

ALIMERA SCIENCES INC  
Form S-1  
November 16, 2012  
Table of Contents

As filed with the Securities and Exchange Commission on November 16, 2012

Registration No. 333-

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

**FORM S-1**  
**REGISTRATION STATEMENT**  
*UNDER*  
*THE SECURITIES ACT OF 1933*

**Alimera Sciences, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of

**2834**  
(Primary Standard Industrial

**20-0028718**  
(I.R.S. Employer

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

(Incorporation or organization)

(Classification Code Number)  
6120 Windward Parkway, Suite 290

(Identification Number)

Alpharetta, GA 30005

(678) 990-5740

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**C. Daniel Myers**

**Chief Executive Officer**

**6120 Windward Parkway, Suite 290**

**Alpharetta, GA 30005**

**(678) 990-5740**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*

**Gregg Griner, Esq.**

**Keith Scherer, Esq.**

**Gunderson Dettmer Stough**

**Villeneuve Franklin & Hachigian, LLP**

**850 Winter Street**

**Waltham, MA 02451**

**(781) 890-8800**

**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this Registration Statement, as determined by the selling stockholders.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b2 of the Exchange Act.

Large accelerated filer " Accelerated filer "

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

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount Registered (1)(2)	Maximum Offering Price Per Unit (3)	Proposed Maximum	
			Aggregate Offering Price (3)	Amount of Registration Fee
Common Stock, \$0.01 par value	19,548,871	\$2.30	\$44,962,404	\$6,132.88

- (1) All of the shares of common stock registered hereunder are held by, or issuable upon conversion or exercise of securities held by, the selling stockholders. Pursuant to Rule 416, this registration statement shall be deemed to cover the additional securities (i) to be offered or issued in connection with any provision of any securities purported to be registered hereby to be offered pursuant to terms that provide for a change in the amount of securities being offered or issued to prevent dilution resulting from stock splits, stock dividends or similar transactions and (ii) of the same class as the securities covered by this registration statement issued or issuable prior to completion of the distribution of the securities covered by this registration statement as a result of a split of, or a stock dividend on, the registered securities.
- (2) Includes approximately 1.19 times the number of shares currently issuable upon voluntary conversion (based on a voluntary conversion price of \$3.16) of (i) the registrant's Series A Convertible Preferred Stock (Series A Preferred Stock) issued on October 2, 2012 to the selling stockholders and (ii) the Series A Preferred Stock or common stock issuable upon conversion of certain warrants (Warrants) issued on October 2, 2012 to the selling stockholders, due to the conversion rate adjustment mechanics of the Series A Preferred Stock. In addition, the registrant is registering an additional 3,093,175 shares of common stock that may become issuable to the selling stockholders upon the exercise or conversion, as applicable, of the Series A Preferred Stock and Warrants in the event that the conversion rate of the Series A Preferred Stock is adjusted because of the occurrence or non-occurrence of certain events.
- (3) Fee calculated in accordance with Rule 457(c) of the Securities Act based on the average of the high and low price for our common stock on the NASDAQ Global Market as of November 13, 2012

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE**

**IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THIS REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.**

**Table of Contents**

**The information in this preliminary prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED NOVEMBER 16, 2012**

**Preliminary Prospectus**

**19,548,871 shares of Common Stock**

This prospectus relates to the resale by certain of our stockholders, or selling stockholders, of up to 19,548,871 shares of our common stock in connection with the resale of up to:

12,658,228 shares of common stock issuable as of the date of this prospectus upon voluntary conversion by the selling stockholders of our Series A Convertible Preferred Stock, par value \$0.01 per share (Series A Preferred Stock);

3,797,468 shares of common stock issuable upon exercise of certain warrants held by the selling stockholders (Warrants) or issuable upon voluntary conversion of the Series A Preferred Stock issuable upon exercise of the Warrants; and

3,093,175 shares of common stock that may become issuable to the selling stockholders upon the exercise or conversion, as applicable, of the Series A Preferred Stock and Warrants in the event that the conversion rate of the Series A Preferred Stock is adjusted because of the occurrence or non-occurrence of certain events, as discussed in the section of this prospectus entitled

Description of Capital Stock Series A Preferred Stock.

The Series A Preferred Stock and the Warrants were issued to the selling stockholders on October 2, 2012 in connection with our private placement of units, each of which consisted of (i) one share of our Series A Preferred Stock and (ii) one Warrant to purchase 0.30 shares of our Series A Preferred Stock.

We are registering these shares of our common stock for resale by the selling stockholders named in this prospectus, or their transferees, pledgees, donees or successors. The selling stockholders may offer to sell the shares of common stock being offered in this prospectus at fixed prices, at prevailing market prices at the time of sale, at varying prices, at negotiated prices or in any other manner specified under the section of this prospectus entitled Plan of Distribution. We do not know when or in what amount the selling stockholders may offer the securities for sale. The selling stockholders may sell any, all or none of the securities offered in this prospectus.

Although we will pay substantially all of the expenses incident to the registration of the shares, we will not receive any proceeds from the sales by the selling stockholders. We will, however, to the extent the Warrants are exercised for cash, receive proceeds from such exercises; to the extent we receive such proceeds, they will be used for general corporate and working capital purposes.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

The selling stockholders and any brokers executing sell orders on behalf of the selling stockholders may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended (Securities Act). Commissions received by a broker executing sell orders may be deemed to be underwriting commissions under the Securities Act.

Our common stock is listed on the NASDAQ Global Market under the symbol ALIM. The last reported sale price of our common stock on the NASDAQ Global Market on November 13, 2012 was \$2.29.

**Investing in our securities involves risks, including those described under Risk Factors beginning on page 6 of this prospectus.**

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendment or supplements to this prospectus carefully before you make your investment decision.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus or the accompanying prospectus is accurate or complete. Any representation to the contrary is a criminal offense.**

The date of this prospectus is \_\_\_\_\_, 2012.

**Table of Contents**

**PROSPECTUS**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>ABOUT THIS PROSPECTUS</u>	1
<u>CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS</u>	1
<u>PROSPECTUS SUMMARY</u>	2
<u>THE OFFERING</u>	3
<u>SUMMARY HISTORICAL AND FINANCIAL AND OTHER DATA</u>	4
<u>RISK FACTORS</u>	6
<u>USE OF PROCEEDS</u>	26
<u>DIVIDEND POLICY</u>	26
<u>MARKET PRICE OF COMMON STOCK</u>	26
<u>SELLING STOCKHOLDERS</u>	27
<u>ABOUT OUR COMPANY</u>	29
<u>OUR CORPORATE INFORMATION</u>	42
<u>DESCRIPTION OF CAPITAL STOCK</u>	43
<u>PLAN OF DISTRIBUTION</u>	47
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	49
<u>DIRECTORS AND EXECUTIVE OFFICERS</u>	64
<u>EXECUTIVE COMPENSATION</u>	71
<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	87
<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	92
<u>SELLING RESTRICTIONS</u>	93
<u>INDUSTRY AND MARKET DATA</u>	96
<u>LEGAL MATTERS</u>	96
<u>EXPERTS</u>	96
<u>CHANGE IN INDEPENDENT ACCOUNTANTS</u>	96
<u>DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES</u>	96
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	97
<u>DOCUMENTS INCORPORATED BY REFERENCE</u>	97
<u>INDEX TO FINANCIAL STATEMENTS</u>	F-1
<b><u>PART II</u></b>	
<u>INFORMATION NOT REQUIRED IN PROSPECTUS</u>	II-1
<u>Item 13. Other Expenses of Issuance and Distribution</u>	II-1
<u>Item 14. Indemnification of Directors and Officers</u>	II-1

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

<u>Item 15. Recent Sales of Unregistered Securities</u>	II-1
<u>Item 16. Exhibits and Financial Statement Schedules</u>	II-2
<u>Item 17. Undertakings</u>	II-5
<u>SIGNATURES</u>	II-7
<u>EXHIBIT INDEX</u>	II-8



---

**Table of Contents**

**ABOUT THIS PROSPECTUS**

In this prospectus, the Company, Alimera, we, us, and our and similar terms refer to Alimera Sciences, Inc. We have registered the trademark ILUVIEN®, which is used throughout this prospectus.

You should read this prospectus together with additional information described under the headings *Where You Can Find More Information* and *Documents Incorporated by Reference*. If there is any inconsistency between the information in this prospectus and the documents incorporated by referenced herein, you should rely on the information in this prospectus.

You should rely only on the information contained in or incorporated by reference into this prospectus. Neither we nor the selling stockholders have authorized any person to provide information different from that contained in this prospectus and the documents incorporated by reference herein. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information appearing in this prospectus is accurate as of the date on the cover page, regardless of time of delivery of the prospectus or any sale of securities. Our business, financial condition, results of operation and prospects may have changed since that date.

**THIS PROSPECTUS IS NOT AN OFFER TO SELL ANY SECURITIES OTHER THAN THE SHARES OF COMMON STOCK FOR SALE BY THE SELLING STOCKHOLDERS. THIS PROSPECTUS IS NOT AN OFFER TO SELL SECURITIES IN ANY CIRCUMSTANCES IN WHICH SUCH AN OFFER IS UNLAWFUL. NEITHER WE NOR THE SELLING STOCKHOLDERS ARE MAKING AN OFFER TO SELL THESE SECURITIES IN ANY JURISDICTION WHERE THE OFFER OR SALE IS NOT PERMITTED.**

**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

Various statements in this prospectus are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties and are based on information currently available to our management. Words such as, but not limited to, anticipate, believe, estimate, expect, intend, may, plan, contemplate, project, target, likely, potential, continue, will, would, should, could, or the negative of these terms and similar expressions or words are forward-looking statements. The events and circumstances reflected in the Company's forward-looking statements may not occur and actual results could differ materially from those projected in the Company's forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to:

delay in or failure to obtain regulatory approval of our product candidates;

uncertainty as to our ability to commercialize (alone or with others), and market acceptance of, ILUVIEN in the EU;

our inability to successfully market and sell ILUVIEN following regulatory approval in additional markets;

the extent of government regulations;

uncertainty as to the pricing and reimbursement guidelines for our product candidates, including ILUVIEN in the various EU countries;

uncertainty as to the relationship between the benefits of our product candidates and the risks of their side-effect profiles;

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

dependence on third-party manufacturers to manufacture our product candidates in sufficient quantities and quality;

uncertainty of clinical trial results;

limited sales and marketing infrastructure; and

our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility. All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in any annual, quarterly or current reports that we may file with the Securities and Exchange Commission.

We encourage you to read the discussion and analysis of our financial condition and our consolidated financial statements contained in this prospectus. We also encourage you to read the **Risk Factors** section of this prospectus, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition, other unknown or unpredictable factors also could affect our results. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

---

**Table of Contents**

**PROSPECTUS SUMMARY**

*This summary, which highlights information contained elsewhere in this prospectus, is not complete and may not contain all of the information that you should consider before investing in our common stock. You should read this entire prospectus. You should also consider, among other things, the information contained in Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes thereto 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, which has received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain, for the treatment of vision impairment associated with diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN has not been approved by the U.S. Food and Drug Administration (FDA).

We currently plan to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and are pursuing pricing and reimbursement in those countries. In July 2012, we received a letter from Germany's Federal Joint Committee indicating that the automatic obligation to submit a dossier on ILUVIEN, per the Arzneimittelmarkt-Neuordnungsgesetz law, would not be necessary, and that a benefit assessment would not be required. This allows us to launch ILUVIEN in Germany without price restriction. In August 2012, we received an appraisal consultation document from the United Kingdom's National Institute for Health and Clinical Excellence (NICE) with a preliminary recommendation that ILUVIEN is not recommended given the cost of £5500 and other variables included in our submission to NICE. This document is not NICE's final guidance and the recommendation may change prior to NICE's final appraisal determination (FAD). We provided further comments on the draft appraisal and additional data in advance of the second appraisal meeting that was held in October 2012. We are currently awaiting additional feedback from NICE.

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

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of September 30, 2012, we have accumulated a deficit of \$225.8 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

complete the clinical development and registration of ILUVIEN;

prepare for the anticipated commercial launch of ILUVIEN in the EU in early 2013, at the earliest;

continue to seek regulatory approval of ILUVIEN in the U.S. and other jurisdictions;

evaluate the use of ILUVIEN for the treatment of other diseases; and

advance the clinical development of other product candidates either currently in our pipeline, or that we may license or acquire in the future.

On October 2, 2012, we sold units consisting of an aggregate of 1,000,000 shares of our Series A Preferred Stock and Warrants to purchase an additional 300,000 shares of Series A Preferred Stock to the selling stockholders for \$40.00 (Original Purchase Price) per unit. The sale of the units resulted in gross proceeds to us of \$40.0 million prior to the payment of related expenses. We believe that we have sufficient funds

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

available to fund our operations beyond the projected commercialization of ILUVIEN in Germany, the United Kingdom and France. We do not expect the generation of revenue until 2013, and therefore do not expect to have positive cash flow from operations until 2014. If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

We are a Delaware corporation incorporated on June 4, 2003. Our principal executive office is located at 6120 Windward Parkway, Suite 290, Alpharetta, Georgia 30005 and our telephone number is (678) 990-5740. Our website address is <http://www.alimerasciences.com>. The information contained in, or that can be accessed through, our website is not part of this prospectus and should not be considered incorporated by reference herein.

