to September 30, 2009	271,844	4.01	4.01
October 1, 2009 to December 31, 2009	23,619	8.47	8.47

The intrinsic value of all outstanding vested and unvested options based on the initial public offering price of $11.00 per share, is $19.7 million based on 2,225,778 common stock options at a weighted average exercise price of $2.14 per share outstanding at December 31, 2009.

Results of Operations

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 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 clinical research organization (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 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.

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.

Income (loss) 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.

Year ended December 31, 2008 compared to the year ended December 31, 2007

Research and development expenses. Research and development expenses increased by approximately $35.4 million, or 423%, to approximately $43.8 million for the year ended December 31, 2008 compared to approximately $8.4 million for the year ended December 31, 2007. The increase was primarily attributable to the restructuring of our agreement with pSivida, which resulted in incremental non-recurring expenses of $29.8 million in 2008. The $29.8 million 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. The remaining increase is primarily due to costs to continue our FAME Study which completed enrollment in October 2007, and preparations for its anticipated registration with the FDA. We incurred increases in our FAME Study of, $1.3 million in technology transfer costs associated with establishing manufacturing capabilities with a third-party manufacturer, $550,000 for clinical supplies, stability testing, and tech transfer assistance paid to pSivida and $490,000 for our PK Study initiated in September 2007. These amounts were offset by decreases in FAME Study trial site costs of $1.9 million and CRO costs of $490,000 due to the completion of enrollment and fewer patient visits per month as the trial progresses, and a decrease of $220,000 associated with the acquisition of patent rights in 2007 to a device similar to our delivery technology in order to avoid the risk of patent infringement. Additionally, total development costs related to Iluvien increased by $4.8 million due to the absence of cost sharing reimbursements due from pSivida as a result of the restructuring of our agreement in March 2008. We also had an increase in payroll and staffing related costs of $720,000 primarily due to additional research and development personnel necessary to monitor the increased activity of our FAME Study and facilitate the technology transfer of Iluvien to our third party

manufacturers, $240,000 in increased stock compensation expense associated with December 2007 option grants and expenses of $170,000 for pilot studies of Iluvien for other indications initiated in 2008.

General and administrative expenses. General and administrative expenses increased by approximately $1.9 million, or 59%, to approximately $5.1 million for the year ended December 31, 2008 compared to

approximately $3.2 million for the year ended December 31, 2007. The increase was primarily attributable to $1.3 million in expenses incurred in preparation for the anticipated 2008 initial public offering of our common stock that was expensed when we determined that an initial public offering was unlikely in the then near term, $410,000 in increased 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, $350,000 in increased payroll costs associated with pay increases and additional staffing, $250,000 in stock compensation expense associated with December 2007 option grants, and $90,000 in software amortization expense related to the acquisition of software in late 2007 and 2008 to support our FAME Study and the planned filing of an NDA for Iluvien. These changes were offset primarily by a decrease of $320,000 in severance and other costs associated with the departure of our Vice President of Business Development in April 2007 and a decrease of $130,000 insurance expense due to the decreased scope of our business associated with the discontinuance of our non-prescription business.

Marketing expenses. Marketing expenses increased by approximately $290,000, or 30%, to approximately $1.3 million for the year ended December 31, 2008 compared to approximately $1.0 million for the year ended December 31, 2007. The increase was primarily attributable to $220,000 for the initiation of pricing studies of the U.S. and European markets for Iluvien in 2008, $100,000 in conventions and key opinion leader development and $80,000 in stock compensation expense associated with December 2007 option grants. These increases were offset by $170,000 decrease associated with reimbursement studies and an Iluvien branding project undertaken in 2007.

Interest income. Interest income decreased by approximately $490,000, or 46%, to approximately $590,000 for the year ended December 31, 2008 compared to approximately $1.1 million for the year ended December 31, 2007. The decrease in interest income was primarily attributable to a substantial drop in the rates of return available on our money market accounts from approximately 4.6% in 2007 to approximately 2.3% in 2008.

Interest expense. For the year ended December 31, 2008 we recognized approximately $1.5 million in interest expense associated with our $15.0 million note payable to pSivida issued in March 2008.

Increase in fair value of preferred stock conversion feature. For the year ended December 31, 2008 we recognized expense of approximately $10.5 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 $2.24 at December 31, 2007 to $3.71 at December 31, 2008, increased volatility in the market values of our peer group and an increase in the term of the redemption features as a result of the issuance our Series C preferred stock in March 2008.

Income (loss) from discontinued operations. We did not have any income (loss) from discontinued operations for the year ended December 31, 2008 due to the sale of our dry eye product to Bausch & Lomb in July 2007. We recognized income from discontinued operations of $5.7 million for the year ended December 31, 2007 due to a gain of $6.0 million on the sale of our dry eye product to Bausch & Lomb, offset by a loss from operations of the non-prescription business.

Liquidity and Capital Resources

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of $171.9 million from our inception through December 31, 2009. Since our inception, we have 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, 2009, we had $4.9 million in cash and cash equivalents. Including the January 2010 receipt of $10.0 million in proceeds from the exercise of Series C-1 warrants and 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 an allergy product acquired from us in 2006 by two years, we had $18.9 million in cash and cash equivalents which we believe is sufficient to fund our operations into September 2010, but not beyond. Our need for additional financing, and current lack of a commercial product raise substantial doubt about our ability to continue as a going concern. On a pro forma as adjusted basis, as of December 31, 2009 we expect to have approximately $66.2 million in cash and cash equivalents which we believe is sufficient to fund

our operations through the projected commercialization of Iluvien as early as the first quarter of 2011. However, we cannot be sure that this offering will be completed, that Iluvien will be approved by the FDA in the fourth quarter of 2010 or that, if approved, future sales of Iluvien will generate revenues sufficient to fund our operations beyond the first quarter of 2011, or ever. In the event additional financing is needed, we may seek to fund our operations through the sale of additional 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. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result and the terms of any new equity securities may have a preference over our common stock. If we attempt to raise additional funds through strategic collaboration agreements and debt financing, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize our product candidates or operate as a business.

Historically through December 2009, we have received $95.1 million from the sale of shares of our common and preferred stock (including securities convertible into our common stock and preferred stock):

- from July 2003 to October 2003, we issued and sold a total of 1,389,684 shares of common stock for aggregate net proceeds of $1.7 million;
- in May 2004 we issued $810,000 of convertible promissory notes which were converted into 190,072 shares of Series A preferred stock and 47,517 shares of common stock in July 2004;
- from July 2004 to October 2005, we issued and sold a total of 6,434,772 shares of Series A preferred stock for aggregate net proceeds of $25.9 million;
- from November 2005 to November 2006, we issued and sold a total of 7,147,894 shares of Series B preferred stock for aggregate net proceeds of $31.9 million;
- from March 2008 to April 2008, we issued and sold a total of 5,807,112 shares of Series C preferred stock for aggregate net proceeds of $29.9 million; and
- in August 2009 we issued and sold 967,845 shares of Series C-1 preferred stock, and warrants exercisable for an additional 1,935,700 shares of Series C-1 preferred stock for aggregate net proceeds of $4.9 million.

In December 2006, we received $10.0 million in proceeds from the sale of our allergy products to Bausch & Lomb. We will receive an additional milestone payment of $8.0 million from Bausch & Lomb if one of the allergy products receives FDA approval. We also sold our dry eye product to Bausch & Lomb in July 2007, resulting in proceeds of $6.7 million to us.

As of December 31, 2009, we had $4.9 million in cash and cash equivalents. We have invested a substantial portion of our available cash in money market funds placed with reputable financial institutions for which credit loss is not anticipated. We have established guidelines relating to diversification and maturities of our investments to preserve principle and maintain liquidity.

Net cash was used in both our continuing and discontinued operations in the years and ended December 31, 2007, 2008 and 2009 as follows:

	Year Ended December 31,		
	2007	2008	2009
	(In millions)		
Continuing Operations	$ 10.4	$ 32.2	$ 17.8
Discontinued Operations	2.5		
Total	$ 12.9	$ 32.2	$ 17.8

Table of Contents

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.

For the year ended December 31, 2007, our cash used in continuing operations of $10.4 million was primarily attributable to our loss from continuing operations of $11.4 million increased by an increase in other current assets of $1.6 million, and offset by an increase in our accounts payable, accrued expenses and other current liabilities of $2.2 million, non-cash stock-based compensation of $190,000, and non-cash depreciation and amortization of $150,000. The increase in prepaid expenses and other current assets was primarily attributable to an increase of $1.2 million in our receivable due from pSivida under our agreement as our FAME Study progressed and $220,000 prepayments to certain clinical trial sites for their participation in our FAME Study. The increase in accounts payable, accrued expenses and other current liabilities was comprised primarily of increases of $1.6 million in amounts payable to our clinical trial sites as we completed enrollment of our FAME Study in 2007, $310,000 in CRO and reading center costs to monitor patients and clinical trial sites, and $100,000 owed to software vendors for installation of trial management software for our FAME Study.

Table of Contents

Net cash was provided by (used in) the investing activities of our continuing and discontinued operations in the years ended December 31, 2007, 2008 and 2009 as follows:

	Year Ended December 31,		
	2007	2008	2009
	(In millions)		
Continuing Operations	$ (0.2)	$ (0.6)	$ (0.1)
Discontinued Operations	6.7		
Total	$ 6.5	$ (0.6)	$ (0.1)

Net cash used in the investing activities of our continuing operations is attributable to purchases of property and equipment in each of the years ended December 31, 2007, 2008 and 2009.

Net cash provided by our financing activities was $4.9 million for the year ended December 31, 2009; $29.8 million for the year ended December 31, 2008 and $80,000 for the year ended December 31, 2007. Net cash provided by financing activities in the year ended December 31, 2009 were 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. In 2008, cash was provided primarily by net proceeds of $29.9 million received from the issuance of our Series C preferred stock. In 2007, cash provided by financing activities were primarily due to the exercise of employee stock options.

Our future capital requirements will depend on numerous forward-looking factors, including, but not limited to:

- the progress and cost of preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of clinical trials and other research and development programs;
- the costs of the development and expansion of our operational, sales and marketing infrastructure;
- the costs and timing of obtaining regulatory approval;
- the ability of our collaborators to achieve development milestones;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses; and
- the cost that we may incur under current and future licensing arrangements relating to other product candidates.

Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2009:

	Payments Due by Future Period				
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	5+ Years
			(In thousands)		
Note payable to pSivida plus accrued interest	$ 19,175	$ 6,750	$ 12,425	$	$
Operating lease	105	105			
Capital leases	6	6			
Total	$ 19,286	$ 6,861	$ 12,425	$	$

Table of Contents

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

The possible acceleration of the note payable to pSivida of $15 million upon the earlier of certain liquidity events (including related and unrelated offerings of our capital stock greater than $75 million in the aggregate), or the occurrence of an event of default under our agreement with pSivida.

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 country (i.e., the United States, 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 United States, 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 United States 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 United States, Canada, and Europe. In accordance with the terms of the agreement, we will incur approximately $17.4 million of expenses with the contract research organization through 2010. Through December 31, 2009 we incurred $13.6 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 2010. Through December 31, 2009 we incurred $1.0 million of expense associated with this agreement.

Table of Contents

Off-Balance Sheet Transactions

To date, we have not had any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Qualitative and Quantitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2009, we had cash and cash equivalents of $4.9 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable 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.

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 United States, 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.

Tax Loss Carry-Forwards

At December 31, 2009, we had U.S. federal and state net operating loss carry-forwards (NOLs) of approximately $79.5 million and $62.7 million, respectively, which expire at various dates beginning in 2018 through 2029. Section 382 of the Internal Revenue Code limits the annual utilization of NOLs and tax credit carry-forwards following an ownership change in our company. If it is determined that significant ownership changes have occurred since we generated these NOLs, 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).

Recent Accounting Pronouncements

In March 2008, the FASB Issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133*, (ASC 815), which requires companies with derivative instruments to disclose information that should enable financial statement users to understand how and why a company uses derivative instruments, how derivative instruments and related hedged items are accounted for under ASC 815, and how these items affect a company s financial position, results of operations and cash flows. ASC 815 affects only these disclosures and does not change the accounting for derivatives. We are applying ASC 815 prospectively beginning with the first quarter of the 2009 fiscal year. The adoption of ASC 815 did not have a material effect on the disclosures in our financial statements.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* (SFAS 168). SFAS 168 authorized the Codification as the sole source for authoritative U.S. GAAP and any accounting literature that is not in the Codification will be considered nonauthoritative. We have commenced utilizing the Codification as its sole source of authoritative U.S. GAAP for its 2009 financial statements.

Table of Contents

BUSINESS

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. We are currently conducting two Phase 3 pivotal clinical trials (collectively, our FAME Study) for Iluvien involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of Iluvien in the treatment of DME. In December 2009 we received the month 24 clinical readout from our FAME Study. Based upon our analysis of this data, we plan to file a New Drug Application (NDA) in the United States for the low dose of Iluvien in the second quarter of 2010, followed by registration filings in certain European countries and Canada. We intend to request Priority Review of our NDA from the U.S. Food and Drug Administration (FDA). If Priority Review is granted, we can expect a response to our NDA from the FDA in the fourth quarter of 2010. If our NDA is approved, we plan to commercialize Iluvien in the United States by marketing and selling Iluvien to retinal specialists as early as the first quarter of 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).

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 17.9 million people in 2007. 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 United States 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. Corticosteroids have shown improved visual acuity in DME patients in non-pivotal clinical trials, but they are associated with increased intraocular pressure (IOP), which may increase the risk of glaucoma, and cataract formation. Both of these alternate therapies are limited by a need for multiple injections to maintain a therapeutic effect.

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 fluocinolone acetonide (FA). Iluvien is inserted with a device that employs a 25-gauge needle which allows for a self-sealing wound. In the United States, 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 FA, a non-proprietary corticosteroid with demonstrated efficacy in the treatment of ocular diseases. 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 with retinal specialists to assess its safety and efficacy for the treatment of dry AMD, wet AMD and 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.

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 Ophthalmics 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 across the United States and Canada. We intend to seek a commercialization partner for sales and marketing activities outside North America.

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. We are currently conducting our FAME Study involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of Iluvien in the treatment of DME. In December 2009 we received the month 24 clinical readout from our FAME Study. Based upon our analysis of this data, we plan to file an NDA in the United States for the low dose of Iluvien in the second quarter of 2010, followed by registration filings in certain European countries and Canada.

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 Ophthalmics) by marketing and selling Iluvien to the approximately 1,600 retinal specialists practicing in the approximately 900 retina centers in the United States and Canada. We intend to seek a commercialization partner for sales and marketing activities 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 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 needs in the treatment of ophthalmic diseases. Toward that end, we intend to leverage management s expertise and its broad

Table of Contents

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 United States. According to the CDC, the number of Americans diagnosed with diabetes has increased from approximately 8.1 million people in 1994 to approximately 17.9 million people in 2007. In addition to diagnosed cases, the CDC estimates that an additional 5.7 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, in the United States 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. 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.

Figures 1 and 2 provide a detailed cross section of a healthy retina and a retina affected by diabetic retinopathy.

Figure 1

Figure 2

© A.D.A.M., Inc.

Table of Contents

Diabetic Macular Edema

DME, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition is called DME. The onset of DME is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision. 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 United States 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 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- VEGF agents. Corticosteroids have been shown to improve visual acuity in DME patients in non-pivotal clinical trials, but are associated with increased IOP, which may increase the risk of glaucoma, and cataract formation. Both of these alternate therapies are limited by a need for multiple injections to maintain a therapeutic effect.

FDA Approved Treatments for DME

Laser Photocoagulation. In laser photocoagulation, light rays are directed into the eye focusing on abnormal blood vessels that are growing within the retina and patches of edema which are near the macula. This laser, which administers heat from a fine-point beam, cauterizes the vessels to seal them from further leakage or destroys retinal tissue associated with the patch of edematous tissue, via thermal destruction, in the hope of preventing further vision loss. Results of clinical trials on laser photocoagulation have shown the procedure reduces vision loss in DME patients. Visual acuity gains have been seen as well, although results have been highly variable and may take more than eight months for median visual acuity to improve. Further, the 2008 Preferences and Trends Survey among retinal specialists showed that 84% of patients treated with laser photocoagulation required an off-label drug therapy or a combination of both additional laser photocoagulation and an off-label drug therapy to treat the disease.

There are no other therapies approved by the FDA for the treatment of DME.

Off-Label Treatments for DME

Intravitreal Triamcinolone Acetonide Injections (IVTA). Triamcinolone acetonide is a corticosteroid administered via an intravitreal injection either as an adjunct to laser photocoagulation or as a stand alone treatment. Typically administered in a 4,000 microgram (μg) suspension, IVTA is relatively inexpensive and has demonstrated temporary visual improvement and reduction of edema in patients with DME. Due to the potential side effects, including increased IOP, which may increase the risk of glaucoma, and cataract formation, as well as the need for multiple injections, the use of IVTA for the treatment of DME is not optimal.

Anti-VEGF Intravitreal Injection. Anti-VEGF therapies are administered via an intravitreal injection. VEGF has been identified as an important mediator in diabetic retinopathy, including DME, and appears to play a role in increasing vascular permeability in this condition. Similar to IVTA, anti-VEGFs require multiple injections, potentially as

frequently as once per month, to sustain a therapeutic effect. Two Phase 3 clinical trials studying the use of Lucentis (ranibizumab injection), a drug sponsored by Genentech, Inc., a wholly-owned member of the Roche Group (Genentech), as a treatment for DME are currently underway, where the

Table of Contents

clinical trial design is based on one injection per month. Results from a single-center study involving 26 patients comparing one injection of IVTA versus Genentech s Avastin (bevacizumab) in patients with refractory DME was published in the October 2007 issue of the British Journal of Ophthalmology. Over the four to eight week period post-injection, IVTA was statistically significantly better at improving vision and reducing macular thickness than Avastin. This head-to-head study supports the anecdotal observations reported by retinal specialists that, in DME, corticosteroids appear to be therapeutically superior to anti-VEGF therapy.

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 FA, 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 United States, 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 FA. The active pharmaceutical ingredient in Iluvien is FA, 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 are studying 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.

Iluvien is expected to deliver a therapeutic effect for up to 36 months. In vitro release kinetics have shown that Iluvien provides sustained delivery of sub-microgram levels of FA over time. Based on these release kinetics, we expect that the low dose of Iluvien will provide sustained therapy for up to 36 months, with actual therapeutic effect to be determined in our ongoing FAME Study.

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 FA and insertion into the back of the eye, a position that we believe optimizes delivery of FA to the retina by utilizing these natural currents, will maximize efficacy and minimize possible side effects.

Iluvien is inserted using a 25-gauge needle. Needle gauge determines the size of the wound that is created. Iluvien is inserted into the eye 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 (FA) is the active compound in Iluvien and a member of the class of steroids known as corticosteroids. FA 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, upregulation of occludin, inhibition of release of certain inflammatory cytokines and suppression of VEGF secretion. These pharmacological actions have the potential to treat various ocular

Table of Contents

conditions, including DME, dry AMD, wet AMD and RVO. However, FA 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 cataract formation.

Iluvien is Positioned to Reduce Side Effects

Based on our analysis of the month 24 clinical readout from our FAME Study, it appears that Iluvien mitigates the incidence of steroid-induced IOP elevations and cataract formation commonly associated with the intraocular use of corticosteroids, which we believe is due to its location in the posterior portion of the eye, as illustrated below. Fluid, or aqueous humor, generated at the ciliary body, located just behind the iris, flows within the eye primarily via two currents as illustrated below. 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. Various publications support the existence of these currents within the eye, including an article by J. Park et. al. published in 2005 in the Journal of Controlled Release, an article by J. Xu et. al. published in 2000 in Pharmaceutical Research and a paper by M. Araie and D.M. Maurice published in the 1991 in the Journal of Experimental Eye Research.

© Nucleus Medical Art

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 FA and mitigates the incidence of IOP elevations and cataract formation commonly associated with the intraocular use of corticosteroids.

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 FA 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. In February 2005, we entered into an agreement with pSivida for the development of

Table of Contents

FA in pSivida s proprietary delivery system. Our agreement with pSivida provides us with a worldwide exclusive license to develop and sell Iluvien for delivery to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis). See Licenses and Agreements below for additional information related to our agreement with pSivida.

The low dose of Iluvien is designed to provide sustained sub-microgram levels of FA and a therapeutic effect for up to 36 months. We believe that Iluvien s ability to deliver sub-microgram levels of FA mitigates the incidence of IOP elevations and cataract formation commonly associated with the intraocular use of corticosteroids. As illustrated in the chart below, in vitro data from multiple clinical supply batches of the low dose of Iluvien show that the daily amount of FA released starts at an average daily release rate 0.23µg per day and continues to release at the month 24 time point. Our analysis of the FA release rate of Iluvien is ongoing.

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 markings to guide retinal specialists to the proper insertion point. As was the case with the modified syringe used during our FAME Study, the Iluvien 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 United States, 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. See Development Program for the Treatment of DME and Iluvien for Other Diseases of the Eye below for additional information with respect to our FAME Study and RVO clinical trial.

Table of Contents

Iluvien Clinical Development Program

The following table summarizes current and planned clinical trials for Iluvien.

Population	Trial Name	Phase	Objectives	Geography	Number of Patients	Enrollment Status
DME	FAME Study (Trial A)	Phase 3	Safety Dosage Efficacy	Northern Regions of the U.S., Europe and India and all of Canada	481	Completed
DME	FAME Study (Trial B)	Phase 3	Safety Dosage Efficacy	Southern Regions of the U.S., Europe and India	475	Completed
DME	PK Study	Phase 2	Pharmaco-kinetics	U.S.	37	Completed
Dry AMD	MAP GA	Phase 2	Safety Dosage Proof of Concept	U.S.	40	On-going
Wet AMD	MAP	Phase 2	Safety Dosage Proof of Concept	U.S.	30	On-going
RVO	FAVOR	Phase 2	Safety Dosage Proof of Concept	U.S.	20	On-going

Development Program for the Treatment of DME

We are currently conducting the FAME Study for Iluvien involving 956 patients in sites across the United States, 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. We believe that the month 24 data supports approval of the low dose of Iluvien for the treatment of DME. Therefore, we plan to proceed with the preparation of a registration dossier and to submit an NDA in the United States for the low dose of Iluvien to the FDA in the second quarter of 2010 with the month 24 clinical data, followed by registration filings in certain European countries and Canada.

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 is 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 requires 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 will be followed for 36 months. Although we will submit the additional 12 months of clinical data to applicable regulatory authorities, the approval of Iluvien by regulatory authorities, including the FDA, will be based on the month 24 clinical data from our FAME Study.

We believe that Iluvien meets the requirements for Priority Review in the United States and we intend to make a formal request for this review classification when we file our NDA with the FDA. Upon receipt, the FDA will notify us within 45 days of Iluvien s final review classification. In the European Union, we will be 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 have 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 United States, Europe and India and all sites in Canada, while sites in the southern regions of the United States, India and Europe comprise Trial B.

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.

The following table describes the baseline characteristics of the patients randomized into our FAME Study.

	Trial A			Trial B		
	Control	Low Dose	High Dose	Control	Low Dose	High Dose
Number of Patients	95	190	196	90	186	199
Mean Age (years)	62.7	64.0	62.3	61.1	61.8	62.2
Mean Baseline Vision (letters)	54.8	53.4	52.5	54.7	53.3	53.3
Male/Female (percent)	50.5/49.5	57.9/42.1	60.2/39.8	66.7/33.3	56.5/43.5	63.8/36.2
Mean Time Since Diagnosis (years)						
Diabetes	16.5	17.4	16.5	16.3	16.8	15.9
DME	4.4	3.9	3.9	3.5	3.3	3.3

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 serves as the control group, undergoing a sham insertion procedure designed to mimic an intravitreal insertion. The treatment groups consist of one group receiving a low dose of Iluvien and another group receiving a high dose of Iluvien. To reduce potential bias, these trials use a randomized, double-masked study design so that neither the patient nor the investigational staff involved with assessing the patient knows to which group the patient belongs. In order to simulate an insertion and help to maintain proper patient masking, the sham insertion procedure includes all steps involved in the insertion procedure, except that a blunt inserter without a needle is 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. Through month 24, 24.5% of patients had been treated with more than one Iluvien insert and 2.5% of patients had been treated with three or more Iluvien inserts.

Primary Efficacy Endpoint. The primary efficacy endpoint for our FAME Study is 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. In December 2009, we received the month 24 clinical readout for our FAME Study and have analyzed the full data set consistent with the recommendations

Table of Contents

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 United States 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.

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 plan to submit an NDA in the United States for the low dose of Iluvien in the second quarter of 2010, followed by registration filings in various European countries and Canada. We intend to request Priority Review of our NDA from the FDA. If Priority Review is granted, we can expect a response to our NDA from the FDA in the fourth quarter of 2010.

Our FAME Study protocol provides for analyses of additional data sets. The all-randomized and treated data set includes 953 patients randomized into our FAME Study and treated, with data imputation employed, using the LOCF method, for data missing because of patients who discontinued the trial or are unavailable for follow-up (the ART Data Set). Three patients who were randomized, but not treated, are included in the Full Data Set and excluded from the ART Data Set. In the ART Data Set, the primary efficacy endpoint was met with statistical significance for both doses of Iluvien in both Trial A and Trial B. The percentage of patients in the ART Data Set achieving improved BCVA of 15 or more letters at month 24 for Trial A is 14.7% for the control group, 26.8%

for the low dose (p-value 0.029) and 26.2% for the high dose (p-value 0.032). The percentage of patients in the ART Data Set achieving improved BCVA of 15 or more letters at month 24 for Trial B is 17.8% for the control group, 30.8% for the low dose (p-value 0.028) and 31.3% for the high dose (p-value 0.026).

The modified ART Data Set includes all 953 patients included in our ART Data Set and excludes data collected subsequent to the use of treatments prohibited by the protocol, such as Avastin, Lucentis, triamcinolone acetonide or vitrectomy (the Modified ART Data Set). In instances when a treatment prohibited by our FAME Study protocol was used, the last observation prior to the protocol violation was imputed forward to month 24 using the LOCF method. The percentage of patients in the Modified ART Data Set achieving improved BCVA of 15 or more letters for Trial A is 12.6% for the control group, 22.6% for the low dose (p-value 0.057) and 24.1% for the high dose (p-value 0.026). Neither dose of Iluvien for Trial A was statistically significant based on the H-B procedure. The percentage of patients in the Modified ART Data Set achieving improved BCVA of 15 or more letters at month 24 for Trial B is 13.3% for the control group, 29.7% for the low dose (p-value 0.004) and 29.3% for the high dose (p-value 0.005). Both doses of Iluvien for Trial B were statistically significant.

Our FAME Study protocol provides that the primary assessment of efficacy is based on the Modified ART Data Set and that other data sets are considered secondary. The protocol did not specify the Full Analysis Set as a data set for analyzing the study; however, consistent with the recommendations regarding the appropriate population for primary analysis as described in the FDA-adopted ICH Guidance E9, we believe that the FDA will consider the Full Analysis Set to be the most relevant data set for determining the safety and efficacy of Iluvien in Trials A and B.

Additional Clinical Observations. In addition to the primary efficacy variable, we also observed a number of other clinically relevant results in the month 24 clinical data from our FAME Study. 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.

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 results of the FAME Study through month 24 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 24. 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.

Table of Contents

Patients With Improved BCVA of 15 or More Letters at Any Time Point. Our analysis of the results of the FAME Study through month 24 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 first 24 months of the FAME Study, 165 out of 376 patients randomized to receive the low dose of Iluvien, or 43.9%, demonstrated improved BCVA of 15 letters or more at any time point compared to 47 out of 185 patients, or 25.4%, randomized to the control group.

Other Levels of BCVA Improvement at Month 24. 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 by retinal physicians. The table below demonstrates the low dose of Iluvien s statistically significant improvements in BCVA versus the control group at month 24 of our FAME Study.

	Trial A & Trial B Combined		
BCVA Improvement	**Control**	**Low Dose**	**p-value**
Greater than 1 letter	54.1%	66.8%	0.005
Greater than 5 letters	40.0%	52.1%	0.010
Greater than 10 letters	26.5%	38.3%	0.009

BCVA Improvement of 15 or More Letters Relative to Baseline BCVA. Our analysis of the results of the FAME Study at month 24 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	11.8%	21.1%	0.027
49 Letters or Less	28.6%	46.1%	0.039

Mean Change in BCVA Letter Score. Our analysis of the results of the FAME Study through month 24 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

Table of Contents

4.4 letters at month 24, peaking at an increase of 6.0 letters at month 6, compared to an increase of 1.7 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 24 (p-value 0.020).

During the first 24 months of follow up in our FAME Study, patients that were phakic (had a natural lens and no prior cataract surgery) at baseline, 50 of 121, or 41.3% of the control group and 182 of 235, or 77.4% of the low dose had cataract formation reported as an adverse event through month 24. For these same phakic patients, 19.8% of the control group and 66.0% 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 24 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.

Table of Contents

BCVA Improvements Beyond Month 24. Analyses of available data from patients that have completed month 27 and month 30 follow up visits in the FAME Study indicate that the low dose of Iluvien maintains a statistically significant advantage in comparison to the control group as demonstrated in the chart below.

	Trial A & Trial B Combined					
BCVA Improvement	**Control (n=64)**	**Month 27 Low Dose (n=125)**	**p-value**	**Control (n=63)**	**Month 30 Low Dose (n=123)**	**p-value**
[3] 1 letter	57.8%	76.8%	0.008	54.0%	81.3%	<0.001
[3] 5 letters	48.4%	68.8%	0.007	50.8%	70.7%	0.009
[3] 10 letters	26.6%	49.6%	0.002	31.7%	54.5%	0.004
[3] 15 letters	15.6%	34.4%	0.005	17.5%	39.8%	0.002
Mean Change in Letter Score	2.9	8.7	0.014	0.9	10.2	0.001

Decrease In Excess Foveal Thickness. In addition to the functional measures of BCVA, we assessed the ability of Iluvien to effect 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 month 24 clinical readout 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 24. At month 24, patients receiving the low dose of Iluvien

Table of Contents

demonstrated a mean decrease in excess foveal thickness of 156.1 microns versus 100.5 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. Iluvien was well tolerated through this readout in both the low and high dose patient populations. Our preliminary 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 cataract formation. Excluding IOP related side effects and cataracts, we observed no significant eye related adverse events when comparing both the low dose and high dose patient populations to control. 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.

The table below summarizes the IOP related adverse events occurring in all patients randomized and treated in our FAME Study.

	Trial A & Trial B Combined		
	Control N=185	**Low Dose N=375**	**High Dose N=393**
IOP > 30 mmHg[(1)]	2.7%	16.3%	21.6%
Trabeculoplasty	0.0%	1.3%	2.5%
IOP-Lowering Surgeries			
Trabeculectomy (filtration)	0.0%	2.1%	5.1%
Vitrectomy	0.0%	0.3%	0.5%
Other Surgery Performed	0.5%	1.6%	2.5%
Percentage of Patients Requiring One or More IOP-Lowering Surgeries	0.5%	3.7%	7.4%

(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 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.

PK Study

We initiated an open-label Phase 2 human pharmacokinetic clinical study (PK Study) in August 2007 to assess the systemic exposure of FA by measuring plasma levels of FA. Analysis of plasma levels through month 18 in September 2009 demonstrated no systemic exposure of FA (plasma levels were below the limit of detection of 100 picograms per milliliter). Based on these results, we intend to file a carcinogenicity waiver with the applicable regulatory authorities, including with the FDA in connection with our NDA submission.

A total of 37 patients were enrolled in the PK Study, 17 patients on the high dose of Iluvien and 20 patients on the low dose of Iluvien. The last patient was enrolled in the study at the end of February 2008. Data from the PK Study are being evaluated on an ongoing basis with interim evaluations at months 3, 6, 12, 18, 24, 30 and 36.

Iluvien for Other Diseases of the Eye

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

Dry AMD. Dry AMD patients account for 90% of AMD patients, with the greatest unmet need among these patients being a treatment for geographic atrophy (GA) for which there are currently no treatments available. Pre-clinical studies in two established rat models of retinal degeneration reported at the Association for Research in Vision and Ophthalmology meetings in 2006, 2007 and 2008, described the efficacious effects of a miniaturized version of Iluvien in 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. Estimates of the prevalence of retinal vein occlusion in the United States range from approximately 800,000 based on data from The Epidemiology of Retinal Vein Occlusion: The Beaver Dam Eye Study in 2000, to approximately 1.6 million based on data from Ten-Year Incidence of Retinal Vein Occlusion in an Older Population: The Blue Mountains Eye Study in 2006.

Additionally, JP Morgan stated in 2007 in an equity research report on Genentech, Inc. that the prevalence in the United States was approximately 1,070,000 patients. 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. 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

Table of Contents

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 United States, 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 will be followed for 36 months. Although we will submit the additional 12 month clinical data to applicable regulatory authorities, the approval of Iluvien by regulatory authorities, including the FDA, will be based on the month 24 clinical data from our FAME Study.

Regulatory Requirements in Other Jurisdictions

There are no specific guidance documents for the clinical development of ophthalmic drug products outside of the United States 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.

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 United States and Canada we intend to distribute Iluvien directly to physicians and through wholesalers and specialty pharmacies utilizing our own specialized sales and marketing infrastructure. Although we anticipate Iluvien being administered as a stand alone 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 Ophthalmics 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 United States and

Canada. 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 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.

Table of Contents

Our plan is to ensure that influential retinal specialists are presenting our FAME Study data at key retina meetings in 2010, 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. We will begin recruiting our sales and marketing infrastructure personnel with extensive ophthalmic based sales experience in the fourth quarter of 2010 in preparation for an expected launch of Iluvien as early as the first quarter of 2011. We expect that our 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. We will hire additional personnel to support the activities of customer service, post-marketing pharmacovigilance, medical affairs and regulatory compliance.

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 are in the process of finalizing long-term agreements with the manufacturer of the active pharmaceutical ingredient in Iluvien (FARMABIOS S.R.L./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).

pSivida is manufacturing our clinical trial materials for our FAME Study, PK Study and the Phase 2 clinical trials being conducted for the use of Iluvien for the treatment of dry AMD and wet AMD. pSivida s manufacturing process is manual and labor intensive and not practical for commercial manufacturing. We worked with Flextronics and Alliance to develop a manufacturing process where automation is employed whenever feasible so that we have a process capable of being scaled-up to produce commercial quantities. The manufacturing process for Iluvien consists of filling the polyimide tube with a matrix consisting of FA 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 to 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 United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) and the German Bundeninstitut fur Arneimittel und Medizinprodukte (BfArM).

For our NDA, we will need to provide the FDA with a description of the manufacturing and packaging procedures and in-process controls. In addition, we will need to submit 12-month stability data from a minimum of three registration batches to demonstrate that the product manufactured using the process as described meets the product specifications. Although a Validation Protocol will be submitted with the NDA, process validation does not need to be completed at the time of our NDA submission. Process validation must be completed prior to commercialization.

In Europe, the manufacturing requirements are different in that data to demonstrate that the process has been validated must be included in the submission. To meet these requirements, validation of the manufacturing process was conducted in conjunction with the manufacture of the registration batches for Iluvien (three batches each for the high and low dose). All six batches have been placed on stability. These were small scale batches and we will be limited to this batch size for product sold in Europe.

We are currently working with the third-party contract manufacturer of Iluvien to identify activities and equipment needed to scale-up for commercial size batches. New equipment for the commercial batch size will require full qualification and some steps, for example the capping step, will require revalidation.

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

Table of Contents

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 showed a 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 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. However, only Lucentis is currently enrolled in Phase 3 clinical trials for the treatment of DME. Lucentis is currently approved in the United States for the treatment of patients with neovascular wet AMD. Avastin is currently marketed as an oncology product. Neither product is 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., Lux Biosciences, Inc. 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 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 FA 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 FA for DME, and share equally in the development expenses. We and pSivida also agreed that after commercialization of such product, profits, as defined in our 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 where commercialization costs were shared equally); and

Table of Contents

make an additional milestone payment of $25.0 million after FDA approval of the first product under the March 2008 agreement to be approved by the FDA.

In addition, pSivida is continuing to provide clinical supply materials for our FAME Study, PK Study and the 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 $15.0 million promissory note accrues interest at 8% payable quarterly and is payable in full to pSivida upon the earlier of a liquidity event as defined in the note (including related and unrelated offerings of our capital stock greater than $75.0 million in the aggregate), the occurrence of an event of default under our agreement with pSivida or September 30, 2012. If the note is not paid in full by March 31, 2010, the interest rate will increase to the lesser of 20% and the highest rate permitted by applicable law per annum effective April 1, 2010, and we will be required to begin making principal payments of $500,000 per month.

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.

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 United States. 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 United States, 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 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.

In connection with the 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 FA (or derivative or pharmaceutically acceptable salt of FA) 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 United States 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.

Alliance Medical Products, Inc.

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. In exchange for Alliance s manufacturing and packaging services, we are required to pay them the agreed upon per unit price for each unit of Iluvien. In addition, we will also pay Alliance an annual charge associated with the maintenance of validation services to support manufacturing. Alliance may increase their fee for the manufacturing and packaging services and the annual charge one time during each subsequent calendar year of the term of the agreement, but such increases shall be limited to proportionate increases in the Producer Price Index for Pharmaceutical Preparations by Rx and OTC Product. 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 United States, 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.

Our agreement with Alliance shall continue for a period of six years 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. Either party may terminate the agreement if the other party is in breach of any of its agreements or obligations under the agreement and has not cured such breach within 60 calendar days after receipt of notice of such breach from the other party (10 business days if the breach is related to a payment default). Either party may also terminate the agreement upon the filing or institution of any bankruptcy, reorganization, liquidation or receivership proceedings by the other party or upon the failure by the other party to discharge any such actions against it for more than 90 days. In addition, we may terminate the agreement if any required license, permit or certificate of Alliance is not approved or issued, or is withdrawn, by any applicable regulatory authority, or if Iluvien is withdrawn by us or by any regulatory authority or any regulatory authority takes any action, or raises any objection, that prevents us from marketing, distributing, importing, exporting or selling Iluvien. Alliance may terminate the agreement if we do not commercially launch Iluvien within the earlier of (1) six months after receipt by us of FDA approval necessary for the marketing, distribution and sale of Iluvien by us in the United States or (2) two years from completion of Alliance s validation of its processes for Iluvien. Alliance may not terminate the agreement for such reason, however, if we choose, within ten days after receipt of such termination notification, to (A) compensate Alliance for the physical space reserved at their facility for the manufacturing of Iluvien and (B) waive a restriction agreed upon between the parties with respect to manufacturing restrictions. Alliance may also terminate the agreement if we cease commercial sale of Iluvien after commercial launch and if we do not purchase at least one full batch of Iluvien during any six month period after initial commercial launch of Iluvien.

Government Regulation

General Overview

Government authorities in the United States 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.

Table of Contents

United States

In the United States, 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 United States 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.

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.

Table of Contents

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 2010, the fee will be $1.4 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 an approvable letter. An approvable letter contains conditions that must be met in order to secure final approval. If and when those conditions have been met to the FDA s satisfaction, the FDA will issue an approval letter authorizing commercial marketing of the drug for the proposed indication(s). If the FDA s evaluation of the NDA submission and audit/inspection of clinical and manufacturing procedures and facilities are not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter.

Priority Review

We plan to file our NDA for the low dose of Iluvien in the United States in the second quarter of 2010 followed by registration filings in certain European countries and Canada. Once our NDA has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. In 1992, under the PDUFA the FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times Standard Review and Priority Review. A Priority Review designation is given to a drug product that has the potential to provide safe and effective therapy where no satisfactory alternate therapy exists or the drug product provides a significant improvement compared to marketed products, including non-drug products. Drug products that do not meet these criteria are automatically given a Standard Review designation. The 2002 amendment to the PDUFA set a goal that a Standard Review of an NDA be accomplished within a ten-month timeframe. A Priority Review means that the time it takes the FDA to review an NDA is reduced such that the goal for completing a Priority Review initial review cycle is six months.

We believe that Iluvien may be eligible for Priority Review under FDA procedures. We will request Priority Review for Iluvien at the time of we submit our NDA. Although the FDA has granted Priority Review to other products that treat retinal disease (including Visudyne, Retisert, Macugen, Lucentis and Ozurdex), Iluvien may not receive similar consideration. If granted, Priority Review may help to shorten the review time of our NDA with respect to Iluvien. However, even in the event that Iluvien is designated for Priority Review, such a designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving Priority Review from the FDA does not guarantee approval within the six-month review/approval cycle.

Following our NDA submission in the United States, we plan to submit registration filings in certain European countries and Canada. Currently, Priority Review (or fast track classification) is not available for applications filed in the European Union using the decentralized procedure. However, we plan to revisit the potential to file for Priority Review (or fast track classification) with MHRA in early 2010. We intend to apply for Priority Review in Canada.

Table of Contents

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.

Foreign Regulations

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

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 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. Our product

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.

Our current strategy is to use the decentralized procedure. The MHRA has agreed to be 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 six 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 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

Table of Contents

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.

Employees

As of March 31, 2010, we had 21 employees, two of which hold Ph.D.s, and one of which holds an O.D. Ten of these employees were engaged in research, development and regulatory activities, and 11 were engaged in administrative support, human resources, finance, information technology and marketing activities.

Facilities

Our facilities consist of 14,000 square feet of leased office space located in Alpharetta, Georgia that houses our corporate headquarters. The corporate headquarters is staffed by those individuals responsible for the administrative support responsibilities of human resources, finance, marketing, information technology, as well as for research, development and regulatory matters. The lease on our headquarters facility expires in May 2010.

We believe that this facility is adequate to meet our current needs. We believe that if additional space is needed in the future, such space will be available on commercially reasonable terms as necessary.

Legal Proceedings

We are not currently a party to any material legal proceedings.

Table of Contents

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information about our executive officers and directors, including their ages and positions as of December 31, 2009.

Name	Age	Position(s)
C. Daniel Myers	55	President, Chief Executive Officer and Director
Richard S. Eiswirth, Jr.	41	Chief Financial Officer
Kenneth Green, Ph.D.	51	Senior Vice President and Chief Scientific Officer
Susan Caballa	65	Senior Vice President, Regulatory and Medical Affairs
David Holland	46	Vice President of Marketing
Philip R. Tracy(1)	67	Chairman of the Board of Directors
Mark J. Brooks(2)(3)	43	Director
Brian K. Halak, Ph.D.(1)(2)	38	Director
Anders D. Hove, M.D.(2)(3)	43	Director
Calvin W. Roberts, M.D.(3)	57	Director
Bryce Youngren(1)	39	Director
Peter J. Pizzo, III(4)	43	Director

(1) Member of the Nominating/Corporate Governance Committee

(2) Member of the Compensation Committee

(3) Member of the Audit Committee

(4) Mr. Pizzo will be elected as a director of our company and will replace Mr. Brooks as a member of our Audit Committee as of the effective time of this offering.

Executive Officers

C. Daniel Myers is one of our co-founders and has served as our President and Chief Executive Officer and as a member of our board of directors since the founding of our company in 2003. Before founding our company, Mr. Myers was a founding member of Novartis Ophthalmics (formerly CIBA Vision Ophthalmics) and served as its Vice President of Sales and Marketing from 1991 to 1997 and as its President from 1997 to 2003. Mr. Myers holds a B.S. in Industrial Management from Georgia Tech. We believe Mr. Myers s qualifications to serve as a director of our company include 27 years of ophthalmic pharmaceutical experience, including 13 years in the role of president and chief executive officer. In addition to serving on our board of directors, Mr. Myers currently holds a directorship with Ocular Therapeutix, Inc.

Richard S. Eiswirth, Jr. has served as Chief Financial Officer of our company since October 2005. From 2003 to 2005, Mr. Eiswirth served as founding partner of Brand Ignition Group, which was engaged in consumer products acquisition activities. From 2002 to 2005, Mr. Eiswirth served as president of Black River Holdings, Inc., a financial

consultancy he founded in 2002. Mr. Eiswirth served as chief financial officer and senior executive vice president of Netzee, Inc., a provider of Internet banking solutions to community banks from 1999 to 2002. Mr. Eiswirth held various positions with Arthur Andersen, where he began his career, from 1991 to 1999. Mr. Eiswirth currently serves as chairman of the board of directors, audit committee chairman and member of the compensation committee of Jones Soda Co., a Seattle, Washington based beverage company, as a director of North Metro Miracle League, and previously served as a director and audit committee chairman of Color Imaging, Inc., a Norcross, Georgia based manufacturer of printer and copier supplies. Mr. Eiswirth was previously a Certified Public Accountant in Georgia. Mr. Eiswirth holds a bachelors in accounting from Wake Forest University.

Kenneth Green, Ph.D. joined us in 2004 as Vice President of Scientific Affairs, and has served as the Senior Vice President and Chief Scientific Officer of our company since January 2007. Prior to joining us, Dr. Green served as the global head of clinical sciences at Novartis Ophthalmics. He has managed ophthalmic clinical development organizations at Storz Ophthalmics, Bausch & Lomb and CIBA Vision. He started his

career in the pharmaceutical industry in 1984, as a basic research scientist in drug discovery at Lederle Laboratories, and has since held positions in many areas of drug development. Dr. Green holds a B.A. in Chemistry from Southern Illinois University and a Ph.D. in Organic Chemistry from Ohio State University.

Susan Caballa has served as the Senior Vice President of Regulatory and Medical Affairs of our company since 2004. Prior to joining us, Ms. Caballa served as the vice president of regulatory and medical affairs at Novartis Ophthalmics from 1999 to 2004. Ms. Caballa also held various regulatory management positions with the following companies engaged in the development and marketing of ophthalmic products: Allergan, Inc. (1983-1987), Iolab Corporation, a Johnson & Johnson Company (1987-1994) and Alcon Laboratories, Inc. (1994-1999). Ms. Caballa holds a B.S. in Chemistry and a Masters in Chemistry from the University of Santo Tomas and University of the Philippines.

David Holland is one of our co-founders and has served as the Vice President of Marketing since the founding of our company in 2003. Prior to founding our company, Mr. Holland served as the vice president of marketing of Novartis Ophthalmics from 1998 to 2003. In 1997, Mr. Holland served as global head of the lens business at CIBA Vision and in 1996, Global Head of the Lens Care Business of CIBA Vision. From 1992 to 1995, Mr. Holland served as the Director of Marketing for CIBA Vision Ophthalmics. From 1989 to 1991, Mr. Holland served as New Products Manager for CIBA Vision. From 1985 to 1989, Mr. Holland served as a Brand Assistant and Assistant Brand Manager for Procter and Gamble. Mr. Holland holds a B.A. in Politics from Princeton University.

Directors

Philip R. Tracy is the chairman of our board of directors and has been a member of our board of directors since 2004. Since 1998, Mr. Tracy has served as a Venture Partner of Intersouth Partners. He is also counsel to the Raleigh, North Carolina law firm Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P. Previously, Mr. Tracy was employed by Burroughs Wellcome Co. from 1974 to 1995 and served as president and chief executive officer from 1989 to 1995. Mr. Tracy holds an L.L.B. from George Washington University and a B.A. from the University of Nebraska. We believe Mr. Tracy s qualifications to serve as a director of our company include his service on the board of directors of three publicly traded companies in the biotechnology and pharmaceutical industries, his experience as president and chief executive officer of Burroughs Wellcome Co. with full responsibility for its North American pharmaceutical business, his legal training and experience as a lawyer including his service as general counsel to Burroughs Wellcome Co., and Mr. Tracy s 10 years of experience in the venture capital industry as a venture partner with Intersouth Partners. In addition to serving on our board of directors, Mr. Tracy currently holds, or within the past five years has held, directorships with the following companies: Argos Therapeutics, Inc. and Burroughs Wellcome Fund.

Mark J. Brooks has been a member of our board of directors since 2004. Since its formation in January 2007, Mr. Brooks has served as a managing director of Scale Venture Partners. Prior to joining Scale Venture Partners, from 1995 Mr. Brooks worked for Bank of America Ventures, ultimately serving as a Managing Director. Mr. Brooks also serves on the board of directors of IPC The Hospitalist Company, Inc., a publicly traded provider of hospitalist services, and also serves on the board of four privately held companies: National Healing Corporation, LivHome, Inc., Spinal Kinetics, Inc., and Oraya Therapeutics, Inc. Mr. Brooks holds an M.B.A. from the Wharton School at the University of Pennsylvania and a B.A. in Economics from Dartmouth College. We believe Mr. Brooks qualifications to serve as a director of our company include his experience as one of six managing directors of Scale Venture Partners, where Mr. Brooks leads investments in healthcare services, medical devices and drug development and his service on the board of directors of a number of Scale Venture Partners portfolio companies. In addition to serving on our board of directors, Mr. Brooks currently holds, or within the past five years has held, directorships on the following companies: Esurg Holdings Corporation, IPC The Hospitalist Company, Inc., LivHome, Inc., SpinalKinetics, Inc., National Healing Corporation, Oraya Therapeutics and U.S. Healthworks, Inc.

Brian K. Halak, Ph.D. has been a member of our board of directors since 2004. Since 2006, Dr. Halak has served as a partner of Domain Associates, L.L.C. Prior to joining Domain Associates, L.L.C., Dr. Halak served as an analyst of Advanced Technology Ventures from 2000 to 2001. From 1993 to 1995, Dr. Halak

served as an analyst of Wilkerson Group. Dr. Halak holds a Doctorate in Immunology from Thomas Jefferson University and a B.S. in Engineering from the University of Pennsylvania. We believe Dr. Halak s qualifications to serve as a director of our company include his service on the board of directors of 10 emerging companies in the life sciences industry in the past 10 years, including Vanda Pharmaceuticals, which completed a public offering on NASDAQ, and Esprit Pharma, a company that was acquired by Allergan. In addition to serving on our board of directors, Dr. Halak currently holds, or within the past five years has held, directorships on the following companies: Carticept Medical, Cortria Corporation, Esprit Pharma, Inc., Fenway Pharmaceuticals, GI Dynamics, Inc., Immune Control, Inc., Oceana Therapeutic, Inc., Optherion, Inc., Tobira Therapeutics, Inc., Vanda Pharmaceuticals, and Zyga Technology.

Anders D. Hove, M.D. has been a member of our board of directors since 2005. Since January 2004, Dr. Hove has been a partner of Venrock Associates, a venture capital firm. From 1996 to 2003, Dr. Hove was a fund manager at BB Biotech Fund, an investment firm, and from 2002 to 2003 he served as chief executive officer of Bellevue Asset Management, an investment company. Dr. Hove serves on the boards of directors of a number of public and privately-held companies. Dr. Hove has an M.D. from the University of Copenhagen, a M.Sc. from the Technical University of Denmark and an MBA from INSEAD. We believe Dr. Hove s qualifications to serve as a director of our company include his experience in the venture capital industry since 1997 and his service on the board of directors of over twelve companies. In addition to serving on our board of directors, Dr. Hove currently holds, or within the past five years has held, directorships with the following companies: AdvanDx, Anacor, Peak Surgical, Quatrx, Still River, Trubion, Virdante and WorldHeart.

Calvin W. Roberts, M.D. has been a member of our board of directors since 2003. Since 1982, Dr. Roberts has served as a clinical professor of ophthalmology at Weill Medical College of Cornell University. Since 1989, Dr. Roberts has also served as a consultant to Allergan, Inc., Johnson & Johnson and Novartis. Dr. Roberts holds an A.B. from Princeton University and an M.D. from the College of Physicians and Surgeons of Columbia University. Dr. Roberts completed his internship and ophthalmology residency at Columbia Presbyterian Hospital in New York and completed cornea fellowships at Massachusetts Eye and Ear Infirmary and the Schepens Eye Research Institute in Boston. We believe Dr. Roberts s qualifications to serve as a director of our company include his understanding of the market for products in ophthalmology and the nature of the relationship between pharmaceutical companies and physicians derived from his 25 years in the practice of medicine as well as his experience in the medical market place and in the processes of drug development and regulatory approval as a consultant to other pharmaceutical companies.