**Table of Contents**

**THE OFFERING**

Common stock being offered by selling stockholders:	We are registering up to an aggregate of 19,548,871 shares of common stock issuable upon conversion and/or exercise, as applicable, of outstanding shares of Series A Preferred Stock and the Warrants. <sup>(1)</sup> The following shares may be offered, from time to time, for resale by the selling stockholders under this prospectus:
	12,658,228 shares of common stock issuable as of the date of this prospectus upon voluntary conversion by the selling stockholders of our Series A Convertible Preferred Stock, par value \$0.01 per share (Series A Preferred Stock);
	3,797,468 shares of common stock issuable upon exercise of certain warrants held by the selling stockholders (Warrants) or issuable upon voluntary conversion of the Series A Preferred Stock issuable upon exercise of the Warrants; and
	3,093,175 shares of common stock that may become issuable to the selling stockholders upon the exercise or conversion, as applicable, of the Series A Preferred Stock and Warrants in the event that the conversion rate of the Series A Preferred Stock is adjusted because of the occurrence or non-occurrence of certain events, as discussed in the section of this prospectus entitled Description of Capital Stock Series A Preferred Stock.
Common stock being offered by us:	None.
Shares of common stock outstanding after this offering:	44,156,730 <sup>(2)</sup> shares of common stock
Use of Proceeds	We will not receive any of the proceeds from the sale of our shares by the selling stockholders. Any proceeds received by us from the exercise of Warrants by the selling stockholders will be used for working capital and general corporate purposes. See Use of Proceeds.
Risk Factors	An investment in our common stock involves various risks, and prospective investors should carefully consider the matters discussed under Risk Factors beginning on page 6 of this prospectus.
NASDAQ Global Market Symbol	ALIM

(1) Each share of Series A Preferred Stock is convertible into shares of our common stock at any time at the option of the holder at the rate equal to \$40.00 divided by the then current conversion price. The Series A Preferred Stock is not convertible at the option of the Company. The conversion price of the Series A Preferred Stock is subject to adjustment from \$2.91 to \$2.66 or \$3.16 based on the occurrence or non-occurrence of certain events, in addition to certain customary price based anti-dilution adjustments, subject to a floor of \$1.00. Any voluntary conversion of the Series A Preferred Stock into common stock at any time prior to the earlier of July 1, 2013 and the adjustment

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

- to either \$2.66 or \$3.16 (as so adjusted, the Final Guidance Price) shall be at a conversion price of \$3.16 (as adjusted for any price-based anti-dilution). The dollar amounts set forth above are subject to adjustment for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Preferred Stock. For a more detailed description of the conversion provisions of the Series A Preferred Stock, see the section of this prospectus entitled "Description of Capital Stock - Series A Preferred Stock."
- (2) The number of shares of common stock outstanding after this offering is based on the number of shares outstanding as of September 30, 2012, including 12,658,228 shares of common stock issuable as of the date of this prospectus upon voluntary conversion by the selling stockholders of our Series A Preferred Stock, and excludes:

3,686,628 shares of common stock reserved for issuance upon the exercise of outstanding stock options at a weighted average exercise price per share of \$3.16; and

82,568 shares of common stock issuable upon the exercise of outstanding warrants (other than the Warrants) at a weighted average exercise price per share of \$6.85; and

69,999 shares of common stock underlying outstanding warrants at an exercise price per share of \$11.00 which are not exercisable.

**Table of Contents****SUMMARY HISTORICAL AND FINANCIAL AND OTHER DATA**

The tables below summarize our financial data. The following statements of operations data for fiscal years 2011, 2010 and 2009, and the balance sheet data as of December 31, 2012 and 2011 have been derived from our audited financial statements and related notes and are included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period. The following summary financial data should be read together with our financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

**Statement of Operations Data**

	Year Ended December 31,			Nine Months Ended September 30,	
	2011	2010	2009	2012	2011
	(in thousands, except per share data)				
Operating expenses					
Research and development	\$ 7,100	\$ 12,581	\$ 15,057	\$ 5,636	\$ 5,732
General and administrative	6,203	4,610	3,407	4,488	4,827
Marketing	8,104	4,880	752	3,704	5,038
Total operating expenses	21,407	22,071	19,216	13,828	15,597
Interest and other income	16	73	37	3	15
Interest expense	(1,125)	(848)	(1,897)	(632)	(863)
Gain on early extinguishment of debt		1,343			
Decrease (increase) in fair value of preferred stock conversion feature		3,644	(23,142)		
Loss from continuing operations	(22,516)	(17,859)	(44,218)	(14,457)	(16,445)
Income from discontinued operations (1)		4,000			
Net loss	(22,516)	(13,859)	(44,218)	(14,457)	(16,445)
Beneficial conversion feature of preferred stock			(355)		
Preferred stock accretion		(466)	(623)		
Preferred stock dividends		(2,638)	(7,225)		
Net loss attributable to common stockholders	\$ (22,516)	\$ (16,963)	\$ (52,421)	\$ (14,457)	\$ (16,445)
Basic and diluted loss per share attributable to common stockholders	\$ (0.72)	\$ (0.77)	\$ (34.56)	\$ (0.46)	\$ (0.52)
Weighted average number of shares used to compute basic and diluted loss per share attributable to common stockholders	31,363	22,168	1,517	31,444	31,443

**Table of Contents****Balance Sheet Data**

	Years Ended December 31,			Nine Months Ended September 30,	
	2011	2010	2009 (unaudited)	2012	2011
	(In thousands)				
Cash and cash equivalents	\$ 33,108	\$ 28,514	\$ 4,858	\$ 17,355	\$ 38,107
Investments	500	26,330			502
Working capital (deficit)	27,783	49,777	(4,428)	13,108	33,877
Total assets	34,698	56,414	6,561	19,826	40,294
Long-term liabilities	3,002	4,785	47,909	1,443	3,510
Preferred stock			113,389		
Additional paid-in capital	235,619	233,338	4,836	236,894	235,155
Accumulated deficit	(211,370)	(188,854)	(171,891)	(225,827)	(205,299)
Total stockholders' equity (deficit)	24,978	45,212	(165,472)	11,797	30,585



---

**Table of Contents****RISK FACTORS**

Investing in our common stock involves risk. You should carefully consider the risks described below as well as those risk factors incorporated by reference herein before making an investment decision. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event the trading price of our common stock could decline, and you may lose all or part of your investment. The risks discussed below and those incorporated by reference also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

**Risks Related to Our Dependence on ILUVIEN**

*We are heavily dependent on the commercial success of our lead product candidate, ILUVIEN, which only recently received marketing authorizations in Austria, the United Kingdom, Portugal, France and Germany, and on the regulatory approval of ILUVIEN for the treatment of DME in the U.S. and other countries, which may never occur.*

We are a biopharmaceutical company with no products yet available for commercial sale. As a result, our future success is currently dependent upon the commercial and regulatory success of ILUVIEN, our lead product candidate, for the treatment of DME in Europe and the U.S. In February 2012, ILUVIEN received a positive outcome from the Decentralized Procedure (DCP) in Europe with the issuance of a Final Assessment Report (FAR) from the United Kingdom Medicines Healthcare products Regulatory Agency (MHRA) indicating that that it is approvable for commercial use to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. Following the issuance of the FAR from the MHRA, ILUVIEN received marketing authorization from governing regulatory bodies in Austria, the United Kingdom, Portugal, France and Germany. ILUVIEN has not yet received marketing authorization in Italy or Spain, however, and we cannot be certain when, or if, it will receive such authorizations. ILUVIEN has not been approved by the FDA in the U.S. and may never receive such approval. The timing of the commercial launch of ILUVIEN in the EU countries is dependent upon each specific EU country's pricing and reimbursement timelines, and we do not anticipate commercial sales of ILUVIEN until 2013, at the earliest. Because we do not currently have any product candidates available for sale or in clinical development other than ILUVIEN, our future success is dependent upon building a commercial operation in the EU to successfully commercialize ILUVIEN in the EU, and/or obtaining regulatory approval from the FDA to market ILUVIEN for the treatment of DME in the U.S., and if approved by the FDA, successfully commercializing ILUVIEN in the U.S.

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom and France, the first three countries in which we intend to make ILUVIEN available for sale. If we do not successfully commercialize ILUVIEN in these countries or other countries in the EU or receive regulatory approval in the U.S. for ILUVIEN for the treatment of DME, our ability to generate revenue may be jeopardized and, consequently, our business may be seriously harmed. We may not succeed in our commercial efforts in the EU; we may not receive regulatory approval in the U.S. for ILUVIEN; and if we do receive regulatory approval in the U.S. for ILUVIEN, we may not be able to commercialize ILUVIEN successfully, all of which would have a material adverse effect on our business and prospects. In the near term, we may experience delays and unforeseen difficulties in the launch of ILUVIEN in one or more of the EU countries, including obtaining unfavorable pricing and/or reimbursement, which could negatively affect our stock price. We may continue to experience delays in obtaining regulatory approval in the U.S. for ILUVIEN, if it is approved at all, and our stock price may be negatively affected.

In addition, we have incurred and expect to continue to incur significant expenses and to utilize a substantial portion of our cash resources as we prepare for the commercial launch of ILUVIEN in Germany, the United Kingdom and France, continue to pursue the approval of ILUVIEN in the U.S. and continue to grow our operational capabilities. This represents a significant investment in the commercial and regulatory success of ILUVIEN, which is uncertain.

We may also fail to develop future product candidates for the reasons stated in Risks Related to Our Business and Industry. If this were to occur, we will continue to be dependent on the successful commercialization of ILUVIEN, our development costs may increase and our ability to generate revenue could be impaired.

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

---

**Table of Contents**

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

In February 2012, ILUVIEN was recommended for marketing authorization in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. Following such recommendation, ILUVIEN received marketing authorization from governing regulatory bodies in Austria, the United Kingdom, Portugal, France and Germany. We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom and France, the first three countries in which we intend to make ILUVIEN available for sale. We currently plan to launch ILUVIEN in 2013. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources. At present, we have no established commercial infrastructure in the EU and are developing our plans to commercialize ILUVIEN on our own in Germany, the United Kingdom and France.

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

We may not be able to establish a commercial operation in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products include:

our inability to recruit and retain adequate numbers of effective personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe our products;

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

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

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

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

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

*ILUVIEN may not be commercially successful.*

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

cost of treatment;

pricing and availability of alternative products;

our ability to obtain third-party coverage or reimbursement for ILUVIEN;

perceived efficacy relative to other available therapies;

shifts in the medical community to new treatment paradigms or standards of care;

relative convenience and ease of administration; and

prevalence and severity of adverse side effects associated with treatment.

Because we have not yet commercialized ILUVIEN, we have limited information with regard to the market acceptance of ILUVIEN in the EU or elsewhere. As a result, we may have to revise our estimates regarding the acceptance of ILUVIEN under our anticipated pricing structure, reevaluate and/or change the anticipated pricing for ILUVIEN.

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

Our commercial opportunities for ILUVIEN will be reduced or eliminated if our competitors develop or market products that:

**Table of Contents**

are more effective;

have fewer or less severe adverse side effects;

are better tolerated;

receive better reimbursement terms;

are more accepted by physicians;

are more adaptable to various modes of dosing;

have better distribution channels;

are easier to administer; or

are less expensive, including but not limited to a generic version of ILUVIEN.

We expect that ILUVIEN may compete in the EU, and, if approved by the FDA, in the U.S., with other products that are being developed for the treatment of DME. There are no ophthalmic drug therapies other than Lucentis, a drug sponsored by Genentech, Inc., a wholly-owned member of the Roche Group, which has been approved by the FDA for the treatment of DME. Lucentis is approved for the treatment of visual impairment due to DME in the EU. Lucentis is expected to provide competition for ILUVIEN. Retinal specialists are currently using laser photocoagulation and off-label therapies for the treatment of DME, and may continue to use these therapies in competition with ILUVIEN. Additional treatments for DME are in various stages of preclinical or clinical testing. Later stage products for the treatment of DME include Ozurdex, a drug sponsored by Allergan, Inc. and Eyelea, a drug sponsored by Regeneron Pharmaceuticals, Inc. and Bayer HealthCare. If approved, these treatments would also compete with ILUVIEN. Other laser, surgical or pharmaceutical treatments for DME may also compete against ILUVIEN. These competitive therapies may result in pricing pressure even if ILUVIEN is otherwise viewed as a preferable therapy.

In addition, there are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research and development of products, some of which may target the same indications as our product candidates. Our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater marketing capabilities than we do.