Bryce Youngren has been a member of our board of directors since 2005. Since 2002, Mr. Youngren has worked at Polaris Venture Partners, most recently as a general partner. Prior to joining Polaris, Mr. Youngren served as a senior associate at Great Hill Partners from 1999 to 2002. From 1996 to 1997, Mr. Youngren served as an analyst for Willis Stein & Partners. From 1994 to 1996, Mr. Youngren served as an analyst for Bear Stearns & Co. Mr. Youngren holds an M.B.A. from The Wharton School at the University of Pennsylvania and a B.A. in Economics from the University of Illinois at Urbana-Champaign. We believe Mr. Youngren s qualifications to serve as a director of our company include his experience in the venture capital industry since 1996 and his service on the board of directors of nine companies (including our company). In addition to serving on our board of directors, Mr. Youngren currently holds, or within the past five years has held, directorships with the following companies: Cardlytics, Xpressdocs, National Electronic Attachment, e-Rewards, Liaison International.

Peter J. Pizzo, III has been a member of our board of directors since April 2010. Since its formation in 2005, Mr. Pizzo has served as the Vice President, Finance and Chief Financial Officer of Carticept Medical, Inc., a private orthopedic medical device company, which he co-founded. From 2002 until its sale in 2005, Mr. Pizzo served as the Vice President, Finance and Chief Financial Officer of Proxima Therapeutics, Inc., a private medical device company that developed and marketed local radiation delivery systems for the treatment of solid cancerous tumors. From 1996 to 2001, Mr. Pizzo worked for Serologicals Corporation, a publicly traded global provider of biological products to

life science companies, ultimately serving as Vice President of Finance and Chief Financial Officer. From 1995 to 1996, Mr. Pizzo served as Vice President of Administration and Controller of ValueMark Healthcare Systems, Inc., a privately held owner-operator of psychiatric hospitals. From 1992 until its sale in 1995, Mr. Pizzo served in various senior financial positions at Hallmark Healthcare

Corporation, a publicly traded hospital management company, most recently as Treasurer. Mr. Pizzo holds a Bachelor of Science with Special Attainments in Commerce from Washington and Lee University. We believe Mr. Pizzo s qualifications to serve as a director of our company include 18 years of experience in medical devices, biologics and healthcare services, including the past ten years in the role of vice president, finance and chief financial officer.

Governance and Board Composition

Classified Board. Our restated certificate of incorporation that will become effective as of the closing of this offering provides for a classified board of directors consisting of three classes of directors, each serving a staggered three-year term. As a result, a portion of our board of directors will be elected each year from and after the closing of the offering. To implement the classified structure upon the consummation of the offering, Class I director nominees will be elected to one-year terms, Class II director nominees will be elected to two-year terms and Class III director nominees will be elected to three-year terms. Thereafter, directors will be elected for three-year terms.

C. Daniel Myers and Calvin W. Roberts have been designated as Class I directors whose term will expire at the 2011 annual meeting of stockholders, assuming the completion of the proposed offering. Bryce Youngren, Anders D. Hove and Phillip R. Tracy have been designated as Class II directors whose term will expire at the 2012 annual meeting of stockholders, assuming completion of the proposed offering. Brian K. Halak, Mark J. Brooks and Peter J. Pizzo, III have been designated as Class III directors whose term will expire at the 2013 annual meeting of stockholders, assuming completion of the proposed offering. Our amended and restated bylaws that will become effective as of the closing of the offering provide that the number of authorized directors may be changed only by resolution of a number of directors that is more than half of the number of directors then authorized (including any vacancies). Any additional directorships resulting from an increase in the number of authorized directors will be distributed among the three classes so that, as nearly as reasonably possible, each class will consist of one-third of the directors. The classification of the board of directors may have the effect of delaying or preventing changes in control of our company.

Independent Directors. Each of our directors other than C. Daniel Myers qualifies as an independent director in accordance with the published listing requirements of the Nasdaq Global Market (Nasdaq). The Nasdaq independence definition includes a series of objective tests, such as that the director is not also one of our employees and has not engaged in various types of business dealings with us. In addition, as further required by the Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our directors reviewed and discussed information provided by the directors and us with regard to each director s business and personal activities as they may relate to us and our management.

Board Structure and Committees. Our board of directors has established an audit committee, a compensation committee and a nominating/corporate governance committee.

Our board of directors and its committees set schedules to meet throughout the year, and also can hold special meetings and act by written consent from time to time as appropriate. The independent directors of our board of directors also will hold separate regularly scheduled executive session meetings at least twice a year at which only independent directors are present. Our board of directors has delegated various responsibilities and authority to its committees as generally described below. The committees will regularly report on their activities and actions to the full board of directors. Each member of each committee of our board of directors qualifies as an independent director in accordance with the Nasdaq standards described above and SEC rules and regulations. Each committee of our board of directors has a written charter approved by our board of directors. Upon the effectiveness of the registration statement of which this prospectus forms a part, copies of each charter will be posted on our Web site at http://www.alimerasciences.com under the Investor Relations section. The inclusion of our Web site address in this

prospectus does not include or incorporate by reference the information on our Web site into this prospectus.

Table of Contents

Audit Committee. Our audit committee currently consists of Mark J. Brooks, Anders D. Hove and Calvin W. Roberts. As of the effective time of this prospectus, our audit committee will consist of Calvin W. Roberts, Anders D. Hove and Peter J. Pizzo, III. The SEC rules and Nasdaq rules require us to have one independent Audit Committee member upon the listing of our common stock on NASDAQ, a majority of independent directors within 90 days of the date of the completion of this offering and all independent Audit Committee members within one year of the date of the completion of this offering. Our board of directors has affirmatively determined that Mr. Roberts and Mr. Pizzo meet the definition of independent directors for purposes of serving on an Audit Committee under applicable SEC and Nasdaq rules, and we intend to comply with these independence requirements within the time periods specified. Dr. Hove currently serves as chairman of the audit committee and as of the completion of this offering Mr. Pizzo will serve as the chairman of the audit committee.

Mr. Pizzo qualifies as an audit committee financial expert as that term is defined in the rules and regulations of the SEC. The designation of Mr. Pizzo as an audit committee financial expert does not impose on him any duties, obligations or liability that are greater than those that are generally imposed on him as a member of our audit committee and our board of directors, and his designation as an audit committee financial expert pursuant to this SEC requirement does not affect the duties, obligations or liability of any other member of our audit committee or board of directors.

The audit committee monitors our corporate financial statements and reporting and our external audits, including, among other things, our internal controls and audit functions, the results and scope of the annual audit and other services provided by our independent registered public accounting firm and our compliance with legal matters that have a significant impact on our financial statements. Our audit committee also consults with our management and our independent registered public accounting firm prior to the presentation of financial statements to stockholders and, as appropriate, initiates inquiries into aspects of our financial affairs. Our audit committee is responsible for establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters, and for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters, and has established such procedures to become effective upon the effectiveness of the registration statement of which this prospectus forms a part. In addition, our audit committee is directly responsible for the appointment, retention, compensation and oversight of the work of our independent auditors, including approving services and fee arrangements. All related party transactions will be approved by our audit committee before we enter into them.

Both our independent auditors and internal financial personnel regularly meet with, and have unrestricted access to, the audit committee.

Compensation Committee. Our compensation committee consists of Mark J. Brooks, Brian K. Halak and Anders D. Hove. Our board of directors has determined that Mr. Brooks, Dr. Halak and Dr. Hove satisfy the independence requirements of the Nasdaq and the SEC rules and regulations. Each member of this committee is a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended. Dr. Halak serves as chairman of the compensation committee.

The compensation committee reviews and approves our compensation policies and all forms of compensation to be provided to our executive officers and directors, including, among other things, annual salaries, bonuses, and other incentive compensation arrangements. In addition, our compensation committee will administer our stock option and employee stock purchase plans, including granting stock options to our executive officers and directors. Our compensation committee also reviews and approves employment agreements with executive officers and other compensation policies and matters.

Nominating/Corporate Governance Committee. Our nominating/corporate governance committee currently consists of Brian K. Halak, Philip R. Tracy and Bryce Youngren. Our board of directors has determined that Dr. Halak, Mr. Tracy and Mr. Youngren satisfy the independence requirements of the Nasdaq and the SEC rules and regulations. Mr. Tracy serves as chairman of the nominating/corporate governance committee.

Table of Contents

Our nominating/corporate governance committee identifies, evaluates and recommends nominees to our board of directors and committees of our board of directors, conducts searches for appropriate directors and evaluates the performance of our board of directors and of individual directors. The nominating/corporate governance committee is also responsible for reviewing developments in corporate governance practices, evaluating the adequacy of our corporate governance practices and reporting and making recommendations to the board concerning corporate governance matters. Our nominating/corporate governance committee has not adopted a policy regarding the consideration of diversity in identifying director nominees.

Code of Ethics and Business Conduct. Our board of directors has adopted a code of ethics and business conduct that will become effective upon the effectiveness of the registration statement of which this prospectus forms a part. This code of ethics and business conduct will apply to all of our employees, officers (including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions) and directors. Upon the effectiveness of the registration statement of which this prospectus forms a part, the full text of our code of ethics and business conduct will be posted on our Web site at www.alimerasciences.com under the Investor Relations section. We intend to disclose future amendments to certain provisions of our code of ethics and business conduct, or waivers of such provisions, applicable to our directors and executive officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) at the same location on our Web site identified above and also in a Current Report on Form 8-K within four business days following the date of such amendment or waiver. The inclusion of our Web site address in this prospectus does not include or incorporate by reference the information on our Web site into this prospectus.

Board Leadership

Our board of directors is led by our chairman of the board. The chairman of the board chairs all board meetings (including executive sessions), approves board agendas and schedules, and oversees board materials. The chairman of the board also acts as liaison between the independent directors and management, approves board meeting schedules and oversees the information distributed in advance of board meetings, is available to our outside corporate counsel to discuss and, as necessary, respond to stockholder communications to our board of directors, and calls meetings of the independent directors. We believe that having different people serving in the roles of chairman of the board and chief executive officer is an appropriate and effective organizational structure for our company.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. None of the current members of our compensation committee has ever been employed by us.

Executive Officers

Each of our executive officers has been elected by our board of directors and serves until his or her successor is duly elected and qualified.

Director Compensation

On October 27, 2009, our board of directors adopted a compensation program for outside directors. This program will begin on the effective date of this Registration Statement. Pursuant to this program, each member of our board of directors who is not our employee will receive a $20,000 annual retainer, except that the chairman of our board of directors will receive a $25,000 annual retainer. The chairman of the audit committee will receive an additional annual

retainer of $7,500, and the chairman of each other committee will receive an additional annual retainer of $3,500. Each other non-employee director serving as a member of a committee will receive an additional annual retainer of $2,000 for service on that committee. All retainer fees will be paid in four quarterly payments.

Table of Contents

Each non-employee director who first becomes a member of the board of directors after the consummation of this offering will receive an initial, one-time option award to purchase 20,000 shares of our common stock upon his or her election to our board of directors. Each non-employee director who served as a board member prior to the consummation of this offering and who continues as a member of the board of directors after such date will receive an initial, one-time option award to purchase 7,500 shares of our common stock upon the consummation of this offering. Each year beginning in 2011, each non-employee director who will continue to be a director after the annual meeting of our stockholders will be granted an option for 7,500 shares of our common stock at that annual meeting. However, a non-employee director who is receiving the 20,000-share option will not receive the 7,500-share option in the same calendar year.

Each initial stock option will vest and become exercisable with respect to 25% of the option shares after one year of service on the board of directors and an additional 6.25% of the option shares for each subsequent three-month period thereafter. Each annual stock option will be vested and exercisable at the date of grant. Each option granted under the directors option grant program that is not fully vested on the date of grant will become fully vested upon a change in control of the company and will also become fully vested if the non-employee director s service terminates due to death. All options granted to the non-employee directors will have an exercise price equal to the fair market value of our common stock on the date of the grant.

We currently have a policy to reimburse directors for travel, lodging and other reasonable expenses incurred in connection with their attendance at board and committee meetings.

Limitation of Liability and Indemnification

Prior to the effective date of this offering, we entered into indemnification agreements with each of our officers and directors. The agreements provide that we will indemnify each of our officers and directors against any and all expenses incurred by that officer or director because of his or her status as one of our officers or directors, to the fullest extent permitted by Delaware law, our restated certificate of incorporation and bylaws. In addition, the agreements provide that, to the fullest extent permitted by Delaware law, but subject to various exceptions, we will advance all expenses incurred by our directors in connection with a legal proceeding.

Our restated certificate of incorporation and bylaws contain provisions relating to the limitation of liability and indemnification of directors. The restated certificate of incorporation provides that our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability:

- for any breach of the director s duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- in respect of unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- for any transaction from which the director derives any improper personal benefit.

Our restated certificate of incorporation also provides that if Delaware law is amended, after the approval by our stockholders of our restated certificate of incorporation, to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law. The foregoing provisions of the restated certificate of incorporation are not intended to

limit the liability of directors or officers for any violation of applicable federal securities laws. As permitted by Section 145 of the Delaware General Corporation Law, our restated certificate of incorporation provides that we may indemnify our directors to the fullest extent permitted by Delaware law and the restated certificate of incorporation provisions relating to indemnity may not be retroactively repealed or modified so as to adversely affect the protection of our directors.

Table of Contents

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws provide that we are authorized to enter into indemnification agreements with our directors and officers and we are authorized to purchase directors and officers liability insurance, which we currently maintain to cover our directors and executive officers.

Compensation Discussion and Analysis

This section discusses our executive compensation polices and decisions and the most important factors relevant to an analysis of these policies and decisions. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our executive officers and offers perspective on the data presented in the tables and narrative that follow.

Compensation Philosophy and Objectives

As a biopharmaceutical company, we operate in an extremely competitive, rapidly changing and heavily regulated industry. We believe that the skill, talent, judgment and dedication of the executive officers and our other key employees are critical factors affecting our long-term stockholder value. Therefore, our goal is to maintain a compensation program that will fairly compensate employees, attract and retain highly qualified employees, motivate the performance of employees towards, and reward the achievement of, clearly defined corporate goals, and align employees long-term interests with those of our stockholders. To that end, our executive officers compensation has three primary components: base compensation or salary, annual incentive compensation or bonus and stock option awards. In addition, we provide our executive officers a variety of benefits that are available generally to all salaried employees.

We view the components of compensation as related but distinct. Although we review the total compensation of our executive officers, we do not believe that significant compensation derived from one component of compensation should negate or reduce compensation from other components. Our executive officer compensation philosophy is to (1) provide overall compensation, when targeted levels of performance are achieved, which is at the median of pay practices of a peer group selected, among other criteria, for similarities in size, business model and stage of development, and (2) emphasize at-risk equity compensation over annual cash compensation to attract and retain officers and align most of their compensation with long-term stockholders interests. Our annual cash incentives and our stock option awards are aligned with our achievement of corporate strategic and operating goals. We believe that successful execution against goals is the best way to enhance long-term stockholder value.

We determine the appropriate level for each compensation component based in part, but not exclusively, on competitive benchmarking consistent with our recruiting and retention goals, our view of internal equity and consistency, our overall performance and other considerations we deem relevant. For annual compensation reviews we evaluate each executive s performance, look to industry trends in compensation levels and generally seek to ensure that compensation is appropriate for an executive s level of responsibility and for promotion of future performance. Except as described below, we have not adopted any formal or informal policies or guidelines for allocating compensation between long-term and currently paid out compensation, between cash and non-cash compensation or among different forms of non-cash compensation. However, our philosophy is to make a greater percentage of an employee s compensation performance-based and to keep cash compensation to a nominally competitive level while providing the opportunity to be well rewarded through equity if we perform well over time. We also believe that for life science companies, stock-based compensation is a significant motivator in attracting employees, and while base salary and the potential for cash bonuses must be at competitive levels, performance is most significantly impacted by appropriately relating the potential for creating stockholder value to an individual s compensation potential through the use of stock options.

We do not have stock ownership guidelines for our officers, because the compensation committee is satisfied that stock and option holdings among our directors and executive officers are sufficient at this time to provide motivation and to align this group s interests with those of our stockholders. In addition, we believe

Table of Contents

that stock ownership guidelines are rare in development-stage biopharmaceutical companies, which means that ownership requirements would put us at a competitive disadvantage.

Compensation Committee

The compensation committee of our board of directors is comprised of three non-employee members of the board of directors. The compensation committee s basic responsibility is to review the performance of our management in achieving corporate objectives and to ensure that the executive officers are compensated effectively in a manner consistent with our compensation philosophy and competitive practice. In fulfilling this responsibility, the compensation committee reviews the performance of each executive officer each year. The chief executive officer, as the manager of the executive team, assesses the executives contributions to the corporate goals and makes a recommendation to the compensation committee with respect to any merit increase in salary, cash bonus and stock option award for each member of the executive team. The compensation committee meets with the chief executive officer to evaluate, discuss and modify or approve these recommendations. The compensation committee also conducts a similar evaluation of the chief executive officer s contributions when the chief executive officer is not present, and determines any increase in salary, cash bonus and annual replenishment equity award.

Compensation Consultant

The compensation committee has not engaged a compensation consultant for advice on matters related to compensation for executive officers, other key employees and non-employee directors.

Peer Group

In late 2007, the compensation committee established a peer group to better align target compensation with competitive data. Our peer group, which is listed below, was selected by the compensation committee, based on a review of biopharmaceutical companies that were similar to us in market capitalization, development stage and business model. The compensation committee intends to continue reviewing and revising the peer group periodically to ensure that it continues to reflect companies similar to us in size and development stage.

Achillion
Aegerion
Amicus
Biolex
Cadence
Cardiovascular Systems (f/k/a Replidyne)
Elixir
Inhibitex
MAP
Neurogesx
Orexigen
Pharmasset
Sirtris
Synta
Targacept
Targanta
Vanda

Principal Elements of Compensation

Base Salaries. Base salaries are set to reflect compensation commensurate with the individual s current position and work experience. Our goal in this regard is to attract and retain high-caliber talent for the position and to provide a base wage that is not subject to performance risk. Salary for the chief executive officer and the other executive officers is established based on the underlying scope of their respective responsibilities, taking into account competitive market compensation. The base salary for each executive officer is targeted at the median compared to similar positions in the peer companies. In certain circumstances in which an executive officer is uniquely critical to our success or due to the intensely competitive environment for highly qualified employees in this industry, base salary levels may exceed the median target for certain executive officers. We review base salaries for the executive officers annually near the end of each year, and the chief executive officer proposes salary adjustments to the compensation committee based on any changes in our competitive market salaries, individual performance and/or changes in job duties and responsibilities. The compensation committee then determines any salary adjustment percentage applicable to the executive officers.

Table of Contents

Prior to 2008, our competitive analysis was primarily based upon salary surveys publicly available to us, or made available to us based upon our participation in the survey. Beginning in late 2007, for purposes of determining the executive salaries for 2008, the competitive market analysis was made in comparison to our peer group. On January 1, 2010, Mr. Myers s salary was increased to $367,744, Mr. Eiswirth s salary was increased to $259,584, Dr. Green s salary was increased to $270,400, Ms. Caballa s salary was increased to $237,952 and Mr. Holland s salary was increased to $227,136.

Annual Incentive Compensation. Annual cash incentives for the executive officers are designed to reward the achievement of overall performance by our executives each year, which we believe in turn should increase stockholder value. Annual incentive awards are determined and paid out based upon the following criteria:

50% based upon the achievement of individual performance goals;

25% based upon our achievement of corporate performance goals; and

25% based upon the subjective assessment by the compensation committee of the progress of the executive team towards our strategic objectives.

The annual performance goals, both corporate and individual, are established at the beginning of the fiscal year and are clearly communicated and measurable. A target bonus is set for each executive officer based on targets for comparable positions and is stated in terms of a percentage of the officer s annualized base salary for the year. The target bonus for each named executive officer is targeted at the median of the peer group. The target bonus for our chief executive officer is 40% of his annualized base salary, and 25% of annualized base salary for each of the other named executives.

Early each year, the executive team proposes a set of corporate performance objectives and proposes percentage weights to be allocated to each goal, with higher weights given to those goals that we believe will have a greater impact on our value and/or are more challenging to achieve within the time frame specified. The compensation committee evaluates and approves the final goals and weightings. The individual goals of our chief executive officer and other named executives are established in a manner to align their performance objectives with, and support the achievement of, our corporate performance goals. Our chief executive officer proposes his annual individual performance goals and percentage weights to the compensation committee for its consideration and approval. The performance goals and percentage weights of the remaining named executives are determined individually by the chief executive officer and the specific named executive.

At the end of each year, our chief executive officer assesses his and the named executives achievement of their individual performance goals for the year, and recommends a percentage payout for each individual for the 50% of the target bonus that is allocated to individual performance goals. The compensation committee accepts and approves that percentage as is, or adjusts it to the extent the compensation committee deems appropriate. Our chief executive officer and his management team also assess our achievement of corporate performance goals, and recommend a percentage payout for the 25% of the target bonus that is allocated to corporate performance goals. The compensation committee accepts and approves that percentage as is, or adjusts it to the extent the compensation committee deems appropriate. The remaining 25% of the annual incentive compensation is determined at the discretion of the compensation committee. The compensation committee evaluates subjective criteria, including, but not limited to, its assessment of the management team s stewardship of the company, contributions to improving stockholder value, and strategic planning for long-term goals.

2009 Annual Incentive Compensation. With input from our chief executive officer, our compensation committee establishes corporate and individual performance goals for each of our named executive officers. In December 2009,

our compensation committee reviewed the status of each corporate and individual goal and determined that bonuses at or above the target level should be paid to all of our named executive officers based on the exceptional progress of our clinical programs and the efforts made by our named executive officers in preparing and positioning our company for various strategic options, including this offering, the submission of a New Drug Application for the use of Iluvien in the treatment of diabetic macular edema in

Table of Contents

the second quarter of 2010, and the commercial launch of Iluvien, its lead product candidate, as early as the first quarter of 2011.

2009 Corporate Goals. For 2009, the corporate goals component of the annual performance goals under our Incentive Compensation Bonus Plan, which accounted for 25% of the amount of bonus potential for each of our named executive officers, the weighting of each goal, and our compensation committee s quantitative assessment of the degree to which each goal was actually achieved, were as follows:

Corporate Goal	Achievement Assessment
One goal of presenting our open-label Phase 2 human pharmacokinetic clinical trial (the PK Study) month 12 study data at a prestigious industry convention (10)%	100%(1)
One goal of completing six registration batches of Iluvien and initiating stability studies on the batches with the Company s third party manufacturers (20)%	90%(2)
One goal of the month 24 readout from our FAME Study demonstrating efficacy and a side effect profile sufficient to support the New Drug Application (NDA) filing for Iluvien (50)%	120%(3)
Two goals of managing the Company s cash and raising additional capital in order to finance the Company beyond December 2009 (20)%	100%(4)

(1) We presented the month 12 readout from our FAME Study at the Angiogenesis Exudation and Degeneration Conference on February 21, 2009.

(2) The manufacture of six registration batches of Iluvien was completed in April 2009 and stability studies on the batches was initiated in May 2009. However, one of the registration batches did not meet manufacturing specifications and therefore needed to be re-manufactured which resulted in additional cost and expense to the Company.

(3) Our month 24 readout from our FAME Study demonstrated efficacy and a side effect profile that exceeded expectations and was sufficient to support the NDA filing for Iluvien. See Business Iluvien Clinical Development Program for a more in-depth discussion regarding the month 24 readout from our FAME Study.

(4) Our cash balance as of December 31, 2009 was $4.9 million in cash and cash equivalents.

With input from our chief executive officer, our compensation committee determined that the corporate goals were achieved at the level of 108% in view of the achievement of each of the corporate goals and, specifically, in light of the month 24 readout from our FAME Study which demonstrated efficacy and a safety profile that exceeded expectations.