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

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

extended collection timelines for accounts receivable and greater working capital requirements;

multiple legal systems and unexpected changes in legal requirements;

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

tariffs, export restrictions, trade barriers and other regulatory or contractual limitations on our ability to sell or develop our products in certain foreign markets;

trade laws and business practices favoring local competition;

potential tax issues, including restrictions on repatriating earnings, multiple and conflicting and complex tax laws and regulations;

weaker intellectual property protection in some countries;

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

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

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

---

## **Table of Contents**

### **Risks Related to Our Business and Industry**

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

We are not currently generating revenues and we cannot estimate with precision the extent of our future losses. Although ILUVIEN recently received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain, we do not currently have any products that are available for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of ILUVIEN. We currently do not expect to generate revenue from the sale of ILUVIEN in the EU until 2013, at the earliest. ILUVIEN has not been approved for marketing in the U.S. and may never receive such approval. As a result of these factors, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. As of September 30, 2012, we have accumulated a net deficit of \$225.8 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

As of September 30, 2012, we had approximately \$17.4 million in cash and cash equivalents. On October 2, 2012, we completed the sale of units consisting of shares of our Series A Preferred Stock and Warrants in a private placement for gross proceeds of \$40.0 million prior to the payment of related expenses. We believe that we have sufficient funds available to fund our operations beyond the projected commercialization of ILUVIEN in the EU countries described above. The commercialization of ILUVIEN is dependent upon numerous factors and we cannot be sure that future sales of ILUVIEN will generate enough revenue to fund our operations beyond its commercialization. If ILUVIEN does not generate sufficient revenue in the EU, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

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

The research, testing, manufacturing and marketing of drug products are subject to extensive regulation by U.S. federal, state and local government authorities, including the FDA and similar entities in other countries. To obtain regulatory approval of a product, we must demonstrate to the satisfaction of the regulatory agencies that, among other things, the product is safe and effective for its intended use. In addition, we must show that the manufacturing facilities used to produce the products are in compliance with current Good Manufacturing Practice (cGMP) regulations.

The process of obtaining regulatory approvals and clearances in the U.S. and other jurisdictions where ILUVIEN is not approved will require us to expend substantial time and capital. Despite the time and expense incurred, regulatory approval is never guaranteed. The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the drug candidate, the disease or condition for which the drug candidate is in development, the jurisdiction in which we are seeking approval and the regulations applicable to that particular drug candidate. Regulatory agencies, including those in the U.S., Canada, the EU and other countries where drugs are regulated, can delay, limit or deny approval of a drug candidate for many reasons, including that:

a drug candidate may not be safe or effective;

regulatory agencies may interpret data from preclinical and clinical testing in different ways from those which we do;

they may not approve of our manufacturing processes;

they may conclude that the drug candidate does not meet quality standards for stability, quality, purity and potency; and

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

they may change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the U.S. For example, the FDA may not approve of certain of our methods for analyzing our trial data, including how we evaluate the relationship between risk and benefit. Further, we may pursue approval of and market other product candidates, outside the U.S. and specifically in Canada and additional countries in the EU. Regulatory agencies within these countries will require that we obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedures within these countries can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain additional foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.



---

## **Table of Contents**

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

The use of corticosteroids in the eye has been associated with undesirable side effects, including increased incidence of cataract formation and elevated intraocular pressure (IOP), which may increase the risk of glaucoma. We have 36 months of clinical data from our FAME Study, but the extent of ILUVIEN's long-term side-effect profile beyond month 36 is not yet known. We have agreed with EU regulatory authorities to conduct a five-year post-authorization, open label registry study of the safety of ILUVIEN in 800 patients with chronic DME. Although ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany, and been recommended for marketing authorization in Italy and Spain, the FDA's current position is that our FAME Study did not demonstrate that ILUVIEN has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. In the event the FDA maintains this conclusion, ILUVIEN may not receive regulatory approval from the FDA. Additionally if other regulatory bodies adopt a conclusion similar to the FDA's we may not receive approval in any other jurisdiction.

***Even if we do receive additional regulatory approvals for ILUVIEN, the FDA or other regulatory agencies may impose limitations on the indicated uses for which ILUVIEN may be marketed, subsequently withdraw approval or take other actions against us or ILUVIEN that would be adverse to our business.***

Regulatory agencies generally approve products for particular indications. If any such regulatory agency approves ILUVIEN for a limited indication, the size of our potential market for ILUVIEN will be reduced. For example, our potential market for ILUVIEN in the U.S. would be reduced if the FDA limited the indications of use to patients diagnosed with only clinically significant DME as opposed to DME, or restricted its use to patients exhibiting IOP below a certain level or having an artificial lens at the time of treatment. ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany, and been recommended for marketing authorization in Italy and Spain for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies which may limit the use of ILUVIEN to a segment of the DME population. Product approvals, once granted, may be withdrawn if problems occur after initial marketing. The marketing, distribution and manufacture of ILUVIEN in the EU, and if approved in the U.S., will be subject to regulation. We will need to comply with facility registration and product listing requirements of the FDA and similar entities in other countries and adhere to the FDA's Quality System Regulations. Noncompliance with applicable FDA and similar entities' requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of ILUVIEN, total or partial suspension of production, refusal of regulatory agencies to grant approvals, withdrawal of approvals by regulatory agencies or criminal prosecution. We would also need to maintain compliance with federal, state and foreign laws regarding sales incentives, referrals and other programs.

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

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

the demonstration of its safety and efficacy;

its cost-effectiveness;

its potential advantages over other therapies;

the reimbursement policies of government and third-party payers with respect to the product candidate; and

the effectiveness of our marketing and distribution capabilities.

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

will ever become profitable.

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

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

---

## **Table of Contents**

***We will rely on a single manufacturer for ILUVIEN, a single manufacturer for the ILUVIEN applicator and a single active pharmaceutical ingredient manufacturer for ILUVIEN's active pharmaceutical ingredient. Our business would be seriously harmed if any of these third-parties are not able to satisfy our demand and alternative sources are not available.***

We do not have, nor currently intend to have, in-house manufacturing capability and will depend completely on a single third-party manufacturer for the manufacture of the ILUVIEN insert (Alliance Medical Products, Inc. (Alliance)), a single third-party manufacturer for the manufacture of the ILUVIEN applicator (Flextronics International, Ltd. or an affiliate of Flextronics International, Ltd. (Flextronics)) and a single third-party manufacturer for the manufacture of ILUVIEN's active pharmaceutical ingredient (FARMABIOS SpA./Byron Chemical Company Inc. (FARMABIOS)). Although we have long-term agreements for the manufacture of the ILUVIEN insert (with Alliance), the manufacture of the ILUVIEN applicator (with Flextronics) and for the supply of ILUVIEN's active pharmaceutical ingredient (with FARMABIOS), if any of the third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with them or get them approved by the applicable regulatory authorities, such as the FDA in the U.S., in a timely manner. Further, all of our manufacturers rely on additional third-parties for the manufacture of component parts. Any inability to acquire sufficient quantities of ILUVIEN inserts, the ILUVIEN applicator or the active pharmaceutical ingredient in a timely manner from these third-parties could delay commercial production of, and impact our ability to fulfill demand for, ILUVIEN.

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

We will rely on our manufacturers to purchase materials from third-party suppliers necessary to produce ILUVIEN and our other product candidates for our clinical trials and expected commercial distribution. Suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. If our manufacturers are unable to obtain these materials for our clinical trials, product testing and potential regulatory approval of ILUVIEN outside the seven EU countries in which it has been recommended for marketing authorization and our other product candidates could be delayed, significantly affecting our ability to develop ILUVIEN and our other product candidates. If we or our manufacturers are unable to purchase these materials in the EU for ILUVIEN, or elsewhere if and when applicable regulatory approval has been obtained for ILUVIEN and our other product candidates, the commercial launch of ILUVIEN and our other product candidates would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of ILUVIEN and our other product candidates. Moreover, although we have finalized agreements for the commercial production of the ILUVIEN insert, the commercial production of the ILUVIEN applicator, and the supply of the active pharmaceutical ingredient in ILUVIEN, the suppliers may be unable or choose not to supply us in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain these supplies, our ability to manufacture ILUVIEN for commercial sale would be delayed, significantly impacting our ability to generate revenue from the sale of ILUVIEN.

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

The manufacture and packaging of pharmaceutical product candidates such as ILUVIEN and our future product candidates are regulated by the FDA and similar foreign regulatory agencies and must be conducted in accordance with the FDA's cGMP and comparable requirements of foreign regulatory agencies. There are a limited number of manufacturers that operate under these cGMP regulations which are both capable of manufacturing ILUVIEN and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In December 2010, we received a CRL from the FDA in which the FDA indicated that it had observed deficiencies in cGMP during its facility inspections of two of our third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls would need to comply with cGMP. Both of these manufacturers received confirmation from the FDA in March 2011 that the deficiencies have been resolved and their respective facility facilities are acceptable. However, if our manufacturers fail to maintain compliance, the production of ILUVIEN could be interrupted, resulting in delays and additional costs. Any significant delays in the manufacture of ILUVIEN could materially harm our business and prospects.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, will require prior FDA review and/or approval of the manufacturing process and procedures in accordance with the FDA's cGMP regulations. There are comparable foreign requirements as well. This review may be costly and time consuming and could delay or prevent the launch of a product. If we elect to manufacture products in our own facility or at the facility of another third-party, we would need to

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

ensure that the new facility and the manufacturing process are in substantial compliance with cGMP and comparable foreign regulations. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA or a foreign regulatory agency may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

## **Table of Contents**

Furthermore, in order to obtain approval of our product candidates by the FDA and foreign regulatory agencies, we need to complete testing on both the active pharmaceutical ingredient and on the finished product in the packaging that we propose for commercial sales. This includes testing of stability, identification of impurities and testing of other product specifications by validated test methods. In addition, we will be required to consistently produce in commercial quantities and of specified quality in a reproducible manner and document our ability to do so. This requirement is referred to as process validation. With respect to ILUVIEN, although we have validated the manufacturing process at smaller scale batches, some of the steps in the manufacturing processes will need to be revalidated when we begin to manufacture larger commercial scale batches, including in connection with our anticipated commercial launch in the EU. If the required testing or process validation is delayed or produces unfavorable results, we may have to launch the product using smaller scale batches, which may impact our ability to fulfill demand for the product. The FDA and similar foreign regulatory agencies may also implement new standards, or change their interpretation and enforcement of existing standards and requirements, for the manufacture, packaging, or testing of products at any time. If we are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business.

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

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

our inability to manufacture or obtain from third-parties materials sufficient for use in preclinical studies and clinical trials;

delays in patient enrollment and variability in the number and types of patients available for clinical trials;

difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

poor effectiveness of product candidates during clinical trials;

unforeseen safety issues or side effects; and

governmental or regulatory delays and changes in regulatory requirements and guidelines.

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

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

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

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

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

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

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

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

---

## **Table of Contents**

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

As of September 30, 2012, we had 20 employees. As our development and commercialization plans and strategies evolve, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize ILUVIEN and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth and related costs. We may not be able to effectively manage a rapid pace of growth and timely implement improvements to our management infrastructure and control systems.

***ILUVIEN and our other potential products may not be commercially viable if we fail to obtain an adequate level of reimbursement for these products from governments, private insurers, the Medicare program and other third-party payers. The market for our products may also be limited by the indications for which their use may be reimbursed or the frequency at which they may be administered.***

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

In the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain, as well as many other foreign countries, the pricing of prescription pharmaceuticals is subject to governmental control. In the EU, each country has a different reviewing body that evaluates reimbursement dossiers submitted by marketing authorization holders of new drugs and then makes recommendations as to whether or not the drug should be reimbursed. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including ILUVIEN, to other available therapies.

In the U.S., in the event that ILUVIEN is approved, we will need to obtain approvals for payment for ILUVIEN from private insurers, including managed care organizations, and from the Medicare program. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. These reforms could significantly reduce payments from Medicare and Medicaid over the next ten years. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling of payments or the imposition of enrollment limitations on new providers, may change the availability, methods and rates of reimbursements from Medicare, private insurers and other third-party payers for ILUVIEN and our other potential products. Some of these changes and proposed changes could result in reduced reimbursement rates for ILUVIEN and our other potential products, which would adversely affect our business strategy, operations and financial results.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of ILUVIEN in determining whether to approve reimbursement for ILUVIEN and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of ILUVIEN from private insurers on a timely or satisfactory basis. Although drugs that are not self-administered are covered by Medicare, the Medicare program has taken the position that it can decide not to cover particular drugs if it determines that they are not reasonable and necessary for Medicare beneficiaries. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Our business could be materially adversely affected if the Medicare program, local Medicare carriers or fiscal intermediaries were to make such a determination and deny or limit the reimbursement of ILUVIEN. Our business also could be adversely affected if retinal specialists are not reimbursed by Medicare for the cost of the procedure in which they administer ILUVIEN on a basis satisfactory to the administering retinal specialists. If the local contractors that administer the Medicare program are slow to reimburse retinal specialists for ILUVIEN, the retinal specialists may pay us more slowly, which would adversely affect our working capital requirements.

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

We expect to experience pricing pressures in connection with the sale of ILUVIEN and our future products due to the potential healthcare reforms discussed above, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals, and the economic health of companies. If reimbursement for our products is unavailable, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.





---

## **Table of Contents**

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

The development and commercialization of new drugs is highly competitive and the commercial success of ILUVIEN will depend on several factors, including, but not limited to, its efficacy and side effect profile, authorization for reimbursement by foreign regulatory bodies, private insurers and Medicare, acceptance of pricing, the development of our sales and marketing organization, an adequate payment to physicians for the insertion procedure (based on a cost assigned by the American Medical Association to the procedure, also known as a CPT code) and our ability to differentiate ILUVIEN from our competitors' products. We will face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to ILUVIEN and to any products that we may develop or commercialize in the future. Our competitors may develop products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. The active pharmaceutical ingredient in ILUVIEN is FAc, which is not protected by currently valid patents. As a result, our competitors could develop an alternative formulation or delivery mechanisms to treat diseases of the eye with FAc. We do not have the right to develop and sell pSivida's proprietary delivery device for indications for diseases outside of the eye or for the treatment of uveitis. Further, our agreement with pSivida permits pSivida to grant to any other party the right to use its intellectual property (i) to treat DME through an incision smaller than that required for a 25-gauge needle, unless using a corticosteroid delivered to the back of the eye, (ii) to deliver any compound outside the back of the eye unless it is to treat DME through an incision required for a 25-gauge or larger needle, or (iii) to deliver non-corticosteroids to the back of the eye, unless it is to treat DME through an incision required for a 25-gauge or larger needle.

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

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

Our business strategy includes entering into collaborations with corporate and academic collaborators for the research, development and commercialization of additional product candidates. We currently do not have any collaboration agreements with third-parties. Areas in which we anticipate potentially entering into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing of ILUVIEN in certain EU countries and elsewhere outside of North America, and future product development arrangements. If we are unable to identify or enter into an agreement with any material third-party collaborator we could be adversely affected financially or our business reputation could be harmed. Any arrangements we do enter into may not be scientifically or commercially successful. The termination of any of these future arrangements might adversely affect our ability to develop, commercialize and market our products.

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

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

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

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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:

---

## **Table of Contents**

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. Several more established companies are also pursuing strategies to license or acquire products in the ophthalmic field. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable product candidates include the following:

we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return from the product;

companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or

we may be unable to identify suitable products or product candidates within our areas of expertise.

Additionally, it may take greater human and financial resources to develop suitable potential product candidates through internal research programs or by obtaining rights than we will possess, thereby limiting our ability to develop a diverse product portfolio.

If we are unable to develop suitable potential product candidates through internal research programs or by obtaining rights to novel therapeutics from third-parties, our business will suffer.

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

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

***We face the risk of product liability claims and may not be able to obtain or maintain insurance.***

Our business exposes us to the risk of product liability claims, which is inherent in the manufacturing, testing and marketing of drugs and related products. If the use of one or more of our products harms people, we may be subject to costly and damaging product liability claims. We have primary product liability insurance that covers our clinical trials for a \$5.0 million general aggregate limit and excess product liability insurance that covers our clinical trials for an additional \$5.0 million general aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of the products that we may develop. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our product development and commercialization efforts.

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

***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.***

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

We are highly dependent upon the principal members of our management team, including C. Daniel Myers, our President and Chief Executive Officer, Richard Eiswirth, our Chief Operating Officer and Chief Financial Officer, Susan Caballa, our Senior Vice President of Regulatory Affairs, Kenneth Green, Ph.D., our Senior Vice President and Chief Scientific Officer, and Dave Holland, our Senior Vice President of Sales and Marketing. These executives have significant ophthalmic, regulatory industry, sales and marketing, operational, and/or corporate finance experience. The loss of any such executives or any other principal member of our management team would impair our ability to identify, develop and market new products.

In addition, our growth will require us to hire a significant number of qualified technical, commercial and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

---

## **Table of Contents**

***If our CROs, third-party vendors and investigators do not successfully carry out their duties or if we lose our relationships with them, our development efforts with respect to ILUVIEN or any of our other product candidates could be delayed.***

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

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

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

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

restrictions on such products or manufacturing processes;

withdrawal of the products from the market;

voluntary or mandatory recall;

fines;

suspension of regulatory approvals;

product seizure; and

injunctions or the imposition of civil or criminal penalties.

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

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

ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany, and been recommended for marketing authorization in Italy and Spain. We intend to continue to pursue market authorizations for ILUVIEN and other product candidates internationally in additional jurisdictions. In order to market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval or approval in the seven EU countries in which ILUVIEN has received or been recommended for marketing authorization. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain additional foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any additional market. The failure to obtain these approvals could harm our business materially.

---

## **Table of Contents**

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

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

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

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

regulatory authorities may withdraw their approval of the product;

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

our reputation may suffer.

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

## **Risks Related to Intellectual Property and Other Legal Matters**

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

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

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

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Our products or potential products may infringe upon other parties' intellectual property rights that are protected by patents or patent applications. Third-parties may now or in the future own or control these patents and patent applications in the U.S. and abroad. These third-parties could bring claims against us or our collaborators that would cause us to incur substantial expenses or divert substantial employee resources from our business and, if successful, could cause us to pay substantial damages or prevent us from developing one or more product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

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



---

## **Table of Contents**

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U.S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

***If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third-parties, we could lose license rights that are important to our business.***

Our licenses are material to our business, and we expect to enter into additional licenses in the future. We hold a license from pSivida to 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. to 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 September 30, 2012, we owned one pending non-provisional U.S. utility patent application, one European patent application, one issued U.S. design patent and corresponding applications in a number of other jurisdictions, relating to our applicator for ILUVIEN. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third-parties from developing or designing around these patents. As of September 30, 2012, the patent rights relating to ILUVIEN licensed to us from pSivida include three U.S. patents that expire between March 2019 and April 2020, one European patent expiring in April of 2021, and counterpart filings to these patents in a number of other jurisdictions. No patent term extension will be available for any of these U.S. patents, European patent or any of our licensed U.S. or European pending patent applications. After these patents expire in April 2020 in the U.S. and April of 2021 in Europe, we will not be able to block others from marketing FAc in an insert similar to ILUVIEN in the U.S. Moreover, it is possible that a third-party could successfully challenge the scope (i.e., whether a patent is infringed), validity and enforceability of our licensed patents prior to patent expiration and obtain approval to market a competitive product.



---

## **Table of Contents**

Further, the patent applications that we license or have filed may fail to result in issued patents. Some claims in pending patent applications filed or licensed by us have been rejected by patent examiners. These claims may need to be amended. Even after amendment, a patent may not be permitted to issue. Further, the existing or future patents to which we have rights based on our agreement with pSivida may be too narrow to prevent third-parties from developing or designing around these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of a breach or termination of the license agreement. Manufacturers may also seek to obtain approval to sell a generic version of ILUVIEN prior to the expiration of the relevant licensed patents. If the sufficiency of the breadth or strength of protection provided by the patents we license with respect to ILUVIEN or the patents we pursue related to another product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize ILUVIEN and our other product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market ILUVIEN and our other product candidates under patent protection would be reduced. We rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our development processes with respect to ILUVIEN and our other product candidates that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

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

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

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.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

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

---

**Table of Contents**

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

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. We face a risk of product liability exposure related to the testing of our product candidates in clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our products are inserted into the eye, and it is possible that we may be held liable for eye injuries of patients who receive our product. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products. Although we maintain primary product liability insurance and excess product liability insurance that cover our clinical trials, our aggregate coverage limit under these insurance policies is \$10.0 million, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover potential liabilities. In addition, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products.

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

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In particular, in March 2010, the Patient Protection and Affordable Care Act, or PPACA, and a related reconciliation bill were signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following:

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

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

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

Pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense. The aggregated industry-wide fee is expected to total \$28 billion through 2019, of which \$2.8 billion will be payable in 2012. Since we expect our branded pharmaceutical sales to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

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

The full effects of the U.S. healthcare reform legislation cannot be known until the new law is implemented through regulations or guidance issued by the Centers for Medicare & Medicaid Services and other federal and state healthcare agencies. The financial impact of the U.S. healthcare reform legislation over the next few years will depend on a number of factors including but not limited to the policies reflected in implementing regulations and guidance and changes in sales volumes for products affected by the new system of rebates, discounts and fees. If ILUVIEN is approved by the FDA, the legislation may also have a positive impact on our future net sales, if any, by increasing the aggregate number of persons with healthcare coverage in the U.S., but such increases are unlikely to be realized until approximately 2014, at the earliest.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

Further, in some foreign countries, including the EU and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval and product launch. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Our business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

---

## **Table of Contents**

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

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations in both the U.S. and Canada govern the use, manufacture, storage, handling and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, operating results and financial condition.

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

At December 31, 2011, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately \$120.4 million and \$103.8 million, respectively, which expire at various dates beginning in 2020 through 2031. At September 30, 2012 we had federal NOL carry-forwards of approximately \$134.6 million and state NOL carry-forwards of approximately \$118.1 million, respectively, that were available to reduce future income otherwise taxable. Section 382 of the Internal Revenue Code limits the annual utilization of NOL carry-forwards and tax credit carry-forwards following an ownership change in our company. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of our company were to occur. In general, an ownership change occurs for purposes of Section 382 if there is a more than 50% change in ownership of a company over a 3-year testing period. We are currently evaluating whether a change in ownership occurred with respect to our Series A Preferred Stock financing.

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and NASDAQ, has imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel are required to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time consuming and costly. These rules and regulations may make it more difficult and more expensive for us to maintain our existing director and officer liability insurance or to obtain similar coverage from an alternative provider.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require us to continue to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

### **Risks Relating to Our Financial Results and Need for Financing**

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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;



**Table of Contents**

our ability to obtain regulatory approval of ILUVIEN in additional jurisdictions;

the emergence of products that compete with our product candidates;

the status of our preclinical and clinical development programs;

variations in the level of expenses related to our existing product candidates or preclinical and clinical development programs;

execution of collaborative, licensing or other arrangements, and the timing of payments received or made under those arrangements;

any intellectual property infringement lawsuits to which we may become a party; and

regulatory developments affecting our product candidates or those of our competitors.

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

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

Our business may require additional capital that we have not yet secured. Including the net proceeds from our recently completed Series A Preferred Stock financing, based on our current plans, we believe our cash, cash equivalents and short-term investments will be sufficient to fund our operations beyond the projected commercialization of ILUVIEN in the United Kingdom, France and Germany and the expected generation of revenue in 2013, at the earliest. However, the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control, and we may need funds sooner than currently anticipated. These factors include but are not limited to:

the amount of our future operating losses;

third party expenses relating to the commercialization of ILUVIEN;

the level of success of the initial commercial launch of ILUVIEN in the United Kingdom, France and Germany;

the status of our new drug application or ILUVIEN in the U.S.;

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

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

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

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

regulatory changes and technological developments in our markets.

General market conditions or the market price of our common stock may not support capital raising transactions such as an additional public or private offering of our common stock or other securities. In addition, our ability to raise additional capital may be dependent upon our stock being quoted on the NASDAQ Global Market or upon obtaining shareholder approval. There can be no assurance that we will be able to satisfy the criteria for continued listing on NASDAQ or that we will be able to obtain shareholder approval if it is necessary. If we are unable to obtain additional funds on a timely basis or on terms favorable to us, we may be required to cease or reduce further commercialization of ILUVIEN, to cease or reduce certain research and development projects, to sell some or all of our technology or assets or business units or to merge all or a portion of our business with another entity. In the event additional financing is needed or advisable, we may seek to fund our operations through the sale of equity securities, additional debt financing and strategic collaboration agreements. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders especially in light of the current difficult financial environment. If we raise additional funds by selling shares of our capital stock, the ownership interest of our current stockholders will be diluted. In addition, our Series A Preferred Stock is entitled to price-based anti-dilution protection in connection with certain financings, which has the potential to further dilute our other stockholders. If we attempt to raise additional funds through strategic collaboration agreements, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize our product candidates or operate our business. For example, under the senior secured credit facility, which we entered into in October 2010 (Credit Facility), we are subject to a variety of affirmative and negative covenants, including required financial reporting, limitations on our cash balances, limitations on the disposition of assets, limitations on the incurrence of additional debt, and other requirements. To secure the performance of our obligations under the Credit Facility, we pledged all of our assets, including our intellectual property to the lenders. Our failure to comply with the covenants under the Credit Facility could result in an event of default, the acceleration of our debt and the loss of our assets. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there may be substantial doubt about our ability to continue as a going concern.

**Table of Contents**

**Risks Related to Our Common Stock**

*Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.*

We completed our IPO in April 2010 at a price of \$11.00 per share. Subsequently, our common stock has traded as low as \$1.09 per share. The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

our ability to successfully commercialize ILUVIEN in the EU, including our ability to build our own commercial infrastructure for the sale of ILUVIEN in the Germany, United Kingdom and France;

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

the ability of ILUVIEN or any of our product candidates, if approved in additional jurisdictions, to achieve commercial success;

results from our clinical trial programs;

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

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

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

announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;

third-party coverage and reimbursement policies;

additions or departures of key personnel;

commencement of, or our involvement in, litigation;

our ability to meet our repayment and other obligations under our Credit Facility;

changes in governmental regulations or in the status of our regulatory approvals;

changes in earnings estimates or recommendations by securities analysts;

any major change in our board of directors or management;

general economic conditions and slow or negative growth of our markets; and

political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, the notification of the results of regulatory filings and the anticipated commercial launch of our product candidates. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of our product and product candidates may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been initiated against these companies. This litigation, if brought against us, could result in substantial costs and a diversion of our management's attention and resources.

---

## **Table of Contents**

***Certain of our stockholders have the ability to control the outcome of matters submitted for stockholder approval and may have interests that differ from those of our other stockholders.***

As of immediately following the closing of our Series A Preferred Stock financing, our executive officers, key employees, directors and their affiliates and the investors that participated in the financing beneficially owned, in the aggregate, approximately 73.8% of the outstanding voting power of our common stock, assuming the exercise of the outstanding Warrants to purchase shares of our Series A Preferred Stock. As a result, these stockholders, if acting together, may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions, and this concentration of voting power may have the effect of delaying or impeding actions that could be beneficial to you, including actions that may be supported by our Board of Directors.