2009 Individual Goals. The individual goals component of the annual performance goals under our Incentive Compensation Bonus Plan are primarily related to the corporate goals for which they are most responsible and, to a lesser extent, individual development or department specific goals, subject to discretionary adjustments that our compensation committee deems appropriate. Our chief executive officer makes recommendations to our compensation committee as to the degree to which those named executive officers have satisfied their individual goals. For 2009, the individual goals component of the annual performance goals under our Incentive Compensation Bonus Plan, which accounted for 50% of the amount of bonus potential for each of our named executive officers, the weighting of each

goal, and our compensation committee s quantitative assessment of the degree to which each goal was actually achieved, were as follows:

Name	Goals
Mr. Myers(1)	One goal of the month 24 readout from our FAME Study demonstrating efficacy and a side effect profile sufficient to support the NDA filing for Iluvien (35)% One goal of managing the company s cash and related to the goal of financing our company beyond December 2009 (10)% One goal of raising additional capital in order to finance our company beyond December 2009 (15)%

Table of Contents

Name	Goals
	One goal of completing six registration batches of Iluvien with the company s third party manufacturers (15)%
	One goal of preparing a draft NDA filing for Iluvien, which included monitoring the completion of 50% of the chemistry, manufacturing and controls section, 80% of the preclinical section and an initial draft of the clinical section (15)%
	One goal of developing a marketing pre-launch plan and analysis of the competitive landscape for Iluvien in preparation for its commercial launch (10)%
Mr. Eiswirth(2)	One goal of completing the 2008 financial audit (20)%
	One goal of managing the company s cash and related to the goal of financing our company beyond December 2009 (20)%
	One goal of raising additional capital in order to finance our company beyond December 2009 (20)%
	One goal to build relationships with financial analyst and investment bankers in preparation for this offering (20)%
	One goal of managing the evaluation of strategic options (20)%
Dr. Green(3)	One goal of the month 24 readout from our FAME Study demonstrating efficacy and a side effect profile sufficient to support the NDA filing for Iluvien (30)%
	Two goals of presenting the month 12 readout of our open-label Phase 2 human pharmacokinetic clinical trial (PK Study) at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO) and completing of the interim clinical study report (CSR) (40)%
	One goal of preparing a draft NDA filing, which included preparing initial drafts of various clinical and preclinical sections of the NDA filing package (30)%
Ms. Caballa(4)	One goal of managing the technology transfer to our commercial manufacturer, which included the review of protocols and final reports and the provision of technical assistance to our commercial manufacturer (10)%
	Two goals of completing six registration batches of Iluvien with the company s commercial manufacturer, which included the review and approval of batch records, process validation, protocols and reports and the provision of technical assistance to our commercial manufacturer (25)%
	One goal of initiating and monitoring stability studies on the registration batches of Iluvien with the company s commercial manufacturer and the provision of technical and regulatory assistance to our commercial manufacturer (15)%
	One goal of meeting with European health authorities, clarifying and resolving any outstanding inquiries and discussing and gaining concurrence on our development and regulatory strategies in Europe (10)%
	Three goals of preparing a draft NDA filing, which included preparing initial drafts of the chemistry, manufacturing and controls section and the clinical and preclinical sections of the NDA filing package (35)%
	One goal of departmental cash management and related to the goal of financing our company beyond December 2009 (5)%

99

Table of Contents

Name	Goals
Mr. Holland(5)	Three goals of meeting with private payers, engaging a third party group to develop a coding position and timeline for our coding submission to the Centers for Medicare & Medicaid Services (CMS) and initiating a global dossier project with respect to Pharmaco-Economics (20)% One goal of public dissemination of information from our FAME Study and PK Studies, including press releases associated with our month 12 and month 18 readouts from our FAME Study, our presentation at industry conferences and the release of top-line data from our FAME Study (20)% Six goals that included developing a key opinion leaders database, communications plan, advisor/speaker list, plan for attendance at 2010 industry conferences and the schedule of speaker engagements for the market development for Iluvien (30)% Three goals of developing the marketing pre-launch plan, analyzing the competitive landscape for Iluvien and preparing for the commercial launch of Iluvien (30%)

(1) Our compensation committee determined that Mr. Myers s individual goals were achieved in full based on the month 24 readout from our FAME Study which demonstrated efficacy and a safety profile that exceeded expectations, our cash and cash equivalent balance of $4.9 million as of December 31, 2009, the completion of six registration batches of Iluvien in April 2009, and the stage of preparedness of our NDA filing and commercial launch plan for Iluvien as of December 31, 2009.

(2) Our compensation committee determined that Mr. Eiswirth s individual goals were achieved in full based on the timely completion of the audit of our 2008 financial statements, our cash and cash equivalent balance of $4.9 million as of December 31, 2009, and Mr. Eiswirth s extensive efforts with respect to this offering, managing the evaluation of strategic alternatives and interactions with financial analysts and investments bankers.

(3) Our compensation committee determined that Dr. Green s individual goals were achieved in full based on the month 24 readout from our FAME Study which demonstrated efficacy and a safety profile that exceeded expectations, presentation of the month 12 readout for our PK Study at the ARVO annual meeting in May 2009, completion of the interim CSR and the stage of preparedness of our NDA filing as of December 31, 2009.

(4) Except with respect to the goal related to the technology transfer to our commercial manufacturer, our compensation committee determined that Ms. Caballa s individual goals were achieved in full based on the completion of six registration batches of Iluvien in April 2009, the initiation of stability studies on the batches of Iluvien in May 2009, the outcome of communications with European regulatory authorities during 2009, the stage of preparedness of our NDA filing as of December 31, 2009 and Ms. Caballa s success in managing our regulatory budget which was instrumental in our ability to achieve a cash and cash equivalent balance of $4.9 million as of December 31, 2009. Our compensation committee determined that Ms. Caballa s individual goal with respect to the technology transfer to our commercial manufacturer was achieved at the level of 70% in view of the failure of one of the registration batches to meet manufacturing specifications which required a re-manufacturing of the batch and caused the Company to incur additional cost and expense in connection with the technology transfer.

(5) Our compensation committee determined that Mr. Holland s individual goals were achieved in full based on the outcome of meetings with third party payers and others with respect to the coding and pricing of Iluvien,

including our submission to CMS, the stage of completion of a global dossier project as of December 31, 2009, the timely dissemination of information to the public with respect to our FAME Study, PK Study and other clinical programs, and the stage of preparedness of our commercial launch plan for Iluvien, including marketing initiatives and analyses, communications plan, speaking engagements and conference attendance and presentation as of December 31, 2009.

Table of Contents

With input from our chief executive officer, our compensation committee determined that each of these named executive officers achieved 100% of their individual goals other than Ms. Caballa for whom our compensation committee determined, in its discretion, performed at the level of 70% solely with respect to Ms. Caballa s goal related to the management and monitoring of the technology transfer to our commercial manufacturer in view of the failure of one of the registration batches to meet manufacturing specifications which required a re-manufacturing of the batch and caused the Company to incur additional cost and expense in connection with the technology transfer.

The remaining 25% of the amount of bonus potential for each of our named executive officers is awarded in the discretion of our compensation committee. In 2009, based on the level that our named executive officers achieved both the corporate and individual goals, including with respect to our clinical programs, strategic options, NDA filing and commercial launch efforts, our compensation committee exercised its discretion to award 100% of the remaining 25% of the bonus potential to each of our named executive officers. The 2009 bonus for our chief executive officer was 41% of salary, and ranged from 25% to 26% of salary for the remaining named executive officers. The bonuses earned by the named executive officers for performance goals in 2009 were $144,269 for Mr. Myers, $63,648 for Mr. Eiswirth, $66,300 for Dr. Green, $57,486 for Ms. Caballa, and $55,692 for Mr. Holland, including the additional bonus amount paid to each named executive officers in 2009 at the discretion of our compensation committee. See the columns titled Bonus and Non-Equity Incentive Compensation in the Summary Compensation Table on page 100 for additional information related to the performance bonuses earned by our named executive officers.

Long-Term Incentive Compensation. We utilize stock options for our long-term equity compensation to ensure that our executive officers have a continuing stake in our long-term success. Because our executive officers are awarded stock options with an exercise price equal to the fair market value of our common stock on the date of grant, the determination of which is discussed below, these options will have value to our executive officers only if the market price of our common stock increases after the date of grant. Typically, our stock option grants to new employees vest at the rate of 25% after the first year of service, with the remainder vesting ratably over the subsequent 36 months. We do not use a targeted cash/equity split to set officer compensation.

Our board of directors has historically determined the value of our common stock based upon the consideration of several factors impacting our valuation. We do not have any program, plan or obligation that requires us to grant equity compensation on specified dates and, because we have not been a public company, we have not made equity grants in connection with the release or withholding of material non-public information. As a public company, we intend to grant equity awards at fair market value (the closing price) on the date that the grant occurs. We anticipate granting equity awards on a periodic basis.

Generally, in order to align his or her interests with those of our stockholders, a significant stock option grant is made to an executive officer at the first regularly scheduled meeting of the compensation committee after the officer commences employment. Generally, the compensation committee determined the amount of the grant with the goal of setting each executive s total beneficial ownership at a level equivalent to the median of the comparable positions within the peer group. In certain circumstances in which an executive officer is uniquely critical to our success, the compensation committee targeted a level of total beneficial ownership in excess of the median.

In August of 2009, subsequent to our acquisition of further equity in the future profits of Iluvien and the closing of the Series C-1 preferred stock sale, the compensation committee made an additional replenishment grant to our executive officers to reduce the dilutive impact of the Series C-1 preferred stock sale to each officer. The amount of the additional grant was in proportion to each officer s total beneficial ownership prior

Table of Contents

to the grant. The exercise price of each grant was $4.01 per share, and the grants covered the number of shares set forth below:

C. Daniel Myers	106,157
Richard S. Eiswirth, Jr.	28,383
Kenneth Green, Ph.D.	36,797
Susan Caballa	24,527
David Holland	27,598

The compensation committee plans to consider future replenishments of equity awards for executive officers annually based upon recommendations from the chief executive officer and in comparison to the peer group. We believe that the resulting overlapping vesting schedule from awards made in prior years, together with the number of shares subject to each award, helps ensure a meaningful incentive to remain in our employ and to enhance stockholder value over time. Stock option grants made to executives generally vest quarterly over a four-year period with an initial one-year cliff.

Severance and Change in Control

Each of our executives has a provision in his or her employment agreement providing for certain severance benefits in the event of termination without cause, or the executive s decision to terminate his or her employment for good reason after a change in control. These severance provisions are described in the Employment Agreements section below.

In June 2008 our board of directors established acceleration provisions for unvested options in the event of a change in control. Under these provisions, unvested options vest in full in the event that the stock options are not continued or replaced with an alternate security, the executive is terminated without cause, or the executive terminates his employment for good reason. See Potential Payments upon Termination or Change in Control below for estimates of severance and change in control benefits.

We believe these severance and change in control arrangements mitigate some of the risk that exists for executives working in a smaller company. These arrangements are intended to attract and retain qualified executives who could have other job alternatives that may appear to them to be less risky absent these arrangements. Because of the significant acquisition activity in the life science industry, there is a possibility that we could be acquired in the future. Accordingly, we believe that the larger severance packages resulting from terminations related to change in control transactions, and bonus and vesting packages relating to the change in control itself, will provide an incentive for these executives to help execute such a transaction from its early stages until closing.

Other Benefits

Executive officers are eligible to participate in all of our employee benefit plans, such as medical, dental, vision, group life, disability and accidental death and dismemberment insurance and our 401(k) plan, in each case on the same basis as other employees, subject to applicable law. We also provide vacation and other paid holidays to all employees, including our executive officers, which are comparable to those provided at peer companies. At this time, we do not provide special benefits or other perquisites to our executive officers.

Policies Regarding Recovery of Awards

Our compensation committee has not adopted a policy on whether or not we will make retroactive adjustments to any cash or equity-based incentive compensation paid to executive officers (or others) where the payment was predicated

upon the achievement of financial results that were subsequently the subject of a restatement. Our compensation committee believes that this issue is best addressed when the need actually arises, when all of the facts regarding the restatement are known.

Tax and Accounting Treatment of Compensation

Section 162(m) of the Internal Revenue Code places a limit of $1.0 million per person on the amount of compensation that we may deduct in any one year with respect to each of our named executive officers other than the chief financial officer. There is an exemption from the $1.0 million limitation for performance-based

Table of Contents

compensation that meets certain requirements. All grants of options or stock appreciation rights under our 2010 Equity Incentive Plan are intended to qualify for the exemption. See Management Equity Benefit Plans 2010 Equity Incentive Plan for additional information. Grants of restricted shares or stock units under our 2010 Equity Incentive Plan may qualify for the exemption if vesting is contingent on the attainment of objectives based on the performance criteria set forth in the plan and if certain other requirements are satisfied. Grants of restricted shares or stock units that vest solely on the basis of service cannot qualify for the exemption. Our current cash incentive plan is not designed to qualify for the exemption. To maintain flexibility in compensating officers in a manner designed to promote varying corporate goals, our compensation committee has not adopted a policy requiring all compensation to be deductible. Although tax deductions for some amounts that we pay to our named executive officers as compensation may be limited by section 162(m), that limitation does not result in the current payment of increased federal income taxes by us due to our significant net operating loss carry-forwards. Our compensation committee may approve compensation or changes to plans, programs or awards that may cause the compensation or awards to exceed the limitation under section 162(m) if it determines that such action is appropriate and in our best interests.

We account for equity compensation paid to our employees under the rules of SFAS 123R, which requires us to estimate and record an expense for each award of equity compensation over the service period of the award. Accounting rules also require us to record cash compensation as an expense at the time the obligation is accrued. We have not tailored our executive compensation program to achieve particular accounting results.

Executive Compensation

2009 Summary Compensation Table

The following table provides information regarding the compensation of each of the individuals who served as our principal executive officer and principal financial officer in 2009 and each of the next three most highly compensated executive officers during 2009. We refer to these executive officers as our named executive officers.

Name	Year	Salary ($)	Bonus(1) ($)	Option Awards(2) ($)	Non-Equity Incentive Plan Compensation(3) ($)	All Other Compensation(4) ($)	Total ($)
C. Daniel Myers President and Chief Executive Officer	2009	353,600	35,360	365,380	108,909	1,721	864,970
Richard S. Eiswirth, Jr Chief Financial Officer	2009	249,600	15,600(5)	97,690	48,048(5)	6,221	417,159
Kenneth Green, Ph.D. Senior Vice President, Scientific Affairs and Chief Scientific Officer	2009	260,000	16,250(5)	126,652	50,050(5)	6,221	459,173
Susan Caballa	2009	228,800	14,300	83,995	43,186	6,174	376,455

Senior Vice President, Regulatory and Medical Affairs							
David Holland Vice President, Marketing	2009	218,400	13,650(5)	94,513	42,042(5)	6,128	374,733

(1) The amounts set forth in this column represent the discretionary bonuses paid to executives based on the board of directors approval. Discretionary bonus amounts were earned in and paid in 2009 for all executives with the exception of Mr. Eiswirth, Dr. Green and Mr. Holland, who were paid the 2009 earned amount in 2010. See Management Principal Elements of Compensation Annual Incentive Compensation for additional information related to the 2009 bonuses of our named executive officers.

Table of Contents

(2) The amounts set forth in this column reflect with respect to options newly granted in 2009 the aggregate grant date fair value of the option, computed in accordance with FASB ASC Topic No. 718. See Note 10 of the Notes to our Financial Statements included elsewhere in this prospectus for a discussion of our assumptions in determining the ASC 718 values of our option awards.

(3) The Non-Equity Incentive Plan Compensation represents the bonus paid to executives based on personal and corporate targets as defined in our Incentive Compensation Bonus Plan and approved by the board of directors. See Management Principal Elements of Compensation Annual Incentive Compensation for additional information related to the 2009 bonuses of our named executive officers.

(4) All Other Compensation represents 401(k) matching contributions and short-term and long-term disability gross-ups paid on an executive s behalf.

(5) Represents amount paid in January 2010 for bonus earned for fiscal year 2009.

In 2009, salary, bonus and non-equity incentive plan compensation accounted for the following percentages of the total compensation of our named executive officers:

Name	Salary	Bonus	Non-Equity Incentive Plan Compensation
C. Daniel Myers	38%	4%	12%
Richard S. Eiswirth, Jr	58%	4%	11%
Kenneth Green, Ph.D.	54%	3%	10%
Susan Caballa	59%	4%	11%
David Holland	56%	3%	11%

2009 Grants of Plan-Based Awards

The following table shows information regarding cash incentive bonus and equity awards during the fiscal year ended December 31, 2009 to the executive officers named in the Summary Compensation Table (in each case, as adjusted to reflect a 3.4-for-one reverse split of our common and preferred stock effected prior to the effective date of this registration statement).

	Estimated Future Payouts Under Non-Equity Incentive Plan Awards				Equity Incentive Plan Awards		
Name	Minimum	Target	Maximum	Grant Date	Number of Securities Underlying Options (#)(1)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Option Awards ($)(3)

C. Daniel Myers	$ 0	$ 141,440	$ 141,440	8/25/2009	106,157	$ 4.01	$ 365,380
Richard S. Eiswirth, Jr.	0	62,400	62,400	8/25/2009	28,383	4.01	97,690
Kenneth Green, Ph.D.	0	65,000	65,000	8/25/2009	36,797	4.01	126,652
Susan Caballa	0	57,200	57,200	8/25/2009	24,527	4.01	83,995
David Holland	0	54,600	54,600	8/25/2009	27,598	4.01	94,513

(1) 25% of the shares subject to this option vest as to 25% of the shares subject to this option on August 25, 2009 and as to an additional 6.25% of the shares subject to this option on each three month anniversary date thereafter. The remaining 75% of the shares subject to this option vest as to 25% of the shares subject to this option on December 22, 2010 and as to an additional 6.25% of the shares subject to this option on each three month anniversary date thereafter.

(2) The amounts set forth in this column reflect with respect to options newly granted in 2009 the aggregate grant date fair value of the option, computed in accordance with FASB ASC Topic No. 718. See Note 10 of the Notes to our Financial Statements included elsewhere in this prospectus for a discussion of our assumptions in determining the ASC 718 grant date fair value of our option awards.

Table of Contents

Outstanding Equity Awards at 2009 Year-End

The following table shows stock options outstanding on December 31, 2009, the last day of our fiscal year, to each of the executive officers named in the Summary Compensation table. No executive officer held unvested shares of stock on that date.

The vesting schedule applicable to each outstanding option is described in the footnote to the table below. See Management Potential Payments upon Termination or Change in Control for additional information regarding the vesting acceleration provisions applicable to the options held by our named executive officers.

		Option Awards			
Name	**Initial Vesting Date**	**Number of Securities Underlying Unexercised Options (#) Exercisable(1)**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($/share)**	**Option Expiration Date**
C. Daniel Myers	7/7/2005	22,775	0	$ 2.04	7/7/2014
	11/22/2006	55,147	0	1.33	1/1/2016
	11/22/2006	55,147	0	1.33	10/12/2016
	12/13/2008	88,941	88,942	1.39	12/13/2017
	3/20/2009	70,047	90,060	2.41	3/20/2018
	8/25/2010	0	26,305	4.01	8/25/2019
	12/22/2010	0	79,851	4.01	8/25/2019
Richard S. Eiswirth, Jr.	10/31/2006	13,625	0	2.04	10/31/2015
	10/31/2006	96,669	0	1.33	1/1/2016
	11/22/2007	38,603	12,868	1.33	10/12/2016
	12/13/2008	16,547	16,547	1.39	12/13/2017
	3/20/2009	20,276	26,070	2.41	3/20/2018
	6/25/2009	11,029	18,382	3.88	6/25/2018
	8/25/2010	0	7,033	4.01	8/25/2019
	12/22/2010	0	21,349	4.01	8/25/2019
Kenneth Green, Ph.D.	8/2/2005	73,529	0	2.04	8/2/2014
	1/3/2006	14,706	0	2.04	1/1/2015
	11/22/2006	44,118	0	1.33	1/1/2016
	11/22/2006	44,118	0	1.33	10/12/2016
	11/22/2007	16,544	5,515	1.33	10/12/2016
	3/1/2008	40,441	18,382	1.39	3/1/2017
	12/13/2008	13,039	13,039	1.39	12/13/2017
	3/20/2009	29,493	37,920	2.41	3/20/2018
	8/25/2010	0	9,118	4.01	8/25/2019
	12/22/2010	0	27,679	4.01	8/25/2019
Susan Caballa	7/7/2005	8,931	0	2.04	7/4/2014
	2/18/2006	20,480	0	2.04	2/18/2015
	11/22/2006	44,118	0	1.33	1/1/2016

11/22/2006	44,118	0	1.33	10/12/2016
3/1/2008	10,110	4,596	1.39	3/1/2017
12/13/2008	1,841	1,841	1.39	12/13/2017
3/20/2009	20,276	26,070	2.41	3/20/2018
8/25/2010	0	6,078	4.01	8/25/2019
12/22/2010	0	18,449	4.01	8/25/2019

Table of Contents

		Option Awards			
Name	Initial Vesting Date	Number of Securities Underlying Unexercised Options (#) Exercisable(1)	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($/share)	Option Expiration Date
David Holland	7/7/2005	26,795	0	$ 2.04	7/7/2014
	11/22/2006	33,088	0	1.33	1/1/2016
	11/22/2006	33,088	0	1.33	10/12/2016
	12/13/2008	977	977	1.39	12/13/2017
	3/20/2009	22,120	28,440	2.41	3/20/2018
	8/25/2010	0	6,839	4.01	8/25/2019
	12/22/2010	0	20,759	4.01	8/25/2019

(1) One-quarter of each option vests upon continuous service through the Initial Vesting Date shown in the table. Thereafter, the option vests in 12 equal quarterly installments over the next three years of service.

Option Exercises and Stock Vested During 2009

There were no option exercises by our named executive officers in 2009. There were no shares of our stock that vested in 2009 for our named executive officers.

Employment Agreements

We have entered into employment agreements with each of our named executive officers. The material terms are as follows:

C. Daniel Myers. We entered into an employment agreement with C. Daniel Myers in July 2004 which was amended and restated in August 2008. The letter agreement provides for a starting salary of $250,000 and a potential bonus of up to $62,500. The agreement also provided that the board grant him an option to purchase 45,551 shares of common stock. The board of directors adjusts Mr. Myers s salary and bonus potential from time to time. The most recent adjustment in December 2009 increased Mr. Myers s annual salary to $367,744 with a bonus potential of 40% of his base salary, or $147,098, effective January 1, 2010. If we terminate Mr. Myers s employment without cause or if Mr. Myers resigns for good reason, he is entitled to one year of his base salary at the rate in effect at the time of his termination paid in 12 equal monthly installments. Mr. Myers will also be entitled to the portion of his bonus earned up until termination. In addition, he is entitled to reimbursement of his premiums for medical insurance coverage under COBRA for 12 months after the date of termination or until he is eligible to be covered under a medical insurance plan by a subsequent employer.

Richard S. Eiswirth, Jr. We entered into an employment agreement with Richard S. Eiswirth Jr. in October 2005 which was amended and restated in August 2008. The letter agreement provided for a starting salary of $190,000 and a bonus of $38,000. The agreement also provided that the board grant him an option to purchase 13,625 shares of common stock. Our board of directors adjusts Mr. Eiswirth s salary and bonus potential from time to time. The most recent adjustment in December 2009 increased Mr. Eiswirth s annual salary to $259,584 with a bonus potential of 25% of his base salary, or $64,896, effective January 1, 2010. If we terminate Mr. Eiswirth s employment without cause or

if Mr. Eiswirth resigns for good reason, he is entitled to one year of his base salary at the rate in effect at the time of his termination paid in 12 equal monthly installments. He is also entitled to the portion of his bonus earned up until his termination. In addition, he is entitled to reimbursement of his premiums for medical insurance coverage under COBRA for 12 months after the date of termination or until he is eligible to be covered under a medical insurance plan by a subsequent employer.

Kenneth Green, Ph.D. We entered into an employment agreement with Kenneth Green in June 2004 which was amended and restated in August 2008. Under the letter agreement Dr. Green s starting salary was

Table of Contents

$185,000 with a potential bonus of up to 20% of his base salary. The agreement also provided that the board grant him an option to purchase 73,529 shares of common stock and an additional option to purchase 14,706 shares of common stock if certain performance goals were met. Our board of directors adjusts Dr. Green s salary and bonus potential from time to time. The most recent adjustment in December 2009 increased Dr. Green s annual salary to $270,400 with a bonus potential of 25% of his base salary, or $67,600, effective January 1, 2010. If we terminate Dr. Green s employment without cause or if Dr. Green resigns for good reason, he is entitled to one year of his base salary at the rate in effect at the time of his termination paid in 12 equal monthly installments. He is also entitled to the portion of his bonus earned up until his termination. In addition, he is entitled to reimbursement of his premiums for medical insurance coverage under COBRA for 12 months after the date of termination or until he is eligible to be covered under a medical insurance plan by a subsequent employer.

Susan Caballa. We entered into an employment agreement with Susan Caballa in June 2004 which was amended and restated in August 2008. The letter agreement provided for a starting salary of $160,000 and a potential bonus of up to 20% of her base salary. In addition, the letter agreement provided that the board grant Ms. Caballa an option to purchase 8,931 shares of common stock. The board of directors adjusts Ms. Caballa s salary and bonus potential from time to time. Pursuant to the most recent adjustment in December 2009, Ms. Caballa s annual salary increased to $237,952 and her bonus potential increased to 25% of her base salary, or $59,488, effective January 1, 2010. If we terminate Ms. Caballa s employment without cause or Ms. Caballa resigns for good reason, she is entitled to one year of her base salary at the rate in effect at the time of her termination paid in 12 equal monthly installments. Ms. Caballa is also entitled to the portion of her bonus earned up until her termination. In addition, she is entitled to reimbursement of her premiums for medical insurance coverage under COBRA for 12 months after the date of termination or until she is eligible to be covered under a medical insurance plan by a subsequent employer.

David Holland. We entered into an employment agreement with David Holland in June 2004 which was amended and restated in August 2008. The letter agreement provided for a starting salary of $175,000 and a bonus potential of 20% of his base salary. In addition, the letter agreement provided that the board grant Mr. Holland an option to purchase 26,795 shares of common stock. The board of directors occasionally adjusts Mr. Holland s salary and bonus potential. In the most recent adjustment in December 2009, the board of directors increased Mr. Holland s annual salary to $227,136 with a bonus potential of 25% of his base salary, or $56,784, effective January 1, 2010. If we terminate Mr. Holland s employment without cause or if Mr. Holland resigns for good reason, he is entitled to one year of his base salary at the rate in effect at the time of his termination paid in 12 equal monthly installments. Mr. Holland will also be entitled to the portion of his bonus earned up until termination. In addition, he is entitled to reimbursement of his premiums for medical insurance coverage under COBRA for 12 months after the date of termination or until he is eligible to be covered under a medical insurance plan by a subsequent employer.

For purposes of severance payments, good reason is defined in all amended and restated employment agreements as an executive resigning within 12 months after one of the following conditions has come into existence without the executive s consent:

- a reduction of the executive s base salary;
- a material adverse change in the executive s primary responsibilities or duties;
- a geographical relocation of our corporate headquarters, or the executive s primary business location, to a location that is more than 35 miles from the present location; or
- any material breach by us of the employment agreement.

The executive must provide us with written notice within 90 days after a good reason condition comes into the existence, and we have 30 days to remedy the condition after receipt of the notice.

Table of Contents

Potential Payments upon Termination or Change in Control

The following table describes the potential payments and benefits upon termination of our named executive officers employment before or after a change in control of the company, as if each officer s employment terminated as of December 31, 2009.

Name	Benefit	Voluntary Resignation or Termination for Cause	Termination without Cause or for Good Reason Prior to Change in Control	Termination without Cause or for Good Reason after Change in Control
C. Daniel Myers				
	Salary	$ 0	$ 353,600	$ 353,600
	Bonus	0	144,269	144,269
	Benefit Continuation	0	5,174	5,174
	Accelerated Vesting			2,369,457
Total value		$ 0	$ 503,043	$ 2,872,500
Richard S. Eiswirth, Jr.				
	Salary	$ 0	$ 249,600	$ 249,600
	Bonus	0	63,648	63,648
	Benefit Continuation	0	15,593	15,593
	Accelerated Vesting			836,566
Total value		$ 0	$ 328,841	$ 1,165,407
Kenneth Green, Ph.D.				
	Salary	$ 0	$ 260,000	$ 260,000
	Bonus	0	66,300	66,300
	Benefit Continuation	0	10,220	10,220
	Accelerated Vesting			937,909
Total value		$ 0	$ 336,520	$ 1,274,429
Susan Caballa				
	Salary	$ 0	$ 228,800	$ 228,800
	Bonus	0	57,486	57,486
	Benefit Continuation	0	10,470	10,470
	Accelerated Vesting			457,066
Total value		$ 0	$ 296,456	$ 753,822

David Holland			
Salary	$ 0	$ 218,400	$ 218,400
Bonus	0	55,692	55,692
Benefit Continuation	0	15,593	15,593
Accelerated Vesting			446,426
Total value	$ 0	$ 289,685	$ 736,111

Bonus payments in the year of termination would be based on the actual earned bonus and may be less than the target bonus. For purposes of accelerated vesting, good reason is defined in all employment agreements as:

a material adverse change in the executive s responsibilities or duties;

a geographical relocation of our corporate headquarters, or the executive s primary business location, to a location that is more than 35 miles from the present location; or

any breach by us of the employment agreement that is material and not cured, or capable of being cured, within 30 days after the executive gives us and our board of directors written notice.

Table of Contents

For purposes of valuing the severance payments in the table above, we used each executive s base salary at the rate in effect at the end of 2009 and the number of accrued but unused vacation days at the end of 2009.

The value of option acceleration shown in the table above was calculated based on the assumption that the officer s employment was terminated and the change in control (if applicable) occurred on December 31, 2009, and that the fair market value of our common stock on that date was $11.00 per share, the initial public offering price set forth on the cover page of this prospectus. The value of the vesting acceleration was calculated by multiplying the number of unvested shares subject to each option by the difference between the fair market value of our common stock as of December 31, 2009, and the exercise price of the option.

2009 Director Compensation

Our directors who serve as the designees of the significant holders of our Series A, Series B, Series C and Series C-1 preferred stock, Dr. Halak, Dr. Hove, Mr. Tracy, Mr. Youngren and Mr. Brooks, received no cash compensation and no equity-based compensation during 2009 for their service on our board of directors or committees of our board of directors. Our independent, non-employee director, Dr. Roberts, receives $12,000 in fees each year and a grant of 4,412 options per year. He received his options for 2006 and 2007 in one grant of 8,824 options on December 14, 2006. We have a policy of reimbursing all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board and committee meetings.

The following table sets forth the total compensation paid to each person who served as a director during 2009, other than a director who also served as a named executive officer.

Name	Fees Earned or Paid in Cash	Total
Philip R. Tracy	$	$
Mark J. Brooks		
Brian K. Halak, Ph.D.		
Anders D. Hove, M.D.		
Calvin W. Roberts, M.D.	12,000	12,000
Bryce Youngren		

On December 31, 2009, the number of shares subject to each option held by a non-employee director, the exercise price per share, the grant date fair value of each option (computed in accordance with SFAS 123R) and the aggregate number of options outstanding were as follows:

Name	Date of Grant	Number of Options Granted	Exercise Price per Share	Grant Date Fair Value(1)	Aggregate Number of Options Outstanding on December 31, 2009

Calvin W. Roberts, M.D.	12/29/2004	4,412	$ 2.04	$ 4,000	26,472
	7/1/2005	4,412	2.04	3,800	
	12/14/2006	8,824	1.33	9,300	
	6/25/2008	4,412	3.88	13,700	
	7/16/2009	4,412	4.01	14,700	

(1) See Note 10 of the Notes to our Financial Statements included elsewhere in this prospectus for a discussion of our assumptions in determining the ASC 718 grant date fair value of our option awards. All director options have a 7-year term and were fully vested upon grant.

Following this offering, our non-employee directors will be eligible for cash compensation and for stock option grants under our 2010 Equity Incentive Plan. See Management Director Compensation for additional information.

Table of Contents

Equity Benefit Plans

2010 Equity Incentive Plan

Our board of directors adopted our 2010 Equity Incentive Plan on April 5, 2010, and our stockholders approved it on April 5, 2010. The 2010 Equity Incentive Plan will take effect on the effective date of the registration statement of which this prospectus is a part. Our 2010 Equity Incentive Plan replaced the 2004 Incentive Stock Plan and the 2005 Incentive Stock Plan. No further grants will be made under either of these plans after this offering. However, the options outstanding after this offering under the 2004 Incentive Stock Plan or the 2005 Incentive Stock Plan will continue to be governed by their existing terms.

Shares Reserved. We have reserved 1,977,686 shares of our common stock for issuance under the 2010 Equity Incentive Plan. The number of shares reserved for issuance under the plan will be increased automatically on January 1 of each year, starting with 2011, by a number equal to the smallest of:

2,000,000 shares;

4% of the shares of common stock outstanding at that time; or

the number of shares determined by our board of directors.

In general, to the extent that awards under the 2010 Equity Incentive Plan are forfeited or lapse without the issuance of shares, those shares will again become available for awards. All share numbers described in this summary of the 2010 Equity Incentive Plan are automatically adjusted in the event of a stock split, a stock dividend, or a reverse stock split.

Administration. The compensation committee of our board of directors administers the 2010 Equity Incentive Plan. The committee has the complete discretion to make all decisions relating to the plan and outstanding awards.

Eligibility. Employees, members of our board of directors who are not employees, and consultants are eligible to participate in our 2010 Equity Incentive Plan.

Types of Award. Our 2010 Equity Incentive Plan provides for the following types of award:

incentive and non-statutory stock options to purchase shares of our common stock;

stock appreciation rights;

restricted shares of our common stock; and

stock units.

Options and Stock Appreciation Rights. The exercise price for options granted under the 2010 Equity Incentive Plan may not be less than 100% of the fair market value of our common stock on the option grant date. Optionees may pay the exercise price by using:

cash;

shares of common stock that the optionee already owns;

an immediate sale of the option shares through a broker approved by us; or

a promissory note, if permitted by applicable law.

All forms of payment other than cash require the consent of the compensation committee. A participant who exercises a stock appreciation right receives the increase in value of our common stock over the base price. The base price for stock appreciation rights may not be less than 100% of the fair market value of our common stock on the grant date. The settlement value of a stock appreciation right may be paid in cash or shares of common stock, or a combination of both. Options and stock appreciation rights vest at the time or times determined by the compensation committee. In most cases, they will vest over a four-year period following the date of grant. Options and stock appreciation rights also expire at the time determined by the compensation committee, but in no event more than 10 years after they are granted. They generally expire

earlier if the participant s service terminates earlier. No participant may receive options or stock appreciation rights under the 2010 Equity Incentive Plan covering more than 50% of the shares of common stock available for issuance pursuant to the 2010 Equity Incentive Plan in any year.

Restricted Shares and Stock Units. Restricted shares and stock units may be awarded under the 2010 Equity Incentive Plan in return for any lawful consideration, and participants who receive restricted shares or stock units generally are not required to pay for their awards in cash. In general, these awards will be subject to vesting. Vesting may be based on length of service, the attainment of performance-based milestones, or a combination of both, as determined by the compensation committee. No participant may receive restricted shares or stock units with performance-based vesting covering more than 50% of the shares of common stock available for issuance pursuant to the 2010 Equity Incentive Plan in any year. Settlement of vested stock units may be made in the form of cash, shares of common stock, or a combination of both.

Performance Goals. The compensation committee may establish performance milestones based on one or more of the following criteria:

Operating profits (including earnings before income, taxes, depreciation and amortization)

Net income (before or after taxes)

Earnings per share

Profit returns and/or margins

Revenue

Stockholder return and/or value

Stock price

Working capital

Customer satisfaction

Implementation, completion or attainment of measurable objectives with respect to research, development, products, projects or recruiting and maintaining personnel

Market share

Return on equity

Revenue growth

Total stockholder return

Increases or growth in any of the foregoing

Change in Control. The compensation committee may determine that an award under the 2010 Equity Incentive Plan will vest on an accelerated basis if a change in control of the company occurs or if the participant is subject to an

involuntary termination after the change in control. In addition, an award will generally vest in full if the surviving corporation does not assume the award, replace it with a comparable award or settle it for cash or securities. A change in control includes:

a merger after which our own stockholders own 50% or less of the surviving corporation or its parent company;

a sale of all or substantially all of our assets;

a proxy contest that results in the replacement of more than one-half of our directors over a 24-month period; or

an acquisition of 50% or more of our outstanding stock by any person or group, other than a person related to the company, such as a holding company owned by our stockholders.

Table of Contents

Amendments or Termination. Our board of directors may amend or terminate the 2010 Equity Incentive Plan at any time. If our board of directors amends the plan, it does not need to ask for stockholder approval of the amendment unless required by applicable law. The 2010 Equity Incentive Plan will continue in effect for 10 years from its adoption date, unless our board of directors decides to terminate the plan earlier.

2004 and 2005 Stock Incentive Plans

Our 2004 Stock Incentive Plan was adopted by our board of directors on June 30, 2004, and our stockholders approved it on June 30, 2004. Our 2005 Stock Incentive Plan was adopted by our board of directors on November 22, 2005, and our stockholders approved it on November 22, 2005. No further awards will be made under our 2004 and 2005 Stock Incentive Plans after this offering. The awards outstanding after this offering under the 2004 and 2005 Stock Incentive Plans will continue to be governed by their existing terms.

Shares Reserved. As of March 31, 2010, 395,782 shares of our common stock are reserved for issuance and options to purchase 395,782 shares of our common stock are outstanding under the 2004 Stock Incentive Plan, and 1,969,143 shares of our common stock are reserved for issuance and options to purchase 1,829,996 shares of our common stock are outstanding under the 2005 Stock Incentive Plan. No other awards are outstanding under our 2004 Stock Incentive Plan or 2005 Stock Incentive Plan.

Administration. The compensation committee of our board of directors administers the 2004 and 2005 Stock Incentive Plans. Our compensation committee has complete discretion to make all decisions relating to the plans.

Eligibility. Employees and non-employee members of our board of directors are eligible to participate in our 2004 and 2005 Stock Incentive Plans.

Types of Award. Our 2004 and 2005 Stock Incentive Plans provide for the following types of award:

incentive and non-statutory stock options to purchase shares of our common stock;

stock appreciation rights;

restricted shares of our common stock; and

stock units.

Vesting and Expiration. Awards vest at the times determined by the compensation committee, generally over a four-year period following the date of grant. All awards vest in full in the event that the company is subject to a change in control. A change in control includes:

a merger;

a sale of at least 50% of our assets;

the dissolution or liquidation of the company;

a proxy contest that results in the replacement of at least one-half of our directors over a two-year period; or

an acquisition of 20% or more of our outstanding stock by any person or group.

Payment. The exercise price for options and stock appreciation rights granted under the 2004 and 2005 Stock Incentive Plans may not be less than 100% of the fair market value of our common stock on the grant date. Optionees may pay the exercise price of options by using:

cash or cash equivalents;

shares of common stock that the optionee already owns; or

an immediate sale of the option shares through a broker designated by us.

Shares and stock units may be awarded under the 2004 and 2005 Stock Incentive Plans in consideration of services rendered to us prior to the grant date of the award.

Table of Contents

Expiration. Options and stock appreciation rights expire not more than 10 years after they are granted but generally expire earlier if the optionee s service terminates earlier.

2010 Employee Stock Purchase Plan

Our board of directors adopted the 2010 Employee Stock Purchase Plan on April 5, 2010, and our stockholders also approved the plan on April 5, 2010. Our 2010 Employee Stock Purchase Plan will become effective on the effective date of the registration statement of which this prospectus is a part. The plan is intended to qualify for preferential tax treatment under Section 423 of the Internal Revenue Code.

Shares Reserved. We have reserved 494,422 shares of our common stock for issuance under the 2010 Employee Stock Purchase Plan. As of January 1 of each year, starting in 2011, the reserve will automatically be restored to the original level. All share numbers described in this summary of the plan are automatically adjusted in the event of a stock split, a stock dividend, or a reverse stock split.

Administration. The compensation committee of our board of directors will administer the 2010 Employee Stock Purchase Plan. The committee has the complete discretion to make all decisions relating to the plan.

Eligibility. All of our employees are eligible to participate in the 2010 Employee Stock Purchase Plan after completing three months of service, if we employ them for more than 20 hours per week and for more than five months per year. However, all 5% stockholders are excluded. Eligible employees may begin participating at the start of any offering period.

Offering Periods. The first offering period under the 2010 Employee Stock Purchase Plan starts on the effective date of the registration statement related to this offering and ends on October 31, 2010. Each subsequent offering period consists of six consecutive months.

Amount of Contributions. The 2010 Employee Stock Purchase Plan permits each eligible employee to purchase common stock through payroll deductions. Each employee s payroll deductions may not exceed 15% of his or her total cash compensation. Participants may reduce, but not increase, their contribution rate during an offering period. Participants may also withdraw their contributions at any time before stock is purchased. Lump sum contributions are not permitted.

Purchases of Shares. Purchases of our common stock under the 2010 Employee Stock Purchase Plan will occur on January 1 and July 1 of each year. Each participant may purchase as many shares as his or her contributions permit, but not more than 2,500 shares per six-month offering period. The value of the shares purchased in any calendar year may not exceed $25,000, with a limited carry-over of unused amounts.

Purchase Price. The price of each share of common stock purchased under the 2010 Employee Stock Purchase Plan will be equal to 85% of the lower of:

the fair market value per share of our common stock on the last trading day before the start of the applicable six-month offering period (or, in the case of the first offering period, the price at which shares are sold to the public in this offering), or

the fair market value per share of common stock on the last trading day in the applicable offering period, which is the purchase date.

Other Provisions. Employees may end their participation in the 2010 Employee Stock Purchase Plan at any time. Participation ends automatically upon termination of employment with us. If a change in control of our company occurs, the plan will end and shares will be purchased with the payroll deductions accumulated to date by participating employees, unless the surviving corporation continues the plan. Our board of directors may amend or terminate the plan at any time, and the plan terminates automatically 20 years after its adoption. If our board of directors increases the number of shares of common stock reserved for issuance under the plan, except for the automatic increases described above, it must seek the approval of our stockholders. Other amendments require stockholder approval only to the extent required by law.

Table of Contents

TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS

In addition to the compensation arrangements with directors and executive officers and the registration rights described elsewhere in this prospectus, the following is a description of each transaction since January 1, 2007 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeds $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of or person sharing the household with any of these individuals (other than tenants or employees), had or will have a direct or indirect material interest.

All of the transactions set forth below were approved by a majority of the board of directors, including a majority of the independent and disinterested members of the board of directors. We believe that we have executed all of the transactions set forth below on terms no less favorable to us than we could have obtained from unaffiliated third-parties. It is our intention to ensure that all future transactions between us and our officers, directors and principal stockholders and their affiliates are approved by a majority of the board of directors, including a majority of the independent and disinterested members of the board of directors, and are on terms no less favorable to us than those that we could obtain from unaffiliated third-parties.

Private Placement Financings

Series C Preferred Stock Financing. On March 17, 2008 and on April 23, 2008, we sold an aggregate of 5,807,112 shares of our Series C preferred stock at a price of $5.17 per share and at an initial conversion rate of one-to-one to various investors, including entities affiliated with Domain Partners VI, L.P., Intersouth Partners VI, L.P., Intersouth Partners VII, L.P., Venrock Associates IV, L.P., Polaris Venture Partners IV, L.P. and BAVP, L.P. and various other entities and individuals. Each of the investors in this financing are parties to the second amended and restated investors rights agreement described below. Additionally, the following members of our board of directors serve as venture, general or managing partners/directors of the investors as follows: Philip R. Tracy, Mark J. Brooks, Brian K. Halak, Ph.D. (Dr. Halak serves as a member of the general partner of the Domain investing entities), Anders D. Hove, M.D., and Bryce Youngren. See Principal Stockholders for additional information regarding the shares held by these entities.

Series C-1 Preferred Stock Financing. On August 25, 2009, we sold an aggregate of 967,845 units, at a price of $5.17 per unit, comprised of 967,845 shares of our Series C-1 preferred stock and warrants exercisable for up to an aggregate of 1,935,700 shares of our Series C-1 preferred stock at an exercise price of $5.17 per share, all of which were exercised in January 2010. The Series C-1 preferred stock was issued with an initial conversion rate of one to one. The units were issued to various investors, including entities affiliated with Domain Partners VI, L.P., Intersouth Partners VI, L.P., Intersouth Partners VII, L.P., Venrock Associates IV, L.P., Polaris Venture Partners IV, L.P. and BAVP, L.P. and various other entities and individuals. Each of the investors in this financing are parties to the second amended and restated investors rights agreement described below. Additionally, the following members of our board of directors serve as venture, general or managing partners/directors of the investors as follows: Philip R. Tracy, Mark J. Brooks, Brian K. Halak, Ph.D. (Dr. Halak serves as a member of the general partner of the Domain investing entities), Anders D. Hove, M.D., and Bryce Youngren. See Principal Stockholders for additional information regarding the shares held by these entities.

Other Transactions with our Executive Officers, Directors, Key Employees and Significant Stockholders

Indemnification Agreements. We have entered into indemnification agreements with each of our directors and executive officers and certain other key employees. The agreements provide that we will indemnify each of our directors, executive officers and such key employees against any and all expenses incurred by that director, executive officer or key employee because of his or her status as one of our directors, executive officers or key employees to the fullest extent permitted by Delaware law, our restated certificate of incorporation and our amended and restated bylaws (except in a proceeding initiated by such person without board approval). In addition, the agreements provide that, to the fullest extent permitted by Delaware law, we

will advance all expenses incurred by our directors, executive officers and key employees in connection with a legal proceeding in which they may be entitled to indemnification.

Stock Option Awards. See Management Director Compensation and Management Executive Compensation for additional information regarding stock options and stock awards granted to our named executive officers and directors.

Prior Employment of the Son of Our Chief Executive Officer. We employed James D. Myers, the son of our chief executive officer, C. Daniel Myers, from August 2004 through February 2007. From August 2004 through October 2005, Mr. J. Myers served as an Associate Sales Representative and from November 2005 through February 2007, Mr. J. Myers served as a Sales Territory Manager. During the course of Mr. J. Myers s employment he received cash compensation in the aggregate amount of $134,000 and equity compensation, in the form of stock options granted under our equity incentive plans, having an aggregate fair market value on the date of grant of $3,900. Mr. J. Myers is no longer employed by our company.

Directed Share Program. Certain of our directors, officers, business associates employees, existing stockholders and certain specified affiliated entities as well as other parties related to us will have the opportunity to purchase up to 1,816,491 shares offered in this prospectus for sale through a directed share program at the initial offering price. The number of shares of our common stock available for sale to the general public will be reduced by the number of directed shares purchased by participants in the program. Any such shares purchased will be subject to a 25-day lock-up period and accordingly, without the prior written consent of each of Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. and subject to certain exceptions, may not be resold or otherwise transferred during such 25-day period. For our officers and directors and holders of substantially all of our outstanding common stock who have entered into lock-up agreements as described in the section titled Underwriting and who have participated in the directed share program, the 180-day lock-up period contemplated in the section titled Underwriting shall govern with respect to their shares purchased under the directed share program. Any directed shares not purchased by participants in the program will be offered by the underwriters to the general public on the same basis as other shares offered in this prospectus. We have agreed to indemnify Credit Suisse Securities (USA) LLC against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the sale of the directed shares. See Underwriting for additional information related to the directed share program and the lock-up period applicable to shares of our common stock acquired under the directed share program.

Table of Contents

PRINCIPAL STOCKHOLDERS

The following table provides information concerning beneficial ownership of our capital stock as of March 31, 2010, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- each stockholder, or group of affiliated stockholders, that we know owns more than 5% of our outstanding capital stock;
- each of our named executive officers;
- each of our directors;
- all of our directors and executive officers as a group.

The following table lists the number of shares and percentage of shares beneficially owned based on 24,501,055 shares of common stock outstanding as of March 31, 2010. This table reflects:

- 1,637,359 shares of common stock;
- the automatic conversion of 6,624,844 shares of our Series A preferred stock into 7,005,145 shares of common stock upon the closing of the offering, including the conversion of certain Series A preferred stock dividends accumulated prior to November 22, 2005 into 380,301 shares of common stock;
- the automatic conversion of 7,147,894 shares of our Series B preferred stock into 7,147,894 shares of common stock upon the closing of the offering;
- the automatic conversion of 5,807,112 shares of our Series C preferred stock into 5,807,112 shares of common stock upon the closing of the offering;
- the automatic conversion of 2,903,545 shares of our Series C-1 preferred stock (which includes 1,935,700 shares of our Series C-1 preferred stock issued upon the exercise of warrants in January 2010) into 2,903,545 shares of common stock upon the closing of the offering; and
- a 3.4-for-one reverse split of our common and preferred stock effected prior to the effective date of this registration statement.

The table also lists the applicable percentage beneficial ownership based on 31,051,055 shares of common stock outstanding upon completion of this offering, assuming no exercise of the underwriters option to purchase up to an aggregate of 982,500 shares of our common stock.

Table of Contents

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, and generally includes voting power and/or investment power with respect to the securities held. Shares of common stock subject to options and warrants currently exercisable or exercisable within 60 days of March 31, 2010 are deemed outstanding and beneficially owned by the person holding such options for purposes of computing the number of shares and percentage beneficially owned by such person, but are not deemed outstanding for purposes of computing the percentage beneficially owned by any other person. Except as indicated in the footnotes to this table, and subject to applicable community property laws, the persons or entities named have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned After the Offering	
Name and Address of Beneficial Owner	**Number**	**Percent**	**Number**	**Percent**
5% Stockholders				
BAVP, LP 950 Tower Lane, Suite 700 Foster City, California 94404	4,499,458(1)	18.36%	4,863,094(1)(17)	15.66%
Domain Associates, L.L.C. One Palmer Square Princeton, New Jersey 08542	4,499,449(2)	18.36%	4,877,477(2)(18)	15.71%
Intersouth Partners 406 Blackwell Street, Suite 200 Durham, North Carolina 27701	4,499,452(3)	18.36%	4,877,480(3)(19)	15.71%
Polaris Venture Partners 1000 Winter Street, Suite 3350 Waltham, Massachusetts 02451	4,499,453(4)	18.36%	4,877,481(4)(20)	15.71%
Venrock Associates 2494 Sand Hill Road, Suite 200 Menlo Park, California 94025	3,642,999(5)	14.87%	3,949,070(5)(21)	12.72%
Directors and Named Executive Officers				
Mark J. Brooks	4,499,458(6)	18.36%	4,863,094(6)(22)	15.66%
Susan Caballa	205,391(7)	0.83%	205,391(7)	0.66%
Richard S. Eiswirth, Jr.	209,987(8)	0.85%	209,987(8)	0.67%
Kenneth Green, Ph.D.	288,265(9)	1.16%	288,265(9)	0.92%
Brian K. Halak, Ph.D.	4,499,449(10)	18.36%	4,877,477(10)(23)	15.71%
David Holland	236,997(11)	0.96%	236,997(11)	0.76%
Anders D. Hove, M.D.	3,642,999(12)	14.87%	3,949,070(12)(24)	12.72%
C. Daniel Myers	462,447(13)	1.86%	462,447(13)	1.47%
Calvin W. Roberts, M.D.	324,802(14)	1.32%	324,802(14)	1.04%
Philip R. Tracy	4,499,452(15)	18.36%	4,877,480(15)(25)	15.71%
Bryce Youngren	4,499,453(16)	18.36%	4,877,481(16)(26)	15.71%
All Current Directors and Named Executive Officers as a Group	**23,368,700**	**95.29%**	**25,172,491**	**81.03%**

(1) The general partner of BAVP, L.P. is Scale Venture Management I, LLC. The managing members of Scale Venture Management I, LLC share voting and investment power with respect to these shares. Mark J. Brooks, a member of our board of directors, is a managing member of Scale Venture Management I, LLC, and shares

voting and investment power with the three other managing members of Scale Venture Management I, LLC. Mr. Brooks disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(2) Represents 4,451,745 shares held by Domain Partners VI, L.P. and 47,704 shares held by DP VI Associates, L.P. The managing members of One Palmer Square Associates VI, L.L.C., the general partner

of Domain Partners VI, L.P. and DP VI Associates, L.P., share voting and investment power with respect to these shares. Brian Halak, a member of our board of directors, is a member of One Palmer Square Associates VI, LLC, but has no voting or investment power and disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

(3) Represents 69,616 shares held by Intersouth Affiliates V, L.P.; 1,518,808 shares held by Intersouth Partners V, L.P.; 1,962,472 shares held by Intersouth Partners VI, L.P.; and 948,556 shares held by Intersouth Partners VII, L.P. Philip R. Tracy, a member of and the chairman of our board of directors, is a member of each of Intersouth Associates V, LLC, Intersouth Associates VI, LLC and Intersouth Associates VII, LLC. Pursuant to powers of attorney granted by each of Intersouth Associates V, LLC, Intersouth Associates VI, LLC and Intersouth Associates VII, LLC, Mr. Tracy shares voting power with respect to the securities owned by the entities for which these entities serve as general partners. Mr. Tracy disclaims beneficial ownership of these shares held by Intersouth Affiliates V, L.P., Intersouth Partners V, L.P., Intersouth Partners VI, L.P., and Intersouth Partners VII, L.P., except to the extent of his pecuniary interest therein.