In addition, the terms of our Series A Preferred Stock provide that certain corporate actions require the prior consent of the holders of at least 70% of the then outstanding shares of Series A Preferred Stock.

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

We do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend on results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. Further, for so long as at least 37.5% of the shares of Series A Preferred Stock originally issued to the investors at the closing of our Series A Preferred Stock financing in October 2012 are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Preferred Stock declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (A) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Preferred Stock is made pursuant to the certificate of designation or (B) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with the implementation of a poison pill rights plan or similar plan by us. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

***Significant sales of our common stock, including under this prospectus, could depress or reduce the market price of our common stock, or cause our shares of common stock to trade below the prices at which they would otherwise trade, or impede our ability to raise future capital.***

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

In addition to our outstanding common stock, as of September 30, 2012, there were a total of 3,686,628 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options granted under our equity incentive plans. Upon the exercise of these options, in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under the SEC's Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

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

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

To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders. In addition, our Series A Preferred Stock is entitled to price-based anti-dilution protection in connection with certain financings, which has the potential to further dilute our other stockholders.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Pursuant to our 2010 Equity Incentive Plan, our Board of Directors is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2010 Equity Incentive Plan increases each year by an amount equal to the lesser of 4% of all shares of our capital stock outstanding as of January 1st of each year, 2,000,000 shares, or such lesser number as determined by our Board of Directors. On January 1, 2012, an additional 1,257,095 shares became available for future issuance under our 2010 Equity Incentive Plan in accordance with the annual increase. In addition, we have reserved 494,422 shares of our common stock for issuance under our 2010 Employee Stock Purchase Plan. The number of shares eligible for purchase increases as of January 1st of each year in an amount equal to the shares purchased under the plan in the preceding year. As such, on January 1, 2012, an additional 21,910 shares became available for future issuance under our 2010 Employee Stock Purchase Plan.

**Table of Contents*****The Series A Preferred Stock contains covenants that may limit our business flexibility.***

For so long as at least 37.5% of the shares of Series A Preferred Stock originally issued to the investors at the closing of our Series A Preferred Stock financing in October 2012 are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Preferred Stock: (i) increase or decrease the authorized number of shares of Series A Preferred Stock; (ii) authorize, create, issue or obligate us to issue (by reclassification, merger or otherwise) any security (or any class or series thereof) or any indebtedness, in each case that has any rights, preferences or privileges senior to, or on a parity with, the Series A Preferred Stock, or any security convertible into or exercisable for any such security or indebtedness, subject to limited exceptions for certain debt transactions; (iii) amend our certificate of incorporation or the certificate of designation of the Series A Preferred Stock, in each case in a manner that adversely affects the rights, preference or privileges of the Series A Preferred Stock; (iv) redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of common stock or preferred stock; provided, however, that this restriction shall not apply to (A) the redemption of rights issued pursuant to any poison pill rights plan or similar plan adopted by us after the closing of the Series A Preferred Stock financing or (B) the repurchases of stock from former employees, officers, directors or consultants who performed services for us in connection with the cessation of such employment or service pursuant to the terms of existing agreements with such individuals; (v) declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (A) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Preferred Stock is made pursuant to the certificate of designation or (B) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with the implementation of a poison pill rights plan or similar plan by us; (vi) authorize or approve any increase to the number of aggregate shares of capital stock reserved for issuance pursuant to stock option, stock purchase plans or other equity incentive plans such that the total aggregate number of shares issued under such plans and reserved for issuance under such plans (on an as-converted basis) exceeds the number of shares issued and reserved for issuance under such plans (on an as-converted basis) on the date of the closing of the Series A Preferred Stock financing by more than 20% (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like), provided that any increases resulting solely from the annual increases resulting from the evergreen provisions of equity incentive plans in effect on the date of the closing of the Series A Preferred Stock financing shall not be subject to this restriction and shall not be included for purposes of determining whether such 20% increase has occurred; (vii) issue stock or other equity securities of any subsidiary (other than to us or another of our wholly-owned subsidiaries or declare or pay any dividend or other distribution of cash, shares or other assets or redemption or repurchase of shares of any subsidiary; or (viii) incur any secured indebtedness other than certain limited debt transactions. There is no guarantee that the holders of the Series A Preferred Stock would approve any such restricted action, even where such an action would be in the best interests of our stockholders. Any failure to obtain such approval could harm our business and result in a decrease in the value of our common stock.

***Anti-takeover provisions in our charter and bylaws and in Delaware law could prevent or delay acquisition bids for us that you might consider favorable and could entrench current management.***

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may deter, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders. In addition, our restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our restated certificate of incorporation and bylaws:

authorize the issuance of blank check preferred stock that could be issued by our Board of Directors to thwart a takeover attempt;

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

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

require that directors only be removed from office for cause;

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

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

limit who may call special meetings of stockholders;



**Table of Contents**

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

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

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

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

**USE OF PROCEEDS**

We will not receive any proceeds from the sale of shares of our common stock by the selling stockholders. A portion of the shares covered by this prospectus are issuable upon exercise of Warrants to purchase our Series A Preferred Stock. The exercise price of a Warrant is \$44.00 per share of Series A Preferred Stock. Upon any exercise of a Warrant for cash, the exercising selling stockholders would pay us the exercise price of the applicable Warrants. In the event all of the Warrants are exercised for cash, we would receive approximately \$13,200,000. Under certain conditions set forth in the Warrants, the Warrants are exercisable on a cashless basis. If a Warrant is exercised on a cashless basis, we would not receive any cash payment from the selling stockholders upon exercise of such Warrant. Instead, the applicable selling stockholder would satisfy its obligation to pay the exercise price through a formula-based transfer of Warrant shares to us. There is no certainty that we will ever receive any proceeds from the exercise of the Warrants. We intend to use any proceeds from the exercise of Warrants for general corporate and working capital purposes.

The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in selling the common stock covered by this prospectus. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares of common stock covered by this prospectus, including, without limitation, all registration and filing fees and expenses of our counsel and our accountants.

**DIVIDEND POLICY**

We have not declared or paid cash dividends on our common stock since our inception. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our Board of Directors, subject to compliance with certain covenants under our credit facilities (including our currently outstanding Credit Facility), which restrict or limit our ability to declare or pay dividends, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our Board of Directors may deem relevant. Consequently, stockholders will need to sell shares of our common stock to realize a return on their investment, if any.

**MARKET PRICE OF COMMON STOCK**

Our common stock has traded on the NASDAQ Global Market under the symbol `ALIM` since April 21, 2010. The table below presents the high and low daily closing sales prices of our common stock, as reported by the NASDAQ Global Market, for each quarter during 2010 and 2011 and for the period from January 1, 2012 through November 13, 2012.

	High	Low
<b>2010</b>		
April 21, 2010 through June 30, 2010	\$ 11.06	\$ 7.44
Three months ended September 30, 2010	\$ 9.57	\$ 6.62
Three months ended December 31, 2010	\$ 12.19	\$ 9.87
<b>2011</b>		

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Three months ended March 31, 2011	\$ 10.77	\$ 6.93
Three months ended June 30, 2011	\$ 8.90	\$ 7.53
Three months ended September 30, 2011	\$ 9.00	\$ 6.64
Three months ended December 31, 2011	\$ 8.52	\$ 1.17
<b>2012</b>		
Three months ended March 31, 2012	\$ 4.37	\$ 1.24
Three months ended June 30, 2012	\$ 3.44	\$ 2.38
Three months ended September 30, 2012	\$ 3.08	\$ 2.14
October 1, 2012 through November 13, 2012	\$ 2.79	\$ 2.29

As of November 13, 2012, we had approximately 31,527,756 shares of common stock outstanding held by approximately 42 record owners. The last reported sale price on the NASDAQ Global Market on November 13, 2012 was \$2.29.

**Table of Contents****SELLING STOCKHOLDERS**

This prospectus relates to the resale of our common stock issuable to the selling stockholders upon conversion of our Series A Preferred Stock and upon exercise of the Warrants or issuable upon conversion of the Series A Preferred Stock issuable upon exercise of the Warrants. In addition, we are registering an additional 3,093,175 shares of common stock that may become issuable to the selling stockholders upon the conversion or exercise, as applicable, of the Series A Preferred Stock and Warrants in the event that the conversion price of the Series A Preferred Stock is reduced to \$2.66 because of the occurrence or non-occurrence of certain events, as discussed in the section of this prospectus entitled "Description of Capital Stock - Series A Preferred Stock."

The following table, based upon information currently known by us, sets forth as of November 1, 2012: (i) the number of shares held of record or beneficially by the selling stockholders as of such date and assuming conversion or exercise (as the case may be) of all Series A Preferred Stock and Warrants held by the selling stockholders as of such date, (ii) the number of shares that may be offered under this prospectus, and (iii) a footnote reference to any material relationship between us and the applicable selling stockholder. The table below includes the additional shares of common stock that may become issuable to the selling stockholders upon the conversion or exercise, as applicable, of the Series A Preferred Stock and Warrants in the event that the conversion price of the Series A Preferred Stock is reduced to \$2.66 because of the occurrence or non-occurrence of certain events.

The percentages of common stock owned after the offering are based on 31,527,756 shares of our common stock outstanding on November 1, 2012. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. In computing the number of shares owned and the percentage ownership of a selling stockholder, shares of common stock that could be issued upon the exercise and conversion (if applicable) of outstanding Series A Preferred Stock, the Warrants or other warrants, options or other rights held by that selling stockholder that are currently exercisable or exercisable within 60 days of November 1, 2012 are considered outstanding. However, such shares are not included in the shares outstanding as of November 1, 2012 when computing the percentage ownership of each other selling stockholder. Unless otherwise noted, each person or group identified possesses sole voting and investment power with respect to the shares, subject to community property laws where applicable. The inclusion of any securities in this table does not constitute an admission of beneficial ownership for the person named below.

<b>Selling Stockholder</b>	<b>Beneficial Ownership Prior to this Offering (1),(2)</b>	<b>Shares that may be Offered and Sold Hereby (1),(3)</b>	<b>Beneficial Ownership After this Offering</b>	<b>% Holding After Completion of this Offering</b>
Palo Alto Investors, LLC (4)	15,364,307	11,729,323	3,634,984	8.4 %
Sofinnova Venture Partners VIII, L.P. (5)	4,887,218	4,887,218	0	*
Growth Equity Opportunities Fund III, LLC (6)	2,932,330	2,932,330	0	*
<b>Total</b>	<b>23,183,855</b>	<b>19,548,871</b>	<b>3,634,984</b>	<b>7.1%</b>

\* Less than 1.0%

- (1) The number of shares offered by the selling stockholders in the table above reflects the shares issuable upon conversion of our Series A Preferred Stock and upon exercise of the Warrants or issuable upon conversion of the Series A Preferred Stock issuable upon exercise of the Warrants in the event that the conversion price of the Series A Preferred Stock is adjusted to \$2.66 as a result of the occurrence or non-occurrence of certain events. In the event that the shares of Series A Preferred Stock (including the shares of Series A Preferred Stock issuable upon exercise of the Warrants) were voluntarily converted by the selling stockholders as of the date of this prospectus (based on the applicable conversion price of \$3.16), the selling stockholders would beneficially own the following number of shares of common stock:

<b>Selling Stockholder</b>	<b>Beneficial Ownership Prior to this Offering</b>
Palo Alto Investors, LLC	13,508,401
Sofinnova Venture Partners VIII, L.P.	4,113,924

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Growth Equity Opportunities Fund III, LLC	2,468,354
<b>Total</b>	20,090,679

**Table of Contents**

- (2) Pursuant to the terms of the Series A Preferred Stock, the Series A Preferred Stock will vote together with our common stock on an as converted basis based on a deemed conversion price of \$2.95 (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Preferred Stock). As such, as of the date hereof, assuming the selling stockholders exercised their Warrants in full, the selling stockholders would be entitled to vote the following number of shares of our common stock at any meeting of our stockholders:

Selling Stockholder	Voting Power Prior to this Offering
Palo Alto Investors, LLC	14,211,255
Sofinnova Venture Partners VIII, L.P.	4,406,779
Growth Equity Opportunities Fund III, LLC	2,644,067
<b>Total</b>	<b>21,262,101</b>

- (3) Assumes that (a) the selling stockholders dispose of all the shares of common stock covered by this prospectus and do not acquire or dispose of any additional shares of common stock and (b) that there is no price-based anti-dilution adjustment to the conversion rate of the Series A Preferred Stock. The selling stockholders are not representing, however, that any of the shares covered by this prospectus will be offered for sale, and the selling stockholders reserve the right to accept or reject, in whole or in part, any proposed sale of shares. We have entered into registration rights agreements with the selling stockholders pursuant to we are required to file a resale registration statement for the shares underlying the Series A Preferred Stock and Warrants to enable the resale of such shares by such selling stockholders on a delayed or continuous basis under Rule 415 of the Securities Act.
- (4) Includes 1,170,492 shares held by Micro Cap Partners, L.P. (Micro Cap), 5,736,262 shares held by Palo Alto Healthcare Master Fund, L.P. (Healthcare Master) and 8,457,553 shares held by Palo Alto Healthcare Master Fund II, L.P. (Healthcare Master II and collectively with Micro Cap and Healthcare Master, PAI). Palo Alto Investors, Inc. (PAI Corp) is the manager of Palo Alto Investors, LLC (PAI LLC). William Leland Edwards is the controlling shareholder of PAI Corp. Dr. Anthony Joonkyoo Yun is the President of PAI LLC and PAI Corp. PAI LLC, PAI Corp, Mr. Edwards and Dr. Yun filed Schedule 13G jointly, but not as members of a group, and each of them expressly disclaims membership in a group. Each of PAI LLC, PAI Corp, Mr. Edwards and Dr. Yun disclaims beneficial ownership of the shares except to the extent of their respective pecuniary interest therein. In addition, Healthcare Master II should not be construed as a member of a group, and it disclaims that it is a beneficial owner. PAI LLC is a registered investment adviser and is the general partner and investment adviser of Healthcare Master II and other investment limited partnerships, and is the investment adviser to other investment funds. PAI LLC's clients have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, the share No individual client, other than Healthcare Master II, separately holds more than five percent of the outstanding shares of the Company. PAI purchased units consisting of an aggregate of 600,000 shares of our Series A Preferred Stock and Warrants to purchase an additional 180,000 shares of Series A Preferred Stock from us on October 2, 2012 in our Series A Preferred Stock financing. In connection with such purchase, we entered into a Registration Rights Agreement with PAI and the other purchasers.