(4) Represents 4,418,655 shares held by Polaris Venture Partners IV, L.P. and 80,798 shares held by Polaris Venture Entrepreneurs Fund IV, L.P. Polaris Venture Management Co., IV, L.L.C., is the sole general partner of Polaris Venture Partners IV, L.P. and Polaris Venture Partners Entrepreneurs Fund IV, L.P. Bryce Youngren, a member of our board of directors, has an assignee interest in Polaris Venture Management Co, IV, L.L.C. To the extent that he is deemed to share voting and investment powers with respect to the shares held by Polaris Venture Partners IV, L.P. and Polaris Venture Partners Entrepreneurs Fund IV, L.P., Mr. Youngren disclaims beneficial ownership of all such shares, except to the extent of his pecuniary interest therein.

(5) Represents 2,965,404 shares held by Venrock Associates IV, L.P.; 604,737 shares held by Venrock Partners, L.P.; and 72,858 shares held by Venrock Entrepreneurs Fund IV, L.P. Venrock Management IV, LLC, Venrock Partners Management, LLC, and VEF Management IV, LLC are the sole general partners of Venrock Associates IV, L.P., Venrock Partners, L.P., and Venrock Entrepreneurs Fund IV, L.P., respectively. Venrock Management IV, LLC, Venrock Partners Management, LLC, and VEF Management IV, LLC disclaim beneficial ownership of all shares held by Venrock Associates IV, L.P., Venrock Partners, L.P., and Venrock Entrepreneurs Fund IV, L.P., except to the extent of their pecuniary interest therein. Anders D. Hove, M.D., a member of our board of directors, is a member of each of Venrock Management IV, LLC, Venrock Partners Management, LLC, and VEF Management IV, LLC. Dr. Hove disclaims beneficial ownership of all shares held by Venrock Associates IV, L.P., Venrock Partners, L.P., and Venrock Entrepreneurs Fund IV, L.P. and beneficially owned by Venrock Management IV, LLC, Venrock Partners Management, LLC, and VEF Management IV, LLC, except to the extent of his pecuniary interest therein.

(6) Mr. Brooks is a managing member of Scale Venture Management I, LLC, the general partner of BAVP, LP. Mr. Brooks is one of four managing members of Scale Venture Management I, LLC who share voting and investment power with respect to these shares. Mr. Brooks disclaims beneficial ownership of the shares held by BAVP, LP referenced in footnote (1) above, except to the extent of his pecuniary interest therein.

(7) Includes 153,921 shares issuable upon exercise of options exercisable within 60 days of March 31, 2010.

(8) Includes 209,987 shares issuable upon exercise of options exercisable within 60 days of March 31, 2010.

(9) Includes 288,265 shares issuable upon exercise of options exercisable with 60 days of March 31, 2010.

(10) Dr. Halak is affiliated with Domain Associates L.L.C. Dr. Halak disclaims beneficial ownership of the shares held by the entities affiliated with Domain Associates referenced in footnote (2) above, except to the extent of

his pecuniary interest therein.

(11) Includes 119,350 shares issuable upon exercise of options exercisable within 60 days of March 31, 2010.

(12) Dr. Hove is affiliated with Venrock Associates. Dr. Hove disclaims beneficial ownership of the shares held by the entities affiliated with Venrock Associates referenced in footnote (5) above, except to the extent of his pecuniary interest therein.

Table of Contents

(13) Includes 313,183 shares issuable upon exercise of options exercisable within 60 days of March 31, 2010.

(14) Includes 26,472 shares issuable upon exercise of options exercisable within 60 days of March 31, 2010 and 39,706 shares issuable upon exercise of warrants exercisable within 60 days of March 31, 2010.

(15) Mr. Tracy is affiliated with Intersouth Partners. Mr. Tracy disclaims beneficial ownership of the shares held by the entities affiliated with Intersouth Partners referenced in footnote (3) above, except to the extent of his pecuniary interest therein.

(16) Mr. Youngren is affiliated with Polaris Venture Partners. Mr. Youngren disclaims beneficial ownership of the shares held by the entities affiliated with Polaris Venture Partners referenced in footnote (4) above, except to the extent of his pecuniary interest therein.

(17) Includes 363,636 shares of common stock to be sold to certain affiliates of BAVP, LP in connection with this offering and pursuant to our directed share program.

(18) Includes 378,028 shares of common stock to be sold to certain affiliates of Domain Associates, L.L.C. in connection with this offering and pursuant to our directed share program.

(19) Includes 378,028 shares of common stock to be sold to certain affiliates of Intersouth Partners in connection with this offering and pursuant to our directed share program.

(20) Includes 378,028 shares of common stock to be sold to certain affiliates of Polaris Venture Partners in connection with this offering and pursuant to our directed share program.

(21) Includes 306,071 shares of common stock to be sold to certain affiliates of Venrock Associates in connection with this offering and pursuant to our directed share program.

(22) Mr. Brooks is a managing member of Scale Venture Management I, LLC, the general partner of BAVP, LP. Mr. Brooks is one of four managing members of Scale Venture Management I, LLC who share voting and investment power with respect to these shares. Mr. Brooks disclaims beneficial ownership of the shares to be sold to entities affiliated with BAVP, LP referenced in footnote (17) above, except to the extent of his pecuniary interest therein.

(23) Dr. Halak is affiliated with Domain Associates L.L.C. Dr. Halak disclaims beneficial ownership of the shares to be sold to entities affiliated with Domain Associates referenced in footnote (18) above, except to the extent of his pecuniary interest therein.

(24) Dr. Hove is affiliated with Venrock Associates. Dr. Hove disclaims beneficial ownership of the shares to be sold to entities affiliated with Venrock Associates referenced in footnote (21) above, except to the extent of his pecuniary interest therein.

(25) Mr. Tracy is affiliated with Intersouth Partners. Mr. Tracy disclaims beneficial ownership of the shares to be sold to entities affiliated with Intersouth Partners referenced in footnote (19) above, except to the extent of his pecuniary interest therein.

(26) Mr. Youngren is affiliated with Polaris Venture Partners. Mr. Youngren disclaims beneficial ownership of the shares to be sold to entities affiliated with Polaris Venture Partners referenced in footnote (20) above, except to

the extent of his pecuniary interest therein.

Table of Contents

DESCRIPTION OF CAPITAL STOCK

General

Following the closing of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01 per share. The following summary of our capital stock and certain provisions of our restated certificate of incorporation and bylaws do not purport to be complete and is qualified in its entirety by the provisions of our restated certificate of incorporation and bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

Common Stock

As of March 31, 2010, there were 1,637,359 shares of common stock outstanding held of record by approximately 92 stockholders.

There will be 31,051,055 shares of common stock outstanding, assuming no exercise of the underwriters option to purchase additional shares in the offering and assuming no exercise after March 31, 2010 of outstanding options, after giving effect to the sale of the shares of common stock to the public offered in this prospectus and the conversion of all outstanding shares of our preferred stock into 22,863,696 shares of common stock, including the conversion of certain Series A preferred stock dividends accumulated prior to November 22, 2005 into 380,301 shares of common stock.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders. The holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the board of directors out of funds legally available, subject to preferences that may be applicable to preferred stock, if any, then outstanding. At present, we have no plans to issue dividends. See Dividend Policy for additional information. In the event of a liquidation, dissolution or winding up of our company, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The common stock has no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and non-assessable, and the shares of common stock to be issued upon completion of this offering will be fully paid and non-assessable.

Preferred Stock

Upon the closing of this offering, outstanding shares of Series A preferred stock will be converted into 7,005,145 shares of common stock (including the conversion of certain Series A preferred stock dividends accumulated prior to November 22, 2005 into 380,301 shares of common stock), outstanding shares of Series B preferred stock will be converted into 7,147,894 shares of common stock, an outstanding shares of Series C preferred stock will be converted into 5,807,112 shares of common stock and outstanding shares of Series C-1 preferred stock, will be converted into 2,903,545 shares of common stock.

Our board of directors is authorized to issue preferred stock in one or more series, to establish the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of such shares and any qualifications, limitations or restrictions thereof. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with

voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others. At present, we have no plans to issue any preferred stock.

Registration Rights

After the completion of this offering, holders of 22,863,696 shares of outstanding common stock and 69,977 shares of common stock issuable upon the exercise of outstanding warrants will be entitled to rights

with respect to the registration of those shares under the Securities Act. Under the terms of the second amended and restated investor rights agreement between us and the holders of these registrable securities, if we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders exercising registration rights, these holders are entitled to notice of registration and are entitled to include their shares of common stock in the registration. The holders of these registrable securities are also entitled to specified demand registration rights under which they may require us to file a registration statement under the Securities Act at our expense with respect to our shares of common stock, and we are required to use our commercially reasonable efforts to effect this registration. Further, the holders of these registrable securities may require us to file additional registration statements on Form S-3. All of these registration rights are subject to conditions and limitations, among them the right of the underwriters of an offering to limit the number of shares included in the registration and our right not to effect a requested registration within six months following the initial offering of our securities, including this offering. Other than as described in the following paragraph, all registration rights in connection with this offering have been waived.

Anti-Takeover Effects of Our Charter and Bylaws and Delaware Law

Some provisions of Delaware law and our restated certificate of incorporation and amended and restated bylaws could make the following transactions more difficult:

acquisition of our company by means of a tender offer, a proxy contest or otherwise; and

removal of our incumbent officers and directors.

These provisions of our restated certificate of incorporation and amended and restated bylaws, summarized below, are expected to discourage and prevent coercive takeover practices and inadequate takeover bids. These provisions are designed to encourage persons seeking to acquire control of our company to negotiate first with our board of directors. They are also intended to provide our management with the flexibility to enhance the likelihood of continuity and stability if our board of directors determines that a takeover is not in the best interests of our stockholders. These provisions, however, could have the effect of discouraging attempts to acquire us, which could deprive our stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices.

Election and Removal of Directors. Our restated certificate of incorporation and our amended and restated bylaws contain provisions that establish specific procedures for appointing and removing members of the board of directors. Under our restated certificate of incorporation and amended and restated bylaws, our board will be classified into three classes of directors and directors will be elected by a plurality of the votes cast in each election. Only one class will stand for election at each annual meeting, and directors will be elected to serve three-year terms. In addition, our restated certificate of incorporation and amended and restated bylaws will provide that vacancies and newly created directorships on the board of directors may be filled only by a majority vote of the directors then serving on the board (except as otherwise required by law or by resolution of the board). Under our restated certificate of incorporation and amended and restated bylaws, directors may be removed only for cause.

Special Stockholder Meetings. Under our restated certificate of incorporation and amended and restated bylaws, only the chairman of the board, our chief executive officer and our board of directors may call special meetings of stockholders.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Delaware Anti-Takeover Law. Following this offering, we will be subject to Section 203 of the Delaware General Corporation Law, which is an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date that the person became an interested stockholder, unless the business

Table of Contents

combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or another transaction resulting in a financial benefit to the interested stockholder. Generally, an interested stockholder is a person who, together with affiliates and associates, owns 15% or more of the corporation s voting stock. The existence of this provision may have an anti-takeover effect with respect to transactions that are not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Elimination of Stockholder Action by Written Consent. Our restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting after this offering.

No Cumulative Voting. Under Delaware law, cumulative voting for the election of directors is not permitted unless a corporation s certificate of incorporation authorizes cumulative voting. Our restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting in the election of directors. Cumulative voting allows a minority stockholder to vote a portion or all of its shares for one or more candidates for seats on the board of directors. Without cumulative voting, a minority stockholder will not be able to gain as many seats on our board of directors based on the number of shares of our stock the stockholder holds as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board s decision regarding a takeover.

Undesignated Preferred Stock. The authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company.

Amendment of Charter Provisions. The amendment of most of the above provisions in our restated certificate of incorporation and our amended and restated bylaws requires approval by holders of at least two-thirds of our outstanding capital stock entitled to vote generally in the election of directors.

These and other provisions could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company. Its telephone number is (212) 936-5100.

Nasdaq Global Market Listing

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol ALIM.

Table of Contents

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and we cannot assure you that a significant public market for our common stock will develop or be sustained after this offering. Future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding options, in the public market after this offering, or the possibility of these sales occurring, could adversely affect the prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock, as well as our ability to raise equity capital in the future.

Based on the number of shares outstanding as of March 31, 2010, upon the completion of this offering, 31,051,055 shares of common stock will be outstanding, assuming no exercise of the underwriters overallotment option and no exercise of outstanding options or warrants following March 31, 2010. The shares to be sold in this offering will be freely tradable, except that any shares acquired by our affiliates, as that term is defined in Rule 144 under the Securities Act, in this offering may only be sold in compliance with the limitations described below.

The remaining 24,501,055 shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements as described below. Following the expiration of the lock-up period, all shares will be eligible for resale in compliance with Rule 144 or Rule 701. Restricted securities as defined under Rule 144 were issued and sold by us in reliance on exemptions from the registration requirements of the Securities Act. These shares may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Lock-Up Agreements

Our officers, directors, and holders of substantially all of our common stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock for a period through the date 180 days after the date of this prospectus, except with the prior written consent of Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. In addition, all holders of our common stock and options to purchase our common stock have previously entered agreements with us not to sell or otherwise transfer any of their common stock or securities convertible into or exchangeable for shares of common stock for a period through the date 180 days after the date of this prospectus.

The 180-day restricted period under the agreements with the underwriters described in the preceding paragraph will be automatically extended if: (1) during the last 17 days of the 180-day restricted period we issue an earnings release or announce material news or a material event; or (2) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 15-day period following the last day of the 180-day period, in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the announcement of the material news or material event.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least

six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144.

Table of Contents

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described above, within any three-month period, a number of shares that does not exceed the greater of:

1% of the number of shares of common stock then outstanding, which will equal approximately 305,011 shares immediately after this offering; or

the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701.

Registration Rights

After the completion of this offering, the holders of 22,863,696 shares of outstanding common stock and 69,977 shares of common stock issuable upon the exercise of outstanding warrants will be entitled to the registration rights described in the section titled Description of Capital Stock Registration Rights. All such shares are covered by lock-up agreements. Following the expiration of the lock-up period, registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by our affiliates.

Form S-8 Registration Statements

Prior to the expiration of the lock-up period, we intend to file one or more registration statements on Form S-8 under the Securities Act to register the shares of our common stock that are issuable pursuant to our 2004 Incentive Stock Plan, 2005 Incentive Stock Plan, 2010 Equity Incentive Plan and 2010 Employee Stock Purchase Plan. See Management Equity Benefit Plans for additional information. Subject to the lock-up agreements described above and any applicable vesting restrictions, shares registered under these registration statements will be available for resale in the public market immediately upon the effectiveness of these registration statements, except with respect to Rule 144 volume limitations that apply to our affiliates.

Table of Contents

MATERIAL UNITED STATES FEDERAL TAX CONSEQUENCES FOR NON-U.S. STOCKHOLDERS

The following is a general discussion of the material U.S. federal income and estate tax consequences of the ownership and disposition of our common stock by a beneficial owner that is a non-U.S. holder. For purposes of this discussion, a non-U.S. holder is a person or entity that is for U.S. federal income tax purposes:

- a non-resident alien individual, other than certain former citizens and residents of the United States;
- a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized under the laws of a jurisdiction other than the United States or any state or political subdivision thereof;
- an estate, other than an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, other than if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust.

A non-U.S. holder does not include an individual who is present in the United States for 183 days or more in the taxable year of disposition of our common stock and is not otherwise a resident of the United States for U.S. federal income tax purposes. Such an individual is urged to consult his or her own tax adviser regarding the U.S. federal income tax consequences of the sale, exchange or other disposition of our common stock.

This discussion is based on the Internal Revenue Code of 1986, as amended (the Code), and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury Regulations, changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein, possibly with a retroactive effect. This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to non-U.S. holders in light of their particular circumstances and does not address any tax consequences arising under the laws of any state, local or foreign jurisdiction.

The discussion below is limited to non-U.S. holders that hold our shares of common stock as capital assets within the meaning of the Code. The discussion generally does not address tax considerations that may be relevant to particular investors because of their specific circumstances, or because they are subject to special rules, including, without limitation, banks, insurance companies, or other financial institutions; controlled foreign corporations or passive foreign investment companies ; persons subject to the alternative minimum tax; tax-exempt organizations; dealers in securities or currencies; traders in securities that elect to use a mark-to-market method of accounting for their securities holdings; certain former citizens or long-term residents of the United States; hybrid entities (entities treated as flow-through entities in one jurisdictions but as opaque in another) and their owners; persons who hold our common stock as a position in a hedging transaction, straddle, conversion transaction, hedge or other risk reduction transaction; or persons deemed to sell our common stock under the constructive sale provisions of the Code.

If a partnership, or any entity treated as a partnership for U.S. federal income tax purposes, is a holder of our common stock, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. A holder that is a partnership, and the partners in such partnership, should consult their own tax advisers regarding the tax consequences of the acquisition, holding and disposition of our common stock.

Prospective holders are urged to consult their tax advisers with respect to the particular tax consequences to them of acquiring, holding and disposing of our common stock, including the consequences under the laws of any state, local or foreign jurisdiction.

Table of Contents

Dividends

As discussed in the section entitled Dividend Policy, we do not anticipate paying any distributions in the foreseeable future. However, if we do make distributions on our common stock, those payments will generally constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed our current and accumulated earnings and profits, they will constitute a return of capital and will first reduce a non-U.S. holder s basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock. Any dividend paid to a non-U.S. holder on our common stock will generally be subject to U.S. withholding tax at a 30% rate. The withholding tax might apply at a reduced rate under the terms of an applicable income tax treaty between the United States and the non-U.S. holder s country of residence. A non-U.S. holder must demonstrate its entitlement to treaty benefits by certifying eligibility. A non-U.S. holder can meet this certification requirement by providing a Form W-8BEN or appropriate substitute form to us or our paying agent. If the holder holds the stock through a financial institution or other agent acting on the holder s behalf, the holder will be required to provide appropriate documentation to the agent. The holder s agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. For payments made to a foreign partnership or other flow-through entity, the certification requirements generally apply to the partners or other owners as well as to the partnership or other entity, and the partnership or other entity must provide the partners or other owners documentation to us or our paying agent. Special rules, described below, apply if a dividend is effectively connected with a U.S. trade or business conducted by the non-U.S. holder.

Gain on Disposition of Common Stock

Non-U.S. holders generally will not be subject to U.S. federal income tax on any gains realized on the sale, exchange, or other disposition of our common stock unless:

- the gain is effectively connected with a trade or business of the non-U.S. holder in the United States, subject to an applicable income tax treaty providing otherwise; or
- we are or have been a U.S. real property holding corporation, as defined below, at any time within the five-year period preceding the disposition or during the non-U.S. holder s holding period, whichever period is shorter.

We are not, and do not anticipate becoming, a U.S. real property holding corporation. Generally, a corporation is a U.S. real property holding corporation if the fair market value of its U.S. real property interests (as defined in the Code and the applicable Treasury regulations) equals or exceeds 50% of the aggregate fair market value of its worldwide real property interests and its other assets used or held for use in a trade or business. Even if we were to become a U.S. real property holding corporation, gain on the sale or other disposition of our common stock by a non-U.S. holder generally would not be subject to U.S. federal income tax, provided that the common stock is regularly traded on an established securities market and the non-U.S. holder does not actually or constructively own more than 5% of our common stock during the shorter of (1) the five-year period ending on the date of the disposition or (2) the period of time during which the holder held such shares.

Dividends or Gain Effectively Connected With a U.S. Trade or Business

If any dividend on our common stock, or gain from the sale, exchange or other disposition of our common stock, is effectively connected with a U.S. trade or business conducted by the non-U.S. holder, then the dividend or gain will be subject to U.S. federal income tax at the regular graduated rates. If the non-U.S. holder is eligible for the benefits of a tax treaty between the United States and the holder s country of residence, any effectively connected dividend or gain generally would be subject to U.S. federal income tax only if it is also attributable to a permanent establishment or

fixed base maintained by the holder in the United States. Payments of dividends that are effectively connected with a U.S. trade or business, and therefore included in the gross income of a non-U.S. holder, will not be subject to the 30% withholding tax. To claim exemption from withholding, the holder must certify its qualification, which can be done by providing a

Table of Contents

Form W-8ECI. If the non-U.S. holder is a corporation, that portion of its earnings and profits that is effectively connected with its U.S. trade or business would generally be subject to a branch profits tax. The branch profits tax rate generally is 30%, although an applicable income tax treaty might provide for a lower rate.

Information Reporting Requirements and Backup Withholding

Information returns will be filed with the Internal Revenue Service in connection with payments of dividends to a non-U.S. holder. Unless a non-U.S. holder complies with certification procedures to establish that it is not a U.S. person, information returns may be filed with the Internal Revenue Service in respect of the proceeds from a sale or other disposition of common stock and the non-U.S. holder may be subject to U.S. backup withholding on payments of dividends or on the proceeds from a sale or other disposition of common stock. The certification procedures required to claim a reduced rate of withholding under a treaty will satisfy the certification requirements necessary to avoid backup withholding as well. The amount of any backup withholding from a payment to a non-U.S. holder will be allowed as a credit against such holder s U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is furnished to the Internal Revenue Service.

Federal Estate Tax

The estates of nonresident alien individuals are generally subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S. situs property and therefore will be included in the taxable estate of a nonresident alien decedent. The U.S. federal estate tax liability of the estate of a nonresident alien may be affected by a tax treaty between the United States and the decedent s country of residence.

THE PRECEDING DISCUSSION OF U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL, AND FOREIGN TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

Table of Contents

UNDERWRITING

Under the terms and subject to the conditions contained in an underwriting agreement that we have entered into with the underwriters, we have agreed to sell to the underwriters named below, for whom Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. are acting as representatives, the following respective numbers of shares of common stock:

Underwriter	Number of Shares
Credit Suisse Securities (USA) LLC	2,456,250
Citigroup Global Markets Inc.	2,456,250
Cowen and Company, LLC	655,000
Oppenheimer & Co. Inc.	982,500
Total	6,550,000

The underwriting agreement provides that the underwriters are obligated to purchase all the shares of common stock in the offering if any are purchased, other than those shares covered by the over-allotment option described below. The underwriting agreement also provides that if an underwriter defaults the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated.

We have granted to the underwriters a 30-day option to purchase on a pro rata basis up to 982,500 additional shares at the initial public offering price less the underwriting discounts and commissions. The option may be exercised only to cover any over-allotments of common stock.

The underwriters propose to offer the shares of common stock initially at the public offering price on the cover page of this prospectus and to selling group members at that price less a selling concession of $0.462 per share. After the initial public offering the representatives may change the public offering price and concession and discount to broker/dealers.

The underwriters will receive an underwriting discount and commission of 7.00% on the sale of all of our common stock, except for the sale of up to 1,803,791 shares of our common stock to certain of our existing stockholders and certain specified affiliates, through the directed share program described below.

The following table summarizes the compensation and estimated expenses we will pay:

	Per Share		Total	
	Without Over-allotment	With Over-allotment	Without Over-allotment	With Over-allotment
Underwriting Discounts and Commissions paid by us (1)	$ 0.56	$ 0.59	$ 3,654,581	$ 4,411,106
Expenses payable by us	0.32	0.28	2,096,500	2,096,500

(1) The underwriting discounts and commissions are equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock.

The underwriters have informed us that they do not expect sales to accounts over which the underwriters have discretionary authority to exceed 5% of the shares of common stock being offered.

We, and each of our officers and directors and holders of substantially all of our outstanding common stock, have agreed that, subject to certain exceptions we will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, enter into a transaction that would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any of these transactions are to be settled by delivery of our common stock or other securities, in cash or otherwise, or publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement, without, in each case, the prior written consent of each of Credit Suisse Securities (USA) LLC and Citigroup

Global Markets Inc. for a period of 180 days after the date of this prospectus. However, in the event that either (1) during the last 17 days of the lock-up period, we release earnings results or material news or a material event relating to us occurs or (2) prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, then in either case the expiration of the lock-up will be extended until the expiration of the 18-day period beginning on the date of the release of the earnings results or the occurrence of the material news or event, as applicable, unless each of Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. waive, in writing, such an extension.

At our request, Credit Suisse Securities (USA) LLC has reserved up to 1,816,491 shares for sale at the initial public offering price to persons who are our directors, officers, business associates, employees and other parties related to us, including certain of our existing stockholders and certain specified affiliated entities, through a directed share program. The number of shares of our common stock available for sale to the general public will be reduced by the number of directed shares purchased by participants in the program. Each person who has not entered into a lock-up agreement described in the immediately preceding paragraph and is buying shares through the directed share program has agreed that, for a period of 25 days from the date of this prospectus, he or she will not, without the prior written consent of each of Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. and subject to certain exceptions, offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock purchased in the program or any securities convertible into or exchangeable or exercisable for any shares of our common stock purchased in the program, enter into a transaction that would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock purchased in the program, whether any of these transactions are to be settled by delivery of our common stock or other securities, in cash or otherwise, or publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement. For our officers and directors and holders of substantially all of our outstanding common stock who have entered into lock-up agreements as described in the immediately preceding paragraph and who have participated in the directed share program, the 180-day lock-up period contemplated in the immediately preceding paragraph shall govern with respect to their shares purchased under the directed share program. Any directed shares not purchased by participants in the program will be offered by the underwriters to the general public on the same basis as all other shares offered in this prospectus. We have agreed to indemnify Credit Suisse Securities (USA) LLC against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the sales of the directed shares.

We have agreed to indemnify the underwriters against liabilities under the Securities Act, or contribute to payments that the underwriters may be required to make in that respect.

Our common stock has been approved for listing on The Nasdaq Global Market under the symbol ALIM.

Certain of the underwriters and their respective affiliates may have from time to time performed and may in the future perform various financial advisory, commercial banking and investment banking services for us in the ordinary course of business, for which they received or will receive customary fees.

Prior to the offering, there has been no market for our common stock. The initial public offering price will be determined by negotiation between us and the underwriters and will not necessarily reflect the market price of the common stock following the offering. The principal factors that will be considered in determining the initial public offering price will include:

- the information presented in this prospectus and otherwise available to the underwriters;
- the history of and the prospects for the industry in which we compete;

the ability of our management;

the prospects for our future earnings;

the present state of our development and our current financial condition;

Table of Contents

the recent market prices of, and the demand for, publicly traded common stock of generally comparable companies; and

the general condition of the securities markets at the time of the offering.

We offer no assurances that the initial public offering price will correspond to the price at which our common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

In connection with the offering the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions, penalty bids and passive market making in accordance with Regulation M under the Securities Exchange Act of 1934 (the Exchange Act).

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

In passive market making, market makers in the common stock who are underwriters or prospective underwriters may, subject to limitations, make bids for or purchases of our common stock until the time, if any, at which a stabilizing bid is made.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The Nasdaq Global Market or otherwise and, if commenced, may be discontinued at any time.

A prospectus in electronic format may be made available on the Web sites maintained by one or more of the underwriters, or selling group members, if any, participating in this offering, and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make Internet distributions on the same basis as other allocations.

Table of Contents

SELLING RESTRICTIONS

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of shares described in this prospectus may not be made to the public in that relevant member state prior to the publication of a prospectus in relation to the shares that has been approved by the competent authority in that relevant member state or, where appropriate, approved in another relevant member state and notified to the competent authority in that relevant member state, all in accordance with the Prospectus Directive, except that, with effect from and including the relevant implementation date, an offer of securities may be offered to the public in that relevant member state at any time:

to any legal entity that is authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity that has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts;

to fewer than 100 natural or legal persons (other than qualified investors as defined below) subject to obtaining the prior consent of the representatives for any such offer; or

in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive.

Each purchaser of shares described in this prospectus located within a relevant member state will be deemed to have represented, acknowledged and agreed that it is a qualified investor within the meaning of Article 2(1)(e) of the Prospectus Directive.

For purposes of this provision, the expression an offer to the public in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

The sellers of the shares have not authorized and do not authorize the making of any offer of shares through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares as contemplated in this prospectus. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of the shares on behalf of the sellers or the underwriters.

Notice to Prospective Investors in France

Neither this prospectus nor any other offering material relating to the shares described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The shares have

not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the shares has been or will be:

released, issued, distributed or caused to be released, issued or distributed to the public in France; or

used in connection with any offer for subscription or sale of the shares to the public in France.

Table of Contents

Such offers, sales and distributions will be made in France only:

to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code *monétaire et financier*;

to investment services providers authorized to engage in portfolio management on behalf of third parties; or

in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code *monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l épargn*e).

The shares may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code *monétaire et financier*.

Notice to Prospective Investors in Germany

The common stock which are the object of this prospectus are neither registered for public distribution with the Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht or BaFin) according to the German Investment Act nor listed on a German exchange. No sales prospectus pursuant to the German Securities Prospectus Act or German Sales Prospectus Act or German Investment Act has been filed with the BaFin. Consequently, the common stock must not be distributed within the Federal Republic of Germany by way of a public offer, public advertisement or in any similar manner and this prospectus and any other document relating to the common stock, as well as information or statements contained therein, may not be supplied to the public in the Federal Republic of Germany or used in connection with any offer for subscription of the common stock to the public in the Federal Republic of Germany or any other means of public marketing.

Notice to Prospective Investors in Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a prospectus within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Notice to Prospective Investors in Israel

In the State of Israel, the shares of common stock offered hereby may not be offered to any person or entity other than the following:

(a)

a fund for joint investments in trust (i.e., mutual fund), as such term is defined in the Law for Joint Investments in Trust, 5754-1994, or a management company of such a fund;

(b) a provident fund as defined in Section 47(a)(2) of the Income Tax Ordinance of the State of Israel, or a management company of such a fund;

(c) an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741-1981, (d) a banking entity or satellite entity, as such terms are defined in the Banking Law (Licensing), 5741-1981, other than a joint

services company, acting for their own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;

(d) a company that is licensed as a portfolio manager, as such term is defined in Section 8(b) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;

(e) a company that is licensed as an investment advisor, as such term is defined in Section 7(c) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account;

(f) a company that is a member of the Tel Aviv Stock Exchange, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;

(g) an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968;

(h) a venture capital fund (defined as an entity primarily involved in investments in companies which, at the time of investment, (i) are primarily engaged in research and development or manufacture of new technological products or processes and (ii) involve above-average risk);

(i) an entity primarily engaged in capital markets activities in which all of the equity owners meet one or more of the above criteria; and

(j) an entity, other than an entity formed for the purpose of purchasing shares of common stock in this offering, in which the shareholders equity (including pursuant to foreign accounting rules, international accounting regulations and U.S. generally accepted accounting rules, as defined in the Securities Law Regulations (Preparation of Annual Financial Statements), 1993) is in excess of NIS 250 million.

Any offeree of the shares of common stock offered hereby in the State of Israel shall be required to submit written confirmation that it falls within the scope of one of the above criteria. This prospectus will not be distributed or directed to investors in the State of Israel who do not fall within one of the above criteria.

Notice to Prospective Investors in Japan

The shares offered in this prospectus have not been registered under the Securities and Exchange Law of Japan. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan, except (i) pursuant to an exemption from the registration requirements of the Securities and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries rights and interest (howsoever

described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;

where no consideration is or will be given for the transfer; or

where the transfer is by operation of law.

Notice to Prospective Investors in Spain

The proposed offer of common stock has not been registered with the *Comision Nacional del Mercado de Valores* (the CNMV). Accordingly, no communication nor any document or offer material may be distributed in Spain or targeted at Spanish resident investors, save in compliance and in accordance with the requirements of Law 24/1988, 28 July, as amended.

Notice to Prospective Investors in Switzerland

The shares of common stock offered pursuant to this prospectus will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to art. 652a or art. 1156 of the Swiss Federal Code of Obligations. The Company has not applied for a listing of the common stock being offered pursuant to this prospectus on the SWX Swiss Exchange or on any other regulated securities market, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the relevant listing rules. The shares of common stock being offered pursuant to this prospectus have not been registered with the Swiss Federal Banking Commission as foreign investment funds, and the investor protection afforded to acquirers of investment fund certificates does not extend to acquirers of the shares of common stock.

Investors are advised to contact their legal, financial or tax advisers to obtain an independent assessment of the financial and tax consequences of an investment in the shares of common stock.

Notice to Prospective Investors in the United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order) or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (each such person being referred to as a relevant person). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

INDUSTRY AND MARKET DATA

We obtained the industry, market and competitive position data throughout this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third-parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, we

Table of Contents

have not independently verified market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source.

LEGAL MATTERS

The validity of the common stock being offered by our company will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, Waltham, Massachusetts. The underwriters are represented by Davis Polk & Wardwell LLP, New York, New York. As of the date of this prospectus, certain partners and employees of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP beneficially owned an aggregate of 11,764 shares of our common stock on an as converted to common stock basis.

EXPERTS

The financial statements of Alimera Sciences, Inc. as of December 31, 2008 and 2009, and for each of the three years in the period ended December 31, 2009, included in this prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein, which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph regarding the company s ability to continue as a going concern. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-162782) under the Securities Act with respect to the shares of common stock we are offering by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information included in the registration statement and its exhibits and schedules. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits and schedules. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, such financial statements have been you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the closing of the offering, we will be subject to the informational requirements of the Exchange Act and we intend to file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, through the Internet at the SEC s Web site at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Washington, D.C. 20549.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facility.

Table of Contents

ALIMERA SCIENCES, INC. INDEX TO FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm	F-2
Financial Statements as of December 31, 2008 and 2009 and for the years ended December 31, 2007, 2008 and 2009:	
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Changes in Stockholders Deficit	F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	F-8

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, 2008 and 2009, and the related statements of operations, changes in stockholders deficit, and cash flows for each of the three years in the period ended December 31, 2009. 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, 2008 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 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, stockholders deficit, need for additional financing, 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 15, 2010
(except for Note 16, as to which the date is April 16, 2010)

Table of Contents

ALIMERA SCIENCES, INC.

BALANCE SHEETS
AS OF DECEMBER 31, 2008 AND 2009

	December 31, 2008	2009	Pro Forma December 31, 2009
	(In thousands except share data)		(Unaudited)
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 17,875	$ 4,858	$ 14,858
Prepaid expenses and other current assets	1,593	634	634
Deferred offering costs		815	815
Total current assets	19,468	6,307	16,307
PROPERTY AND EQUIPMENT at cost less accumulated depreciation	796	254	254
TOTAL ASSETS	$ 20,264	$ 6,561	$ 16,561
LIABILITIES AND STOCKHOLDERS DEFICIT			
CURRENT LIABILITIES:			
Accounts payable	$ 1,575	$ 1,758	$ 1,758
Accrued expenses	2,308	3,314	3,314
Outsourced services payable	1,024	1,157	1,157
Note payable (Note 8)		4,500	4,500
Capital lease obligations	10	6	6
Total current liabilities	4,917	10,735	10,735
LONG-TERM LIABILITIES:			
Note payable less current portion (Note 8)	15,000	10,500	10,500
Capital lease obligations less current portion	6		
Fair value of preferred stock conversion feature	12,656	36,701	
Other long-term liabilities	555	708	708
COMMITMENTS AND CONTINGENCIES (Note 8)			
PREFERRED STOCK:			
Series A preferred stock, $.01 par value 6,624,866 shares authorized and 6.624,844 shares, issued, and outstanding at December 31, 2008 and 2009; liquidation preference of $34,883 and $37,019 at December 31, 2008 and 2009	34,199	36,467	
Series B preferred stock, $.01 par value 7,147,912 shares authorized and 7,147,894 shares, issued, and outstanding at December 31, 2008 and 2009; liquidation preference of $38,509 and $41,057 at	37,963	40,617	

December 31, 2008 and 2009			
Series C preferred stock, $.01 par value 5,807,131 shares authorized and 5,807,112 shares, issued and outstanding at December 31, 2008 and 2009; liquidation preference of $31,881 and $34,281 at December 31, 2008 and 2009	30,855	33,452	
Series C-1 preferred stock, $.01 par value 2,903,565 shares authorized; 967,845 shares issued and outstanding at December 31, 2009; liquidation preference of $5,140 at December 31, 2009		2,853	
STOCKHOLDERS DEFICIT:			
Common stock, $.01 par value 26,470,588 shares authorized, 1,490,113 shares issued and outstanding at December 31, 2008 and 29,411,764 shares authorized, 1,598,571 shares issued and outstanding at December 31, 2009 and 29,411,764 shares authorized, 24,462,267 shares issued and outstanding at December 31, 2009 on a pro forma basis (unaudited)	51	54	283
Additional paid-in capital	3,474	4,836	164,560
Series C-1 preferred stock warrants		1,472	
Common stock warrants	58	57	57
Accumulated deficit	(119,470)	(171,891)	(170,282)
TOTAL STOCKHOLDERS DEFICIT	(115,887)	(165,472)	(5,382)
TOTAL LIABILITIES AND STOCKHOLDERS DEFICIT	$ 20,264	$ 6,561	$ 16,561

See Notes to Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2007, 2008, AND 2009

	Years Ended December 31		
	2007	2008	2009
	(In thousands except share and per share data)		
RESEARCH AND DEVELOPMENT EXPENSES	$ 8,363	$ 43,764	$ 15,057
GENERAL AND ADMINISTRATIVE EXPENSES	3,184	5,058	3,407
MARKETING EXPENSES	969	1,259	752
OPERATING EXPENSES	12,516	50,081	19,216
INTEREST INCOME	1,079	585	37
INTEREST EXPENSE	(2)	(1,514)	(1,897)
DECREASE (INCREASE) IN FAIR VALUE OF PREFERRED STOCK CONVERSION FEATURE	1	(10,454)	(23,142)
LOSS FROM CONTINUING OPERATIONS	(11,438)	(61,464)	(44,218)
INCOME FROM DISCONTINUED OPERATIONS (NOTE 3)	5,733		
NET LOSS	(5,705)	(61,464)	(44,218)
BENEFICIAL CONVERSION FEATURE OF PREFERRED STOCK (NOTE 9)			(355)
PREFERRED STOCK ACCRETION	(248)	(718)	(623)
PREFERRED STOCK DIVIDENDS	(4,685)	(6,573)	(7,225)
NET LOSS APPLICABLE TO COMMON SHAREHOLDERS	$ (10,638)	$ (68,755)	$ (52,421)
NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS Basic and diluted	$ (7.09)	$ (45.52)	$ (34.55)
WEIGHTED - AVERAGE SHARES OUTSTANDING Basic and diluted	1,499,922	1,510,496	1,517,365
PRO FORMA NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS Basic and diluted (Unaudited)			$ (0.94)
PRO FORMA WEIGHTED - AVERAGE SHARES OUTSTANDING Basic and diluted (Unaudited)			22,495,810

See Notes to Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2007, 2008, AND 2009

	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, 2006	1,450,911	49	2,571		58	(40,077)	(37,399)
Preferred stock accretion and dividends						(4,933)	(4,933)
Stock compensation expense			185				185
Stock option exercises	65,478	3	111				114
Net loss						(5,705)	(5,705)
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
			355			(355)	

Accretion of Series C-1 preferred stock beneficial conversion feature (Note 9)							
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)

See Notes to Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2007, 2008, AND 2009

	Years Ended December 31,		
	2007	2008	2009
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (5,705)	$ (61,464)	$ (44,218)
Income from discontinued operations	(5,733)		
Depreciation and amortization	147	241	1,098
Change in fair value of preferred stock conversion feature	(1)	10,454	23,142
Stock compensation expense and other	185	750	551
Noncash research and development expense (Notes 5 and 6)		17,809	300
Changes in assets and liabilities:			
Prepaid expenses and other current assets	(1,551)	(1,213)	591
Accounts payable	181	615	183
Accrued expenses and other current liabilities	2,060	85	705
Other long-term assets		24	
Other long-term liabilities	(18)	540	153
Net cash used in operating activities of continuing operations	(10,435)	(32,159)	(17,495)
Net cash (used in) provided by operating activities of discontinued operations	(2,502)	43	(43)
Net cash used in operating activities	(12,937)	(32,116)	(17,538)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(172)	(640)	(65)
Net cash used in investing activities of continuing operations	(172)	(640)	(65)
Net cash provided by investing activities of discontinued operations	6,719		
Net cash provided by (used in) investing activities	6,547	(640)	(65)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Offering costs of sale of Series B preferred stock net	(23)		
Proceeds from sale of Series C preferred stock net		29,938	
Proceeds from sale of Series C-1 preferred stock net			4,897
Proceeds from exercise of stock options	114		7
Repurchase of common stock		(150)	
Proceeds from exercise of warrants		6	31
Deferred offering costs			(339)
Payments on capital lease obligations	(11)	(10)	(10)

Net cash provided by financing activities	80	29,784	4,586
NET DECREASE IN CASH	(6,310)	(2,972)	(13,017)
CASH Beginning of period	27,157	20,847	17,875
CASH End of period	$ 20,847	$ 17,875	$ 4,858

Table of Contents

ALIMERA SCIENCES, INC.

STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2007, 2008, AND 2009 (Continued)

	Years Ended December 31,		
	2007	2008	2009
	(In thousands)		
SUPPLEMENTAL DISCLOSURES:			
Cash paid for interest	$	$ 957	$ 1,200
Supplemental schedule of noncash investing and financing activities:			
Note payable issued in conjunction with amendment to pSivida agreement (Note 7)	$	$ 15,000	$
Property and equipment acquired under capital leases	$ 18	$	$
Common stock issued for research and development expense (Note 6)	$	$	$ 300

There were no income tax or dividend payments made for the years ended December 31, 2007, 2008, and 2009.

See Notes to Financial Statements.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2008 AND 2009 AND
FOR THE YEARS ENDED DECEMBER 31, 2007, 2008 AND 2009

1. NATURE OF OPERATIONS

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 4).

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 enrollment of 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 United States, Canada, Europe and India to assess the efficacy and safety of Iluvien in the treatment of DME.

The Company is owned by management and venture capital and angel investors.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Unaudited pro forma presentation The pro forma balance sheet as of December 31, 2009 reflects the conversion of all outstanding shares of the Company s Series A, Series B, Series C and Series C-1 preferred stock (including shares of Series C-1 preferred stock issued upon exercise the of warrants in January 2010) into an aggregate of 22,863,696 shares of common stock, the receipt of $10,000,000 in net cash proceeds from the exercise of the warrants for Series C-1 preferred stock, and an incremental gain of $1.6 million on the revaluation of the embedded conversion feature based on the initial public offering price of $11.00 per share immediately prior to the conversion of our Series A, Series B, Series C and Series C-1 preferred stock.

Pro forma earnings per share as of December 31, 2009 reflects the conversion of all outstanding shares of the Series A, Series B, Series C and Series C-1 preferred stock (including shares of Series C-1 preferred stock issued upon exercise of warrants in January 2010) into an aggregate of 22,863,696 shares of common stock. Pro forma earnings per share excludes the effect of changes to the fair value of the preferred stock conversion feature, preferred stock accretion and preferred stock dividends.

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

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

Cash and Cash Equivalents Cash and cash equivalents include cash and highly liquid investments that are readily convertible into cash and have a maturity of 90 days or less when purchased.

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

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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 SFAS No. 109, *Accounting for Income Taxes*, (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 FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*, (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 value in accordance with the provisions of SFAS 123(R), *Share-Based Payment*, (ASC 718). The fair values for the options are estimated at the dates of grant using a Black-Scholes option-pricing model.

Derivative Financial Instruments The Company s preferred stock (see Note 9) contains certain features which are considered embedded derivatives. The Company accounts for such embedded derivative financial instruments in

accordance with FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities*, (ASC 815). The Company records derivative financial instruments as assets or liabilities in the Company s balance sheet measured at fair value (see Note 14). The Company records the changes in fair value of such instruments as noncash gains or losses in the statement of operations. The Company does not enter into derivatives for trading purposes.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Fair Value of Financial Instruments The carrying amounts of the Company s financial instruments, including cash and cash equivalents, accounts receivable, and current liabilities approximate their fair value because of their short maturities. The weighted average interest rate of the Company s note payable to pSivida US, Inc. (pSivida) (see Note 7) approximates the rate at which the Company could obtain alternative financing, therefore, the carrying amount of the note approximates its fair value.

Earnings (Loss) Per Share (EPS) Basic EPS is calculated in accordance with SFAS No. 128, *Earnings per Share*, (ASC 260), 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,		
	2007	**2008**	**2009**
Series A preferred stock and convertible accrued dividends	7,005,145	7,005,145	7,005,145
Series B preferred stock	7,147,894	7,147,894	7,147,894
Series C preferred stock		4,570,674	5,807,112
Series C-1 preferred stock			339,408
Series C-1 preferred stock warrants			678,820
Common stock warrants	3,271	30,271	45,297
Stock options	222,318	987,170	1,125,916
Total	14,378,628	19,741,154	22,149,592

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

The following accounting policies were primarily related to the discontinued operations of the Company s non-prescription business disclosed in Note 3.

Accounts Receivable The Company extended credit on an uncollateralized basis to wholesale drug distributors and retail pharmacies in connection with its non-prescription business. Receivables were considered delinquent when they were 30 days past due. Delinquent receivables did not accrue interest. The Company was required to estimate the level of accounts receivable which ultimately would not be paid. This estimate was made based on an analysis of the customer s financial health and payment patterns.

Inventories Inventory was historically valued at the lower of cost or market (net realizable value). Inventory cost included the cost of purchased product, product packaging, and in-bound freight. Cost was determined using the first-in, first-out method. Inventory was manufactured by an unrelated third-party.

License Agreements License agreements included agreements for the use of patents, know how and other technology for the development and marketing of ophthalmic pharmaceuticals associated with the non-prescription business. License agreements were amortized using the straight-line method over the estimated economic lives of the agreements (see Note 6).

Revenue Recognition The Company recognized revenue when products were shipped and ownership and risk of loss transferred to the customer. Revenue is included within loss from discontinued operations within the accompanying statements of operations. Customers were generally offered a cash discount for the early payment of receivables. These discounts were recorded as a reduction of revenue, within loss from

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

discontinued operations within the accompanying statements of operations, and accounts receivable in the period of sale.

As is customary in the pharmaceutical industry, customers may generally return product from six months prior to the expiration date of the product until twelve months after the expiration date of the product. In determining estimated returns, the Company utilized actual returns history, knowledge of and communications with its customers and their purchasing patterns, industry experience, and returns history for comparable products. Estimated returns of $22,000 for the year ended December 31, 2007 were recorded as a reduction of net sales, in the income from discontinued operations within the accompanying statements of operations, and a current liability. Adjustments to reserves for estimated returns are made in the period in which any new information becomes available regarding future return levels.

The Company also participates in retail promotional incentive programs including sales rebate and incentive programs which are recorded as a reduction of revenue in the period the programs are run, which are included in the (loss) income from discontinued operations within the accompanying statements of operations.

Cost of Goods Sold Cost of goods sold was comprised of inventory, shipping and handling, royalties, and third-party distribution costs, and is included within (loss) income from discontinued operations within the accompanying statements of operations.

Royalties The Company paid royalties on the sale of its product. These royalties are included in the income from discontinued operations in the accompanying statements of operations.

Samples Samples consist of product samples used in the sales and marketing efforts of the Company s product. Samples were expensed upon distribution and recorded as a selling expense and are included in (loss) income from discontinued operations in the accompanying statements of operations.

Promotional and Advertising Costs Promotional and advertising costs are expensed as incurred. Promotional and advertising expense totaled $52,000 for the year ended December 31, 2007 and is included in income from discontinued operations in the accompanying statements of operations.

Recent Accounting Pronouncements In March 2008, the FASB Issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133*, (ASC 815), requires companies with derivative instruments to disclose information that should enable financial statement users to understand how and why a company uses derivative instruments, how derivative instruments and related hedged items are accounted for under ASC 815, and how these items affect a company s financial position, results of operations, and cash flows. ASC 815 affects only these disclosures and does not change the accounting for derivatives. ASC 815 is to be applied prospectively beginning with the first quarter of the 2009 fiscal year. The adoption of ASC 815 did not have a material effect on the disclosures in the Company s financial statements.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* (SFAS 168). SFAS 168 authorized the Codification as the sole source for authoritative U.S. GAAP and any accounting literature that is not in the Codification will be considered nonauthoritative. The Company has commenced utilizing the Codification as its sole source of authoritative U.S. GAAP for its 2009 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 initiation of an effort to sell the assets of the Company s OTC Business and also the termination of its sales and marketing personnel.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

In connection with the plan, management notified 38 employees that they would be terminated upon dates ranging from December 2006 to February 2007. As a result of these terminations, the Company incurred severance expenditures of $535,000, substantially all of which was paid to affected employees prior to December 31, 2007.

In December 2006, the Company entered into an agreement to sell its two ophthalmic allergy products within its OTC business to a third-party for a total purchase price of $21,500,000, including $13,500,000 in cash at closing and $8,000,000 in contingent consideration. As a condition of closing that agreement, $3,500,000 of the $13,500,000 in cash to be received at closing was paid directly to the third-party manufacturer of the products in order to induce the manufacturer to accept the assignment of its five-year supply agreement to the acquiring company. The Company received the remaining $10,000,000 in cash at closing. The contingent consideration will be paid upon the acquiring company s receipt of FDA approval for the second generation allergy products. Subsequent to the closing of this transaction, the acquiring company became responsible for the development of that product. In January 2010, the Company received a $4,000,000 option payment from the acquiring company to provide it with an additional two years to develop the second generation allergy product.

In connection with the agreement to sell the allergy products, the Company and the acquiring company agreed to negotiate the sale of the Company s dry eye product. In February 2007, negotiations were completed and an agreement was entered into between the two parties to sell the dry eye product to the acquiring company for between $5,000,000 and $7,500,000 depending upon the level of net sales of the dry eye product between January 2007 and July 2007. In May 2007, the two parties agreed to amend the net sales measurement period to end in May 2007. The closing of the sale of the Company s dry eye product occurred on July 31, 2007, and the Company received $6,719,000 in cash proceeds. The Company recognized a gain of $6,024,000 on this disposal. This gain is included in income from discontinued operations in the accompanying statement of operations for the year ended December 31, 2007.

The Company has 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 for the year ended December 31, 2007. There were no revenues or expenses from discontinued operations during the years ended December 31, 2008 and 2009. Net income from discontinued operations for the year ended December 31, 2007 was as follows (in thousands, except share and per share data):

Net sales	$ 1,427
Cost of goods sold	457
Gross margin	970
Marketing and selling expenses	1,062
Research and development expenses	25
General and administrative expenses	174
Loss on discontinued operations before disposal	(291)
Gain on disposal	6,024

Net income from discontinued operations	$	5,733
NET INCOME FROM DISCONTINUED OPERATIONS PER SHARE Basic and diluted	$	3.82
NET LOSS FROM CONTINUING OPERATIONS PER SHARE Basic and diluted	$	(7.63)
WEIGHTED-AVERAGE SHARES OUTSTANDING Basic and diluted		1,499,922

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

4. FACTORS AFFECTING OPERATIONS

To date the Company has incurred recurring losses, negative cash flow from operations, and has accumulated a deficit of $171,891,000 from the Company s inception through December 31, 2009. As of December 31, 2009, the Company has $4,858,000 in cash and cash equivalents. In January 2010, the Company received $10,000,000 in cash proceeds from the exercise of warrants to purchase 1,935,700 shares of the Company s Series C-1 preferred stock at $5.17 per share, and a $4,000,000 option payment from the acquirer of the OTC business. The Company believes its cash and cash equivalents at December 31, 2009 and the aforementioned $14,000,000 received in January 2010 are sufficient to fund its operations into September 2010, but not beyond. The Company s ability to continue as a going concern beyond September 2010 is dependent on its ability to raise additional capital.

The Company does not expect to generate revenues from its product candidates until 2011, if at all, and therefore will have no cash flow from operations until that time. Until the Company can generate significant cash from operations, the Company expects to continue to fund its operations with cash resources generated from the proceeds of public or private offerings of its equity securities, strategic collaboration agreements and debt financings. There can be no assurance 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 the Company.

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.

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31,	
	2008	2009
	(In thousands)	
Furniture and fixtures	$287	$290
Office equipment	272	290
Software	470	470
Leasehold improvements	12	12
Manufacturing equipment	366	40
Total property and equipment	1,407	1,102
Less accumulated depreciation and amortization	611	848
Property and equipment net	$796	$254

Depreciation and amortization expense associated with property and equipment of the continuing operations totaled $147,000, $241,000 and $1,098,000 for the years ended December 31, 2007, 2008, and 2009, respectively.