**Table of Contents**

- (5) The securities are owned directly by Sofinnova Venture Partners VIII, L.P. (SVP VIII). Sofinnova Management VIII, L.L.C. (SM VIII), the general partner of SVP VIII, and Garheng Kong, Michael Powell, and James I. Healy, the managing members of SM VIII, may be deemed to have shared voting and dispositive power over the shares owned by SVP VIII. Such persons and entities disclaim beneficial ownership over the shares owned by SVP VIII except to the extent of any pecuniary interest therein. SVP VIII purchased units consisting of an aggregate of 250,000 shares of our Series A Preferred Stock and Warrants to purchase an additional 75,000 shares of Series A Preferred Stock from us on October 2, 2012 in our Series A Preferred Stock financing. In connection with such purchase, we entered into a Registration Rights Agreement with SVP VIII and the other purchasers.
- (6) The securities are owned directly by Growth Equity Opportunities Fund III, LLC (GEO). New Enterprise Associates 14, L.P. (NEA 14), which is the sole member of GEO; NEA Partners 14, L.P. (NEA Partners 14), which is the sole general partner of NEA 14; NEA 14 GP, LTD (NEA 14 GP), which is the sole general partner of NEA Partners 14; and Michael James Barrett, Peter J. Barris, Forest Baskett, Ryan D. Drant, Anthony A. Florence, Jr., Patrick J. Kerins, Krishna S. Kolluri, David M. Mott, Scott D. Sandell, Peter W. Sonsini, Ravi Viswanathan and Harry R. Weller (collectively, the Directors). The Directors are the individual directors of NEA 14 GP. GEO, NEA 14, NEA Partners 14, NEA 14 GP and the Directors are sometimes referred to collectively herein as the NEA Reporting Persons. Each NEA Reporting Person disclaims beneficial ownership of such shares of common stock except for the shares, if any, such NEA Reporting Person holds of record. GEO purchased units consisting of an aggregate of 150,000 shares of our Series A Preferred Stock and Warrants to purchase an additional 45,000 shares of Series A Preferred Stock from us on October 2, 2012 in our Series A Preferred Stock financing. In connection with such purchase, we entered into a Registration Rights Agreement with GEO and the other purchasers.

**ABOUT 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, which has received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain, for the treatment of vision impairment associated with diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN has not been approved by the U.S. Food and Drug Administration (FDA).

We submitted a New Drug Application (NDA) in June 2010 for the low dose of ILUVIEN in the U.S. with the U.S. Food and Drug Administration (FDA), followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain under the EU's Decentralized Procedure (DCP) in July 2010 with the United Kingdom acting as the Reference Member State (RMS). The RMS is responsible for coordinating the review and approval process between itself and the other involved countries, or Concerned Member States.

In November 2010, we received a Preliminary Assessment Report (PAR) from the RMS and in December 2010, we received a Complete Response Letter (CRL) from the FDA regarding our respective registration filings. The primary concerns expressed in both the PAR and the CRL centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of the data from our two Phase 3 pivotal clinical trials (collectively, the FAME™ Study) through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filings.

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

In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its then current form stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. At the time, the FDA indicated that we would need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. During the second quarter of 2012, we met with the FDA in an effort to gain a better understanding of the regulatory path for ILUVIEN in the U.S. Based upon this meeting, we plan to submit to the FDA a response to the second CRL to include additional analysis of the benefits and risks of ILUVIEN based upon clinical data available from the FAME Study.

---

## **Table of Contents**

After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a Final Assessment Report (FAR) from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the DCP was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries. During the national phase, labeling in each country's local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients with chronic DME. ILUVIEN has received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies.

We currently plan to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and are pursuing pricing and reimbursement in those countries. In July 2012, we received a letter from Germany's Federal Joint Committee indicating that the automatic obligation to submit a dossier on ILUVIEN, per the Arzneimittelmarkt-Neuordnungsgesetz law, would not be necessary, and that a benefit assessment would not be required. This allows us to launch ILUVIEN in Germany without price restriction. In August 2012, we received an appraisal consultation document from the United Kingdom's National Institute for Health and Clinical Excellence (NICE) with a preliminary recommendation that ILUVIEN is not recommended given the cost of £5500 and other variables included in our submission to NICE. This document is not NICE's final guidance and the recommendation may change prior to NICE's final appraisal determination (FAD). We provided further comments on the draft appraisal and additional data in advance of the second appraisal meeting that was held in October 2012. We are currently awaiting additional feedback from NICE.

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

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of September 30, 2012, we have accumulated a deficit of \$225.8 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

complete the clinical development and registration of ILUVIEN;

prepare for the anticipated commercial launch of ILUVIEN in the EU in early 2013, at the earliest;

continue to seek regulatory approval of ILUVIEN in the U.S. and other jurisdictions;

evaluate the use of ILUVIEN for the treatment of other diseases; and

advance the clinical development of other product candidates either currently in our pipeline, or that we may license or acquire in the future.

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

As of September 30, 2012, we had approximately \$17.4 million in cash and cash equivalents.

We plan to proceed with the direct commercialization of ILUVIEN in the United Kingdom, France and Germany in 2013. We believe that we have sufficient funds available to fund our operations beyond the projected commercialization of ILUVIEN in Germany, the United Kingdom and France. We do not expect the generation of revenue until 2013, and therefore do not expect to have positive cash flow from operations until 2014. If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

In April 2012, we established a wholly-owned subsidiary in the United Kingdom, Alimera Sciences Limited, to facilitate transacting business in the EU. As of November 13, 2012 Alimera Sciences Limited had three employees.

### **Business Strategy**

We are presently focused on diseases affecting the back of the eye, or retina, because we believe these diseases are not well treated with current therapies and represent a significant market opportunity. Our business strategy is to:

*Maximize the Commercial Success of ILUVIEN.* We intend to commercialize ILUVIEN, initially in Germany, the United Kingdom and France directly, and in other countries directly or with a partner.

*Pursue FDA Approval for ILUVIEN.* Alimera met with the FDA in June 2012 to discuss the CRL. Based on that meeting, Alimera intends to resubmit its NDA for ILUVIEN. If approved by the FDA, we intend to directly commercialize ILUVIEN to retina centers in the U.S.



---

## **Table of Contents**

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

*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 with retinal specialists to assess the safety and efficacy of ILUVIEN for the treatment of these diseases of the eye.

*Expand Our Ophthalmic Product Pipeline.* We believe there are further unmet medical needs in the treatment of ophthalmic diseases. Toward that end, we intend to leverage our management's expertise and its broad network of relationships to continue to evaluate in-licensing and acquisition opportunities for compounds and technologies with potential treatment applications for diseases affecting the eye.

### **Disease Overview and Market Opportunity**

#### ***Diabetes and Diabetic Retinopathy***

Diabetes mellitus, with its systemic and ophthalmic complications, represents a global public health threat. The estimated prevalence of diabetes worldwide in 2011 increased to 366 million people and is expected to increase to 522 million people by 2030. In the EU countries in which ILUVIEN has received or been recommended for marketing authorization, according to the International Diabetes Foundation, Diabetes Atlas, Fifth Edition, there are approximately 19.0 million diabetics of whom we estimate approximately 1.1 million suffer from DME.

According to the CDC, the number of Americans diagnosed with diabetes has increased from approximately 8.1 million people in 1994 to approximately 18.8 million people in 2010. In addition to diagnosed cases, the CDC estimates that an additional 7.0 million Americans with diabetes are currently undiagnosed and are therefore not being monitored and treated to control their disease and prevent systemic and ophthalmic complications. With better diagnostics and improved public awareness, the number of persons diagnosed with and being treated for diabetes is expected to increase.

All patients with diabetes are at risk of developing some form of diabetic retinopathy, an ophthalmic complication of diabetes with symptoms including the swelling and leakage of blood vessels within the retina or the abnormal growth of new blood vessels on the surface of the retina. According to the American Diabetes Association, diabetic retinopathy causes approximately 12,000 to 24,000 new cases of blindness in the U.S. each year; making diabetes the leading cause of blindness in adults aged 20 to 74. Diabetic retinopathy can be divided into either non-proliferative or proliferative retinopathy. Non-proliferative retinopathy (also called background retinopathy) develops first and causes increased capillary permeability, micro aneurysms, hemorrhages, exudates, macular ischemia and macular edema (thickening of the retina caused by fluid leakage from capillaries). Proliferative retinopathy is an advanced stage of diabetic retinopathy which, in addition to characteristics of non-proliferative retinopathy, results in the growth of new blood vessels. These new blood vessels are abnormal and fragile, growing along the retina and along the surface of the clear, vitreous gel that fills the inside of the eye. By themselves, these blood vessels do not cause symptoms or vision loss. However, these blood vessels have thin, fragile walls that are prone to leakage and hemorrhage.

Diabetic macular edema (DME) is a common ocular complication of diabetes mellitus. As the incidence of diabetes continues to increase worldwide, the incidence of DME and other complications is predicted to rise as well. A majority of patients who suffer from diabetes do not meet glycemic (glucose or blood sugar) targets, resulting in chronic hyperglycemia (elevated levels of glucose in the blood). This, in turn, leads to the development of micro-vascular complications, the most common of which is diabetic retinopathy. Diabetic retinopathy is the leading cause of new-onset blindness in patients aged 20 to 70, with DME accounting for a majority of vision loss in patients with diabetic retinopathy. Vision loss from DME affects both patients and caregivers, who must assist the patient with doctor visits.

#### ***Diabetic Macular Edema***

DME, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition is called DME. The onset of DME is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision. We estimate there are approximately 1.1 million patients suffering from DME in the seven EU countries in which ILUVIEN has received or been recommended for marketing authorization.



---

## **Table of Contents**

### **Limitations of Current Treatments for DME**

The current standard of care for DME is laser photocoagulation, often combined with the use of both approved and off-label intravitreal injections of anti-VEGF agents and corticosteroid therapies. Laser photocoagulation is a retinal procedure in which a laser is used to apply a burn or a pattern of burns to cauterize leaky blood vessels to reduce edema. Visual acuity gains are seen with this therapy, although results are highly variable and it may take more than eight months for median visual acuity to improve. Further, this is a destructive procedure that has undesirable side effects including partial loss of peripheral and night vision. As a result of these side effects and a desire for improved visual outcomes, retinal specialists have supplemented laser photocoagulation with alternate therapies, including injections of corticosteroids and anti-VEGF agents.

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

There are no ophthalmic drug therapies other than Lucentis, which was approved by the FDA for treatment of DME in the U.S. Lucentis has recently been approved by the European Medicines Agency (EMA) for use in DME in the EU, and is the only ophthalmic drug therapy approved to treat DME in the seven EU countries in which ILUVIEN has received or been recommended for marketing authorization.

## **ILUVIEN**

### ***Overview***

Our most advanced product candidate is ILUVIEN, an intravitreal implant providing a therapeutic effect for up to 36 months in the treatment of vision impairment associated with DME by delivering sustained sub-microgram levels of Fluocinolone Acetonide (FAc), a non-proprietary corticosteroid with demonstrated efficacy in the treatment of ocular disease. Intravitreal refers to the space inside the eye behind the lens that contains the jelly-like substance called vitreous. DME is a disease of the retina which affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN is implanted in the back of the patient's eye in a non-surgical procedure using an implantation device (the ILUVIEN applicator) employing a 25-gauge needle, which allows for a self-sealing wound. This implantation is very similar to the administration of an intravitreal injection, a procedure commonly employed by retinal specialists. If approved, in the U.S. the non-surgical procedure will be performed in the retinal specialist's office, while in the EU it will be performed in a hospital or private clinic setting. Based on data from our FAME Study, we believe ILUVIEN improves vision while mitigating side effects commonly associated with the use of corticosteroids for the following reasons:

*ILUVIEN delivers FAc.* The active pharmaceutical ingredient in ILUVIEN is FAc, which has demonstrated efficacy in the treatment of DME in our FAME Study.

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

*ILUVIEN delivers a therapeutic effect for up to 36 months.* In vitro release kinetics have shown that ILUVIEN provides sustained delivery of sub-microgram levels of FAc over time. Based on the results of the FAME Study, ILUVIEN provides a sustained, therapeutic effect in the treatment of DME through 36 months.

*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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

*ILUVIEN is implanted using a 25-gauge needle.* Needle gauge determines the size of the wound that is created. ILUVIEN is implanted into the eye in a non-surgical procedure using a 25-gauge needle, which results in a wound that is small enough to seal itself after the needle is removed, thus eliminating the need for additional intervention. Using a larger needle would require a more complicated implantation procedure to create a self-sealing wound.

### ***Fluocinolone Acetonide***

Fluocinolone acetonide, a non-proprietary corticosteroid, is the active compound in ILUVIEN and a member of the class of steroids known as corticosteroids. Corticosteroids have demonstrated a range of pharmacological actions, including inhibition of inflammation, inhibition of leukostasis, up regulation of occludin, inhibition of the release of certain inflammatory cytokines and suppression of VEGF secretion. These pharmacological actions have the potential to treat various ocular conditions, including DME, dry AMD, wet AMD and RVO. However, FAc shares many of the same side effects as other corticosteroids currently available for intraocular use, including increased IOP, which may increase the risk of glaucoma, and the acceleration of cataract formation.

---

## **Table of Contents**

### ***ILUVIEN is Positioned to Mitigate IOP Increases***

Based on our analysis of the final clinical readout from our FAME Study through month 36, it appears that ILUVIEN mitigates the incidence of steroid-induced IOP elevations commonly associated with the intraocular use of corticosteroids, which we believe is due to its implantation location in the posterior portion of the eye.

The side effect of increased IOP associated with corticosteroids in certain people is directly related to the interaction of corticosteroids with the cells of the trabecular meshwork, a specialized tissue that acts as a filter located in the front of the eye. In some individuals, corticosteroids result in a build-up of debris in this meshwork, increasing resistance to outflow, and increasing pressure inside the eye. The positioning of ILUVIEN allows it to take advantage of the posterior flow of fluid away from the trabecular meshwork of the eye. We believe this positioning minimizes the anterior chamber exposure to FAc and mitigates the incidence of IOP elevations.

### ***ILUVIEN Provides Sustained Sub-Microgram Delivery***

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

### ***The ILUVIEN Applicator***

We developed a custom, proprietary applicator for ILUVIEN, which includes improvements over the modified syringe used during our FAME Study. These improvements include ergonomic design features, a transparent window to visually confirm ILUVIEN's presence within the applicator, a longer needle and markings to guide retinal specialists to the proper insertion point. As was the case with the modified syringe used during our FAME Study, the ILUVIEN applicator uses a 25-gauge needle, which results in a wound that is small enough to seal itself after ILUVIEN has been implanted into the back of the eye and the needle has been removed. We believe that a 25-gauge needle is the smallest needle capable of delivering ILUVIEN into the back of eye. If approved, in the U.S. the non-surgical procedure will be performed in the retinal specialist's office, while in Europe it will be performed in a hospital or private clinic setting.

## **ILUVIEN Clinical Development Program**

### ***Development Program for the Treatment of DME***

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

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

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

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its current form stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. The FDA has indicated that we will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. During the second quarter of 2012, we met with the FDA in an effort to gain a better understanding of the regulatory path for ILUVIEN in the U.S. Based upon this meeting, we plan to submit to the FDA a response to the second CRL to include additional analysis of the benefits and risks of ILUVIEN based upon clinical data available from the FAME Study.

## **Table of Contents**

After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a FAR from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries. During the national phase labeling in each country's local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients with chronic DME.

### **ILUVIEN for Other Diseases of the Eye**

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

*Dry AMD.* Dry AMD patients account for 90% of AMD patients, with the greatest unmet need among these patients being a treatment for geographic atrophy (GA) for which there are currently no treatments available. Pre-clinical studies in two established rat models reported at the Association for Research in Vision and Ophthalmology meetings in 2006, 2007 and 2008, described the efficacious effects of a miniaturized version of ILUVIEN in retinal degeneration. Based on these results, we began enrollment of a pilot study in December 2008 to assess the safety and efficacy of ILUVIEN in patients with bilateral GA secondary to AMD. Our Phase 2 study (the MAP GA Trial) is comparing ILUVIEN and a higher dose of ILUVIEN to a sham injection in patients with bilateral GA secondary to AMD. The change from baseline in the size of GA will be assessed over time.

*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) was initiated to assess the safety and efficacy of ILUVIEN and a higher dose in conjunction with Lucentis in patients with wet AMD. The study involved patients who had been treated with Lucentis for at least six months and whose visual acuity has plateaued prior to enrollment. At baseline, subjects received either ILUVIEN or a higher dose of ILUVIEN and an injection of Lucentis. Subjects receive additional Lucentis injections during the study only if subretinal or intraretinal fluid persists. Outcome measures include the change from baseline visual acuity at six months, and mean number of injections of Lucentis over the six-month study period versus the six months prior to study entry. The study was suspended after the enrollment of six patients in order to assess the structure of the trial.

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

### **ILUVIEN Registration Plan**

#### ***U.S. Regulatory Requirements and Status***

In the U.S., the FDA's requirement for the clinical evidence of the effectiveness of ILUVIEN for the treatment of DME from our FAME Study was based on two time-point comparisons. The primary efficacy variable was the proportion of patients who had visual acuity improvement in their study eye, referred to as the responder rate, based on the change from baseline in Best Corrected Visual Acuity (BCVA) as measured on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart. BCVA improvement is defined as an increase from baseline of 15 or more letters in BCVA as measured on the ETDRS eye chart. Our primary efficacy endpoint was defined at month 24 of our FAME Study using this variable. Based on the month 24 clinical readout, ILUVIEN demonstrated efficacy in the treatment of DME in our FAME Study. Then, as required by the FDA, another numerical comparison of the responder rates at months 18 and 24 of our FAME Study was conducted to

demonstrate that the responder rates at month 24 are numerically greater than or equal to the month 18 responder rates. Patients enrolled in our FAME Study were followed for 36 months. Although we submitted the month 24 results to the FDA in our NDA for ILUVIEN for approval, we received a CRL from the FDA in December 2010, which, among other things, requested the additional 12 months of clinical data from the completed FAME Study through month 36 for review. The primary concerns expressed in the CRL centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of our FAME Study data through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filing. We submitted our response to the CRL to the FDA in May 2011, including additional safety and efficacy data through the final readout at month 36 of the FAME Study with an emphasis on the chronic DME subgroup. In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its current form stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. At the time, the FDA indicated that we would need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. During the second quarter of 2012, we met with the FDA in an effort to gain a better understanding of the regulatory path for ILUVIEN in the U.S. Based upon this meeting, we plan to submit to the FDA a response to the second CRL to include additional analysis of the benefits and risks of ILUVIEN based upon clinical data available from the FAME Study.



---

**Table of Contents*****Regulatory Requirements in Other Jurisdictions***

There are no specific guidance documents for the clinical development of ophthalmic drug products outside of the U.S. for the treatment of diabetic retinopathy or DME. We met with regulatory authorities in Canada, Germany, Spain, France, Portugal and the United Kingdom and presented our overall preclinical, technical, clinical and statistical development plans which included the use of visual function as the primary efficacy endpoint and an anatomical measure as a co-primary efficacy endpoint or key secondary efficacy endpoint. In July 2010, we submitted a data package regarding the efficacy and safety of ILUVIEN through the end of the FAME Study to the applicable regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a FAR from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries. During the national phase labeling in each country's local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients with chronic DME. ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies.

We currently plan to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and are pursuing pricing and reimbursement in those countries. In July 2012, we received a letter from Germany's Federal Joint Committee indicating that the automatic obligation to submit a dossier on ILUVIEN, per the Arzneimittelmarkt-Neuordnungsgesetz law, would not be necessary, and that a benefit assessment would not be required. This allows us to launch ILUVIEN in Germany without price restriction. In August 2012, we received an appraisal consultation document from the United Kingdom's National Institute for Health and Clinical Excellence (NICE) with a preliminary recommendation that ILUVIEN is not recommended given the cost of £5500 and other variables included in our submission to NICE. This document is not NICE's final guidance and the recommendation may change prior to NICE's final appraisal determination (FAD). We provided further comments on the draft appraisal and additional data in advance of the second appraisal meeting that was held in October 2012. We are currently awaiting additional feedback from NICE.

***Commercialization***

ILUVIEN is the only single treatment drug therapy providing a sustained therapeutic effect of up to 36 months in the treatment of patients with chronic DME that has received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain. ILUVIEN has not been approved by the FDA. We intend to continue pursuit of approval for ILUVIEN in the U.S. for use in the treatment of DME and other diseases of the retina. In the seven EU countries in which ILUVIEN has received or been recommended for marketing authorization for the treatment of DME, we intend to pursue approval of ILUVIEN for use in the treatment of other diseases of the retina. In addition, we intend to pursue approval in other countries of the EU and certain jurisdictions around the world for the use of ILUVIEN in the treatment of DME and other diseases of the retina. Our commercialization strategy is to establish ILUVIEN as a leading therapy for the treatment of vision loss in chronic DME patients and subsequently for other indications for which ILUVIEN proves safe and effective. We currently plan to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and are pursuing pricing and reimbursement in those countries. If approved in the U.S., we intend to distribute ILUVIEN to physicians and retina centers through specialty distributors and pharmacies. Although we anticipate ILUVIEN being administered as a standalone therapy, we do not foresee the use of ILUVIEN as precluding the administration of other therapies in conjunction with ILUVIEN. Our commercialization strategy in any jurisdiction is subject to and dependent upon the regulatory approval of ILUVIEN in such jurisdiction.

***Sales and Marketing***

We are led by an executive team with extensive commercialization expertise with ophthalmic products including the launch and management of Visudyne, a drug product sponsored by Novartis and the first pharmacological treatment indicated for the treatment of wet AMD.

We plan to proceed with the direct commercialization of ILUVIEN in Germany, the United Kingdom and France in 2013. Currently we are engaged, with the assistance of local consultants, in the pricing and reimbursement process in these countries and are developing related market access plans. We plan to create a commercial infrastructure of approximately fifty people in management and the field combined including sales representatives, market access personnel and medical science liaisons primarily using outsourced third party providers.

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 ILUVIEN in Germany, the United Kingdom and France.



---

## **Table of Contents**

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

### ***Manufacturing***

We do not have, and do not intend to establish an in-house manufacturing capability for our products and as a result we will continue to depend heavily on third-party contract manufacturers to produce and package our products. We rely on these manufacturers to produce active pharmaceutical ingredients, or APIs, and finished drug products in accordance with current Good Manufacturing Practices (cGMPs) and all other applicable laws and regulations. We anticipate that we will rely on contract manufacturers to develop and manufacture our products for commercial sale. We maintain agreements with potential and existing manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

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

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

In February 2010, we entered into a commercial manufacturing agreement with Alliance whereby Alliance agreed to manufacture and package ILUVIEN for us at its Irvine, California facility. Certain equipment at Alliance's facility was purchased by us and is used solely for the purpose of allowing Alliance to manufacture and package ILUVIEN for us. Under the agreement, we are also responsible for supplying Alliance with the ILUVIEN applicator and the API. Pursuant to our agreement with Alliance, we have agreed to order from Alliance at least 80% of our total requirements for new units of ILUVIEN in the U.S., Canada and Europe in a calendar year; provided that Alliance is able to fulfill our supply requirements and is not in breach of its agreements or obligations to us. Unless terminated earlier in accordance with the provisions thereof, our agreement with Alliance has an initial term of six years and will automatically renew for successive terms of one year unless either party delivers written notice of non-renewal to the other at least 12 months prior to the end of the then current term.

In our NDA and Marketing Authorization Application (MAA) for ILUVIEN, we provided the FDA and the EU regulatory authorities with a completed process validation package on three lots which described manufacturing and packaging procedures and in-process controls. Validation was conducted on small scale, 400 unit batches but in the U.S., this can be scaled up to 10 times. However, in the EU, the manufacturing process for ILUVIEN is considered a non-standard process. In order to scale-up to a larger batch size, a new validation package has to be submitted as a variation to the MAA. Three 800 unit batches have been completed at Alliance and we expect to submit a variation to the MAA in the fourth quarter of 2012 in order to fulfill this requirement in the EU.

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

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



---

## **Table of Contents**

### **Competition**

The development and commercialization of new drugs and drug delivery technologies is highly competitive. We will likely face competition with respect to ILUVIEN and any products we may develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide, many of whom have substantially greater financial and other resources than we do. In the countries in which ILUVIEN has been recommended for marketing authorization or becomes approved for use in the treatment of DME, it will compete against laser photocoagulation and the use of anti-VEGF and corticosteroid injections, or other therapies that may be approved in the future. There are other companies working to develop other drug therapies and sustained delivery platforms for DME and other indications. We believe that the following companies provide potential competition to ILUVIEN:

Genentech Inc.'s (Genentech) products Lucentis (ranibizumab injection) and Avastin (bevacizumab) are both anti-VEGF antibodies. Lucentis is currently approved for the treatment of patients with neovascular wet AMD and the treatment of macular edema following RVO, and the treatment of DME in the U.S. and the EU and has recently received marketing authorization by the EMA for use in DME in Europe. Avastin, an oncology product, is used by retinal specialists in both the U.S. and the EU in the treatment of numerous retinal diseases but is not indicated for any ophthalmic use. Genentech is a wholly-owned member of the Roche Group.