Depreciation and amortization expense associated with property and equipment of the discontinued operations totaled $11,000 for the year ended December 31, 2007 and is included in income from discontinued operations in accompanying statements of operations.

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.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

6. LICENSE AGREEMENTS

In November 2007, the Company entered into a license agreement with Dainippon Sumitomo Pharma Co., Ltd. (Dainippon) whereby Dainippon granted us 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 United States by the FDA.

In August 2007, the Company entered into an exclusive option agreement with Emory University for the licensing of certain patents for a class of compounds that the Company intends to evaluate for the treatment of diseases of the eye, primarily the dry form of age related macular degeneration. The Company made an initial payment of $75,000, which was expensed as research and development in the accompanying statement of operations for 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. 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 United States, 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. 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. The Company would owe the Emory University up to $5,775,000 in additional development and regulatory milestones under the terms of this license 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. 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 United States, 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. 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. The Company would owe Emory University up to $5,850,000 in additional development and regulatory milestones under the terms of this license 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.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

7. PSIVIDA AGREEMENT

In 2005, the Company finalized a collaboration agreement with pSivida US, Inc. (pSivida) whereby the Company and pSivida agreed to jointly develop products for treating eye diseases in humans. Under the terms of the agreement, the Company was granted a license to certain proprietary technology for the delivery of medications to the eye, and the companies agreed to begin developing a product for the treatment of diabetic macular edema. In connection with the agreement, the Company made initial license fee payments totaling $750,000 in 2004. The Company also made an additional license fee payment of $750,000 upon the initiation of the Phase 3 trial for the first product in 2005. The initial license fee payments were expensed as research and development expenses when paid.

As part of the collaboration agreement, the Company and pSivida agreed to share the cost to develop the product equally. Historically, the Company recorded its costs of developing the product net of amounts due from pSivida. On December 31, 2007, the Company had $3,927,000 in amounts due from the third-party for development costs incurred on its behalf included in prepaid expenses and other current assets. pSivida failed to make payments totaling $1,990,000, representing its share of development costs from February 2006 to December 2006. In accordance with the terms of the agreement, pSivida could maintain compliance with the terms of the collaboration agreement as long as the total amount past due did not exceed $2,000,000. pSivida began making payments again in December 2006 in order to maintain compliance with the agreement. Management fully reserved $2,000,000 of the amount due from pSivida at December 31, 2007. In 2006, $1,747,000 was recorded as incremental development costs in connection with the establishment of this reserve.

pSivida incurred penalties and interest on the payments it failed to make. In accordance with the terms of the agreement, the Company was due approximately $995,000 in penalties at December 31, 2007. Accrued interest on the outstanding payments and penalties was $969,000 at December 31, 2007. Given the uncertainty surrounding the collectibility of the original amounts, the Company fully reserved the penalties and interest in the accompanying financial statements as of December 31, 2007.

On March 14, 2008 the Company amended and restated its collaboration agreement with pSivida for the development of its product, Iluvien, for the treatment of diabetic macular edema to increase its equity in the future profits of the product from 50% to 80%. Total consideration to pSivida in connection with the execution of the March 2008 agreement was $33,800,000, which consisted of a cash payment of $12,000,000, the issuance of a $15,000,000 note payable, and the forgiveness of $6,800,000 in outstanding receivables. The note payable accrues interest at 8% per annum, payable quarterly. Principal is payable upon the earlier of a liquidity event as defined in the agreement (including related and unrelated offerings of our capital stock greater than $75.0 million in the aggregate), the occurrence of an event of default under our agreement with pSivida or September 30, 2012. If the note is not paid in full by March 31, 2010, the interest rate will increase to 20% per annum effective April 1, 2010, and the Company will be required to begin making principal payments of $500,000 per month. The Company also agreed to forgive all outstanding development payments, penalties and interest totaling $2,800,000, net of a $4,000,000 reserve, as of the amendment date, and assume all financial responsibility for the remaining development of the product. In connection with this transaction the Company recognized incremental research and development expense of $29,810,000 in March 2008. The Company will owe an additional milestone payment of $25,000,000 to pSivida upon FDA approval.

Upon commercialization, 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, 2007, 2008 and 2009 the Company was owed $365,000, $511,000 and $958,000, respectively, in commercialization costs. Due to the uncertainty of FDA approval, the Company has fully reserved these amounts in the accompanying financial statements.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

8. COMMITMENTS

pSivida Note Payable In March 2008, in conjunction with the amendment and restatement of the Company s collaboration agreement with pSivida, the Company issued to pSivida a note payable of $15,000,000 (see Note 7). The note payable accrues interest at 8% per annum, payable quarterly. The principal is payable upon the earlier of a liquidity event as defined in the agreement (including an initial public offering of our common stock greater than $75,000,000), the occurrence of an event of default under our agreement with pSivida or September 30, 2012. If the note is not paid in full by March 31, 2010, the interest rate will increase to 20% per annum effective April 1, 2010, and the Company will be required to begin making principal payments of $500,000 per month.

As of December 31, 2009, a schedule of future minimum payments under the pSivida Note Payable is as follows (in thousands):

Years Ending December 31	
2010	$ 4,500
2011	6,000
2012	4,500
	$ 15,000

The effective interest rate on the note payable is 12.64%. As of December 31, 2008 and 2009, the Company has accrued and unpaid interest payable to pSivida of $550,000 and $708,000, respectively, which is classified as other long-term liabilities, and $0 and $543,000, respectively, which is included in accrued expenses in the accompanying balances.

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. The Company has recorded a deferred rent obligation in the accompanying balance sheets to reflect the excess of rent expense over cash payments since the Company s inception of the lease. Deferred rent obligations totaled approximately $15,000 and $0 at December 31, 2008 and 2009 respectively. In May 2009, the Company signed an extension of its lease for office space for a period ended May 31, 2010. The Company s future minimum payments under this operating lease from December 31, 2009 to May 31, 2010 are $105,000.

Rent expense under all operating leases totaled approximately $217,000 for each of the years ended December 31, 2007 and 2008, respectively, and $229,000 for the year ended December 31, 2009.

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, 2009, 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):

Year ended December 31, 2010	$ 6
Total	6
Less amount representing interest	0
Present value of minimum lease payments	6
Less current portion	6
Noncurrent portion	$ 0

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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

	December 31, 2008	2009
	(In thousands)	
Office equipment	$ 42	$ 42
Less accumulated amortization	(27)	(37)
Total	$ 15	$ 5

Depreciation expense associated with office equipment under capital leases was $11,000, $10,000 and $10,000 during the years ended December 31, 2007, 2008 and 2009, 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 diabetic macular edema in the United States, Canada, and Europe. In accordance with the terms of the agreement, the Company will incur approximately $16,000,000 in costs with the contract research organization through 2010. For the years ended December 31, 2007, 2008, and 2009, the Company incurred $3,700,000, $3,300,000, and $3,900,000 respectively, of expense associated with this agreement. At December 31, 2008 and 2009, $976,000 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 diabetic macular edema 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 2010. For the years ended December 31, 2007, 2008, and 2009, the Company incurred $318,000, $248,000, and $240,000, respectively, of expense associated with this agreement. At December 31, 2008 and 2009, $48,000, and $53,000, respectively, are included in outsourced services payable.

Employment Agreements The Company is party to employment agreements with five executives. The agreements generally provide for annual salaries, bonuses, and benefits 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, 2009, the salaries ranged from $218,000 to $354,000. Effective January 1, 2010, the salaries were adjusted to a range of $227,000 to $368,000. 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.

9. PREFERRED STOCK

On July 7, 2004, the Company entered into a Series A preferred stock purchase agreement with certain investors. Under the agreement, the investors agreed to purchase up to 6,635,720 shares of the Company s Series A preferred stock at a purchase price of $4.03 per share. The agreement contemplated the purchase of such shares in five tranches based upon the Company s achievement of certain milestones. The first sale of shares was completed in July 2004 when the Company issued 2,096,046 shares of Series A preferred stock in exchange for $8,450,000 in cash, less transaction costs. In 2005, the remaining 4,338,726 shares were issued in four separate tranches in exchange for a total of $17,490,000 in cash, less transaction costs. At December 31, 2008 and 2009, the Company had authorized and issued 6,624,844 shares of Series A preferred stock with a par value of $0.01 per share.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

On November 22, 2005, the Company entered into a Series B preferred stock purchase agreement with certain investors. Under the agreement, the investors agreed to purchase up to 7,134,329 shares of the Company s Series B preferred stock at a purchase price of $4.46 per share. The agreement contemplated the purchase of such shares in two tranches. The first sale of shares was completed in November 2005 when the Company issued 3,563,090 shares of Series B preferred stock in exchange for $15,880,000 in cash, less transaction costs. The Company issued an additional 13,565 shares to a director on December 1, 2005, for $60,000 in cash. The remaining 3,571,239 shares were issued in November 2006 in exchange for $15,917,000 in cash, less transaction costs. At December 31, 2008 and 2009 the Company had issued 7,147,894 shares of Series B preferred stock with a par value of $0.01 per share.

On March 17, 2008, the Company entered into a Series C preferred stock purchase agreement with certain investors. Under the agreement, the investors agreed to purchase up to 5,807,112 shares of the Company s Series C preferred stock at a purchase price of $5.17 per share. The agreement contemplated the purchase of such shares in two tranches. The first sale of shares was completed on March 17, 2008 when the Company issued 5,504,542 shares of Series C preferred stock in exchange for $28,437,000 in cash less transaction costs. The Company completed the second sale of the remaining 302,570 shares on April 23, 2008 for $1,563,000 in cash less transaction costs. At December 31, 2008 and 2009, the Company had issued 5,807,112 shares of Series C preferred stock with a par value of $0.01 per share.

On August 25, 2009, the Company entered into and completed a Series C-1 preferred stock and warrant purchase agreement with certain investors. Under the agreement, the investors agreed to purchase up to 967,845 units at a purchase price of $5.17 per unit, comprised of 967,845 shares of our Series C-1 preferred stock and warrants exercisable for up to an aggregate of 1,935,700 shares of our Series C-1 preferred stock at an exercise price of $5.17 per share for $5,000,000 in cash less transaction costs. The warrants expire unless exercised by the later of January 14, 2010 or 30 days after the delivery of the month 24 top line data from the Company s FAME Study. The Company allocated the purchase price of each unit to the Series C-1 preferred stock and the warrants based on their relative fair values on the issuance date. As a result, $1.53 of each unit, or $1,472,000 of the aggregate consideration, was allocated to the warrants. The remaining $3.64 of each unit, or $3,528,000 of the aggregate consideration, was allocated to the Series C-1 preferred stock. Because the Series C-1 preferred stock was convertible at issuance on a one for one basis into shares of the Company s common stock which had a fair value of $4.01 per share on the issuance date, the Series C-1 preferred stock was issued with a beneficial conversion feature of $0.37 per share, or $355,000 in aggregate. As a result the Company recognized a $355,000 dividend to the holders of the Series C-1 preferred stock in the accompanying statements of operations and changes in stockholders deficit for the year ended December 31, 2009. At December 31, 2009, the Company had issued 967,845 of Series C-1 preferred stock with a par value of $0.01 per share. On January 8, 2010 the Series C-1 preferred stock warrants 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.

Significant terms of Series A, Series B, Series C and Series C-1 preferred stock are as follows:

Holders of the preferred stock are entitled to the number of votes equal to the number of shares of common stock into which such shares of preferred stock could then be converted and have voting rights and powers equal to the voting rights and powers of the common stock. In addition, the holders of the preferred stock have the right, voting separately from common stockholders, to elect five out of seven members of the Company s Board of Directors. The remaining two members are elected by both the common and preferred stockholders.

Dividends are cumulative and accrue on a daily basis at the rate of 8% per annum beginning on the date of issuance and based on the original issue price, $4.03 per share for the Series A preferred stock, $4.46 per share

for the Series B preferred stock, and $5.17 per share for the Series C and Series C-1 preferred stock, as adjusted for any stock dividend, stock split, combination, or other event involving the preferred stock. Dividends will accrue, whether or not declared, annually and will be due and

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

payable when and if declared by the Board of Directors, upon a liquidating event, as defined, upon redemption of the preferred stock, as defined, or on the date that the preferred stock is otherwise acquired by the Company. Accumulated, accrued, and unpaid dividends were:

	December 31, 2008	2009
	(In thousands)	
Series A preferred stock	$ 8,177	$ 10,313
Series B preferred stock	6,652	9,200
Series C preferred stock	1,881	4,281
Series C-1 preferred stock		140
	$ 16,710	$ 23,934

Upon any liquidation, dissolution, or winding up of the Company, the preferred stockholders are entitled to a liquidation preference payment equal to (i) the sum of the liquidation value ($4.03 per share for the Series A preferred stock, $4.46 per share for the Series B preferred stock and $5.17 per share for the Series C and Series C-1 preferred stock) 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 were:

	December 31, 2008	2009
	(In thousands)	
Series A preferred stock	$ 34,883	$ 37,019
Series B preferred stock	38,509	41,057
Series C preferred stock	31,881	34,281
Series C-1 preferred stock		5,140
	$ 105,273	$ 117,497

Each share is convertible, at the option of the holder, into one share of common stock (subject to adjustments for events of dilution). In addition, all shares of preferred stock are automatically converted upon the completion of a public offering of common shares yielding proceeds of at least $50,000,000 and a price of at least five times the original issue price of the Series A preferred stock of $4.03 per share (subject to adjustments for events of dilution).

At any time subsequent to March 17, 2013, the holders of a majority of the preferred stock may require the Company to redeem all or any portion of the preferred stock. If the preferred stock is redeemed, the redemption will occur in equal installments over a three-year period. The price paid by the Company to redeem the shares would be 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.

The holders of the preferred stock have the right but not the obligation to participate proportionately in certain types of future financings.

Because the preferred stock provides the holders the right to require the Company to redeem such shares for cash after March 17, 2013 at the greater of (a) the original issue price plus any accrued but unpaid dividends or (b) the fair market value of the preferred stock being redeemed, the embedded conversion feature requires separate accounting under SFAS No. 133. Consequently, the conversion feature must be bifurcated from the preferred stock and accounted for separately at each issuance date. The carrying value of the

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

embedded derivative is adjusted to fair value at the end of each reporting period and the change in fair value is recognized in the statement of operations.

Upon the issuance of the first tranche of the Series A preferred stock, the estimated fair value of the conversion feature was $10,000 which was recorded as a liability. The derivative, when combined with other offering costs of $634,000, reduced the recorded value of the Series A preferred stock to $8,572,000. The cumulative estimated fair value of the conversion feature associated with the four tranches issued in 2005 was $3,000 which was recorded as a liability. Combined with the other offering costs of $401,000, the derivative reduced the recorded value of the Series A preferred stock issued in 2005 to $17,087,000.

Upon the issuance of the first tranche of the Series B preferred stock in November 2005 and the incremental issuance on December 1, 2005, the estimated fair value of the conversion feature was $7,000 which was recorded as a liability. The derivative, when combined with other offering costs of $339,000, reduced the recorded value of the first tranche of the Series B preferred stock to $15,595,000. Upon the issuance of the second tranche of the Series B preferred stock in November 2006, the estimated fair value of the conversion feature was $326 which was recorded as a liability. Combined with the other offering costs of $23,000, the derivative reduced the recorded value of the preferred stock issued in 2006 to $15,893,000.

Upon the issuance of the first tranche of the Series C preferred stock in March 2008, the estimated fair value of the conversion feature was $1,058,000 which was recorded as a liability. The derivative, when combined with other offering costs of $60,000, reduced the recorded value of the first tranche of the Series C preferred stock to $27,318,000. Upon issuance of the second tranche of the Series C preferred stock in April 2008, the estimated fair value of the conversion feature was $61,000 which was recorded as a liability. The derivative, when combined with other offering costs of $2,000, reduced the recorded value of the second tranche of the Series C preferred stock to $1,501,000.

Upon the issuance of the Series C-1 preferred stock in August 2009, the estimated fair value of the conversion feature was $903,000 which was recorded as a liability. The derivative, when combined with other offering costs of $102,000, further reduced the initial recorded value of the Series C-1 preferred stock to $2,522,000.

At each reporting date, the Company adjusts the carrying value of the embedded derivatives to estimated fair value and recognizes the change in such estimated value in its statement of operations. The estimated fair value of the derivatives at December 31, 2008 and 2009, were $12,656,000 and $36,701,000, respectively, and the Company recognized losses of $10,454,000 and $23,142,000 associated with the change in fair value for the years ended December 31, 2008 and 2009, respectively, and a gain of $1,000 associated with the change in fair value for the year ended December 31, 2007.

The Company accretes the carrying value of the Series A, Series B, Series C and Series C-1 preferred stock to their redemption values over the redemption period from the date of the issuance based upon the three-year redemption feature. The accreted values of the Series A, Series B, Series C and Series C-1 preferred stock, including accumulated, accrued, and unpaid dividends were:

	December 31,	
	2008	2009

	(In thousands)	
Series A preferred stock	$ 34,199	$ 36,467
Series B preferred stock	37,963	40,617
Series C preferred stock	30,855	33,452
Series C-1 preferred stock		2,853
	$ 103,017	$ 113,389

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

10. STOCK 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 120-month term. Options granted to directors typically vest immediately and have a 60-month term.

As of December 31, 2009, the Company was authorized to grant under the Company s plans up to 446,577 shares under the 2004 Stock Option Plan and up to 2,001,428 shares under the 2005 Stock Option 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,					
	2007		2008		2009	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options at beginning of period	1,268,674	$ 1.56	1,419,808	$ 1.50	1,959,726	$ 1.80
Grants	414,515	1.39	539,918	2.55	295,463	4.35
Forfeitures	(197,903)	1.56			(25,551)	1.84
Exercises	(65,478)	1.73			(3,860)	1.70
Options at end of period	1,419,808	1.50	1,959,726	1.80	2,225,778	2.14
Options exercisable at period end	563,855	1.63	921,055	1.56	1,427,649	1.70
Weighted average per share fair value of options granted during the period	$ 0.88		$ 1.73		$ 3.74	

The following table provides additional information related to outstanding stock options, fully vested stock options, and stock options expected to vest as of December 31, 2009:

	Weighted Average Exercise	Weighted Average Contractual	Aggregate Intrinsic

	Shares	Price	Term	Value (In thousands)
Outstanding	2,225,778	$ 2.14	7.28 years	$ 14,251
Exercisable	1,427,649	1.70	6.52 years	9,765
Expected to vest	718,320	2.92	8.63 years	4,037

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,		
	2007	2008	2009
Risk-free interest rate	3.98%	2.87%	3.44%
Volatility factor	64.16%	73.78%	112.57%
Grant date fair value of common stock	$ 1.39	$ 2.55	$ 4.35
Weighted-average expected life	6.13 years	6.15 years	6.18 years
Assumed forfeiture rate	10.00%	10.00%	10.00%

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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

	Years Ended December 31,		
	2007	2008	2009
	(In thousands)		
Marketing	$ 9	$ 109	$ 43
Research and development	36	269	161
General and administrative	45	372	307
Total employee stock-based compensation expense	$ 90	$ 750	$ 511

The total estimated fair value of options granted during the years ended December 31, 2007, 2008 and 2009 was $360,000, $930,000 and $1,100,000, respectively, and the total estimated value of options granted prior to 2007 was $1,156,000.

The following table summarizes outstanding and exercisable options at December 31, 2009:

	Options Outstanding		Options Exercisable	
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable	Weighted Average Remaining Contractual Life
$1.33	700,024	6.33	674,979	6.31
1.39	396,868	7.78	212,633	7.74
2.04	305,269	4.79	305,270	4.79
2.24	10,294	8.16	4,504	8.16
2.41	470,214	8.22	205,722	8.22
3.26	5,882	8.39	2,206	8.39
3.88	33,824	8.49	15,441	8.49
4.01	271,844	9.65	4,412	9.55
5.03	5,882	8.66	1,838	8.66
5.44	2,059	8.67	644	8.67
8.47	23,618	9.96		
	2,225,778		1,427,649	

11. COMMON STOCK WARRANTS

The Company has issued warrants to purchase common stock to various members of the board of directors and third-parties for services. The Company also issued warrants to purchase common stock to a third party in connection with a license agreement (see Note 6). Total warrants to purchase common stock issued and outstanding were 349,464 and 248,181 at December 31, 2008 and 2009, respectively, at exercise prices ranging from $1.70 to $4.05 per share. The warrants are exercisable for a period of seven to ten years from the issuance date.

No warrants to purchase common stock were issued in the years ended December 31, 2007, 2008 and 2009.

12. STOCK RESTRICTION AGREEMENTS

In 2004 the Company entered into stock restriction agreements with six employee stockholders of the Company for a total of 591,178 shares of common stock. Under the agreements, the Company had a right to repurchase the common stock owned by the employees at a purchase price of $2.04 per share upon the

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

termination of the employee s employment by the Company with cause or by the employee without good reason, as defined in the agreement. The repurchase rights expired ratably through June 2007, and no shares were repurchased.

The Company accounted for these as restricted stock grants under the provisions of FASB Interpretation (FIN) No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Options Award Plans*. Over the lifetime of the restriction agreements, the Company recognized a total of $715,000 in compensation expense based on a value of $1.22 per share on the date the Company entered into the restriction agreements. The Company recognized $95,000 in expense for the year ended December 31, 2007 due to the lapse of the restrictions in the normal course.

13. INCOME TAXES

The components of the income tax benefit were as follows:

	Years Ended December 31,		
	2007	2008	2009
	(In thousands)		
Deferred benefit (expense):			
Federal	$ 1,877	$ 17,119	$ 6,649
State	18	2,202	774
	1,895	19,321	7,423
Valuation allowance	(1,895)	(19,321)	(7,423)
Income tax benefit	$	$	$

As required by ASC 740, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Management has concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company will not realize the benefit of its deferred tax assets. Accordingly, the net deferred tax assets have been fully reserved. Management reevaluates the positive and negative evidence on an annual basis.

At December 31, 2008 and 2009, the Company had federal net operating loss (NOL) carry-forwards of approximately $57,509,000 and $79,494,000 and state net operating losses of approximately $40,681,000, 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 2029 and the state NOL carry-forwards will expire at various dates between 2018 and 2029.

Net deferred tax assets (liabilities) were as follows:

	December 31,		
	2007	2008	2009

	(In thousands)		
Depreciation and amortization	$ (65)	$ (17)	$ 268
Other deferred tax assets	179	227	338
NOL carry-forwards	12,157	21,167	29,512
Research and development costs		11,013	10,039
Collaboration agreement receivable reserves	1,506	194	364
Other		514	
Valuation allowance	(13,777)	(33,098)	(40,521)
Total	$	$	$

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

If changes in ownership of the Company were to occur, NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law).

The income tax provision (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,					
	2007		2008		2009	
	Amount	Percent	Amount	Percent	Amount	Percent
	(In thousands, except percentages)					
Federal tax benefit at statutory rate	$ (1,940)	34.0%	$ (20,898)	34.0%	$ (15,035)	34.0%
State tax net of federal benefit	(31)	0.5	(2,434)	4.0	(1,751)	4.0
Permanent items	63	(1.1)	4,226	(6.9)	8,938	(20.2)
Change in state deferred tax rate	13	(0.2)	(160)	0.3		
Other			(55)		425	(1.0)
Increase in valuation allowance	1,895	(33.2)	19,321	(31.4)	7,423	(16.8)
Total tax expense	$	%	$	%	$	%

The Company has evaluated the impact of ASC 740-10 on its financial statements, which was early adopted effective January 1, 2007. The Company believes that its income tax filing positions are more likely than not of being sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position; therefore, no ASC 740-10 liabilities and no related penalties and interest have been recorded. The Company did not record a cumulative effect adjustment related to the adoption of ASC 740-10. 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.

14. FAIR VALUE MEASUREMENTS

The Company adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (ASC 820), effective January 1, 2008. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the exit price) in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. The hierarchy of those valuation approaches is broken down into three levels based on the reliability of inputs as follows:

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

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

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

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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

	December 31, 2008			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash and cash equivalents - government-backed money market funds(1)	$ 17,421	$	$	$ 17,421
Assets measured at fair value	$ 17,421	$	$	$ 17,421
Liabilities:				
Beneficial conversion feature of preferred stock(2)	$	$	$ 12,656	$ 12,656
Liabilities measured at fair value	$	$	$ 12,656	$ 12,656

	December 31, 2009			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash and cash equivalents - government-backed money market funds(1)	$ 4,668	$	$	$ 4,668
Assets measured at fair value	$ 4,668	$	$	$ 4,668
Liabilities:				
Beneficial conversion feature of preferred stock(2)	$	$	$ 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) The fair value of the beneficial conversion feature of preferred stock (see note 9) 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;

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 United States Department of Treasury.

Table of Contents

ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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 year ended December 31, 2009 (in thousands):

Balance of beneficial conversion feature of preferred stock at December 31, 2008	$ 12,656
Issuance of Series C-1 preferred stock (See Note 9)	903
Change in fair value of beneficial conversion feature of preferred stock during the year ended December 31, 2009	23,142
Balance of beneficial conversion feature of preferred stock at December 31, 2009	$ 36,701

15. EMPLOYEE BENEFIT PLAN

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 $61,000 and $70,000 for the years ended December 31, 2008 and 2009, respectively. The Company may also make an annual discretionary profit-sharing contribution. No such discretionary contributions were made during the years ended December 31, 2007, 2008 and 2009.

16. SUBSEQUENT EVENTS

On April 5, 2010, the Company s board of directors approved a 3.4-for-one reverse split of the Company s common and preferred stock to be effected prior to the effective date of the Company s registration statement. In connection with the reverse split, the Company filed a Certificate of Amendment of the Restated Certificate of Incorporation with the Secretary of State of Delaware on April 16, 2010 making the reverse split legally effective. All share and per share amounts have been retroactively restated in the accompanying financial statements and notes for all periods presented.

******

Table of Contents