Allergan, Inc.'s (Allergan) product Ozurdex (dexamethasone intravitreal implant), is a bioerodable extended release implant that delivers the corticosteroid dexamethasone. Ozurdex is approved for macular edema following branch or central RVO and non-infectious uveitis affecting the posterior segment of the eye in both the U.S. and the EU. Ozurdex demonstrates peak efficacy at 60 days and duration of therapy of three to five months.

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

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

In addition, there are a number of other companies, including MacuSight, Inc., Thrombogenics NV and Novagali Pharma S.A., which are developing drug therapies or sustained delivery platforms for the treatment of ocular diseases. These companies are seeking to apply their technologies to ophthalmic indications in early stage clinical trials.

We believe we will be less likely to face generic competition for ILUVIEN because of the bioequivalency requirements of a generic form of ILUVIEN. A generic pharmaceutical competitor to ILUVIEN would need to establish bioequivalency through the demonstration of an equivalent pharmacodynamic endpoint in a clinical trial. We believe conducting such a clinical trial would be cost prohibitive and time consuming.

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

### **Licenses and Agreements**

#### ***pSivida US, Inc.***

In February 2005, we entered into an agreement with pSivida to obtain a worldwide exclusive license to develop and sell ILUVIEN for delivery to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis). This agreement also provides us with a worldwide non-exclusive license to develop and sell pSivida's proprietary delivery device to deliver other corticosteroids to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis) or to treat DME by delivering a compound to the back of the eye

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

through a direct delivery method through an incision required for a 25-gauge or larger needle. We do not have the right to develop and sell pSivida's proprietary delivery device in connection with indications for diseases outside of the eye or for the treatment of uveitis.

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

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

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

pay \$12.0 million to pSivida upon execution;

issue a \$15.0 million promissory note to pSivida;

forgive all outstanding development payments, penalties and interest as of the effective date, which totaled \$6.8 million;

continue responsibility for regulatory, clinical, preclinical, manufacturing, marketing and sales for the remaining development and commercialization of the products;

---

## **Table of Contents**

assume all financial responsibility for the development of the products and assume 80% of the commercialization costs of the products (instead of 50% as provided under the February 2005 agreement);

make an additional milestone payment of \$25.0 million after the first product has been approved by the FDA; and

share 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined by the agreement.

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

Our license rights to pSivida's proprietary delivery device could revert to pSivida if we (i) fail twice to cure our breach of an obligation to make certain payments to pSivida following receipt of written notice thereof; (ii) fail to cure other breaches of material terms of our agreement with pSivida within 30 days after notice of such breaches or such longer period (up to 90 days) as may be reasonably necessary if the breach cannot be cured within such 30-day period; (iii) file for protection under the bankruptcy laws, make an assignment for the benefit of creditors, appoint or suffer appointment of a receiver or trustee over our property, file a petition under any bankruptcy or insolvency act or have any such petition filed against us and such proceeding remains undismissed or unstayed for a period of more than 60 days; or (iv) we notify pSivida in writing of our decision to abandon our license with respect to a certain product using pSivida's proprietary delivery device. We were not in breach of our agreement with pSivida as of September 30, 2012.

### ***Emory University***

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

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

### ***Dainippon Sumitomo***

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

## **Government Regulation**

### ***General Overview***

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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



## Table of Contents

### *U.S.*

In the U.S., the FDA, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other federal and local statutes and regulations, subjects pharmaceutical products to review. If we do not comply with applicable regulations, the government may refuse to approve or place our clinical studies on clinical hold, refuse to approve our marketing applications, refuse to allow us to manufacture or market our products, seize our products, impose injunctions and monetary fines on us, and prosecute us for criminal offenses.

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

completion of preclinical laboratory and animal testing and formulation studies conducted under Good Laboratory Practices (GLP) regulations;

submission of an Investigational New Drug Application (IND) which must become effective before human clinical trials may begin;

completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational drug for its intended use; the studies must be conducted under Good Clinical Practices (GCP) regulations;

submission of a NDA or Biologics License Application (BLA);

satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess compliance with cGMP regulations; and

FDA review and approval of the NDA or BLA.

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

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. They are typically conducted in three sequential phases but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent Institutional Review Board before it can begin.

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

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

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

Once all the clinical studies are completed, the sponsor submits a NDA containing the results of non-clinical and clinical trials, together with detailed CMC information for the product and proposed labeling. It is also important that the sponsor provide a detailed description and justify the risk/benefit relationship of the drug to the patient. Under the Prescription Drug User Fee Act (PDUFA), the applicant has to pay a user fee, which was \$1.5 million in 2011, increasing to \$1.8 million in 2012.

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

---

## **Table of Contents**

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

resubmit the NDA addressing all deficiencies identified in the CRL;

withdraw the NDA without prejudice to a subsequent submission; or

request an opportunity for a hearing on the question of whether there are grounds for denying approval of the NDA. Within 60 days of the date of request, or within a different time period to which the applicant and the FDA agree, the FDA will either approve the NDA or refuse to approve the NDA. If the FDA refuses to approve the NDA, it will give the applicant a written notice of an opportunity for a hearing on the question of whether there are grounds for denying approval of the NDA.

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

Within one year after receipt of the CRL, the applicant is required to take one of the actions cited above. If the applicant does not take one of these actions, the FDA will consider the lack of response as a request to withdraw the NDA. The applicant can also request an extension of time to resubmit the NDA. A resubmission must fully address all the deficiencies cited. A partial response to the CRL will not be processed as a resubmission and will not start a new review cycle.

### ***Other Regulatory Requirements***

*Risk Evaluation and Mitigation Strategy (REMS).* The Food and Drug Administration Amendments Act of 2007 (FDAAA), gives the FDA authority to require a drug-specific REMS to ensure the safe use of the drug. In determining whether a REMS is necessary, the FDA must consider the size of the population most likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events and whether or not the drug is a new chemical entity. If the FDA determines a REMS is necessary, the sponsor must propose the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health providers of the drug's risks, a limitation on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure safe use of the drug.

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

*Post-Marketing Requirements.* There are post-marketing safety surveillance requirements that are required to be met to continue marketing an approved product. Adverse experiences with the product must be reported to the FDA and could result in imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety and/or efficacy of the product occur following approval. The FDA may also, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

With respect to product advertising and promotion of marketed products, the FDA imposes a number of complex regulations which include, among others, standards for direct-to-consumer advertising, off-label promotions, industry-sponsored scientific and educational activities and Internet promotional activities. The FDA has very broad enforcement authority under the FD&C Act, and failure to abide by these regulations can result in penalties, including the issuance of warning letters directing the sponsor to correct deviations from FDA standards, a requirement that future advertising and promotional materials are pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

The manufacturing facility that produces our product must maintain compliance with cGMP and is subject to periodic inspections by the FDA. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal and regulatory action, including Warning Letters, seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. In the initial CRL, the FDA notified us that the methods used in and the facilities and controls used for the manufacturing, processing, packing, or holding of the drug product at two of our manufacturers did not comply with cGMPs during pre-approval inspections. Both of these manufacturers have received confirmation from the FDA that the deficiencies have been resolved and that their respective facilities are acceptable.

### *Foreign Regulations*

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

---

## **Table of Contents**

Under the EU regulatory system, applications for drug approval may be submitted either in a centralized or decentralized procedure. Under the centralized procedure, a single application to the EMA, if approved, would permit marketing of the product throughout the EU (currently 27 member states). The centralized procedure is mandatory for new chemical entities, biotech and orphan drug products and products to treat AIDS, cancer, diabetes and neuro-degenerative disorder, auto-immune diseases, other immune dysfunctions and viral diseases. Products that constitute a significant therapeutic, scientific or technical innovation or which are in the interests of patients in the EU may also be submitted under this procedure. We believe ILUVIEN would have potentially qualified for this procedure as a product that constitutes a significant therapeutic, scientific or technical innovation. However, we chose to pursue the decentralized procedure in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain due to our limited resources. The decentralized procedure provides for applications to be submitted for marketing authorization in a select number of EU countries. The process is managed by a central Reference Member State that coordinates the review process with the Concerned Member States.

Based on our analysis of the data through month 24 of the FAME Study, in July 2010, we submitted a data package regarding the efficacy and safety of ILUVIEN to the applicable regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain with the United Kingdom acting as the RMS. In November 2010, we received a PAR from the RMS regarding our registration filings. The primary concerns expressed in the PAR centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of our FAME Study data through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filings. In July 2011, we submitted a draft response to the PAR to the MHRA, the regulatory body in the RMS, including additional safety and efficacy data through the final readout at month 36 of the FAME Study with an emphasis on the chronic DME subgroup. After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a FAR from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries Concerned Member States. During the national phase labeling in each country's local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients with chronic DME. ILUVIEN has received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies.

We currently plan to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and are pursuing pricing and reimbursement in those countries. In July 2012, we received a letter from Germany's Federal Joint Committee indicating that the automatic obligation to submit a dossier on ILUVIEN, per the Arzneimittelmarkt-Neuordnungsgesetz law, would not be necessary, and that a benefit assessment would not be required. This allows us to launch ILUVIEN in Germany without price restriction. In August 2012, we received an appraisal consultation document from NICE with a preliminary recommendation that ILUVIEN is not recommended given the cost of £5500 and other variables included in our submission to NICE. This document is not NICE's final guidance and the recommendation may change prior to NICE's FAD. We provided further comments on the draft appraisal and additional data in advance of the second appraisal meeting that was held in October 2012. We are currently awaiting additional feedback from NICE.

A mutual recognition procedure of nationally approved decisions is available to pursue marketing authorizations for ILUVIEN in the remaining EU countries once marketing authorization has been received in any EU country. Under the mutual recognition procedure, the holders of national marketing authorization in one of the countries within the EU may submit further applications to other countries within the EU, who will be requested to recognize the original authorization based on the FAR provided by the RMS.

### **Third-party reimbursement and pricing controls**

In the EU, U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. In the U.S., following regulatory approval, if any, it will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payers. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us or our partners to sell our products on a competitive or profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

In many foreign markets, including the countries in the EU, pricing of pharmaceutical products is subject to governmental control. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

### **Patents and Proprietary Rights**

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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.

---

## **Table of Contents**

As of September 30, 2012, we owned or have licensed three U.S. utility patents, one U.S. design patent and five U.S. patent applications as well as numerous foreign counterparts to many of these patents and patent applications relating to ILUVIEN or the ILUVIEN applicator. We licensed one European patent from pSivida directed to our low-dose device and have an application pending directed to an applicator system for ILUVIEN. We licensed our patent rights relating to ILUVIEN from pSivida. Pursuant to our agreement with pSivida, we only have the right to our ILUVIEN-related patent rights for diseases of the human eye (other than uveitis). Our licensed patent portfolio includes U.S. patents (with no currently pending or issued corresponding European applications or patents) with claims directed to methods for administering a corticosteroid with an implantable sustained delivery device to deliver the corticosteroid to the vitreous of the eye wherein aqueous corticosteroid concentration is less than vitreous corticosteroid concentration during release, with no currently pending or issued corresponding European applications or patents. Our licensed patent portfolio also includes one U.S. patent and a pending U.S. patent application directed to our high-dose ILUVIEN insert.

U.S. utility patents generally have a term of 20 years from the date of filing. The utility patent rights relating to ILUVIEN licensed to us from pSivida include three U.S. patents that expire between March 2019 and April 2020 and counterpart filings to these patents in a number of other jurisdictions. A single European patent is licensed to us from pSivida directed to our low-dose device that expires in April of 2021. No patent term extension will be available for any of these U.S. patents or any of our licensed U.S. pending patent applications.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before such product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

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

## **Research and Development**

We have built a research and development organization that includes extensive expertise with ophthalmic products including the launch and management of Visudyne, a drug product sponsored by Novartis and the first pharmacological treatment indicated for patients with wet AMD. We operate cross-functionally and are led by an experienced research and development management team. We use rigorous project management techniques to assist us in making disciplined strategic research and development program decisions and to help limit the risk profile of our product pipeline. We also access relevant market information and key opinion leaders in creating target product profiles and, when appropriate, as we advance our programs to commercialization. We engage third parties to conduct portions of our preclinical research. In addition, we utilize multiple clinical sites to conduct our clinical trials; however we are not substantially dependent upon any one of these sites for our clinical trials nor do any of them conduct a major portion of our clinical trials.

We invested \$7.1 million, \$12.6 million and \$15.1 million in research and development in 2011, 2010 and 2009, respectively.

## **Employees**

As of September 30, 2012, we had 20 employees, one of whom holds a Ph.D. Eight of these employees are engaged in research, development and regulatory activities, and 12 are engaged in administrative support, finance, information technology and sales and marketing activities. None of our employees is represented by a labor union and we consider our employee relations to be good.

## **OUR CORPORATE INFORMATION**

We were incorporated in Delaware in June 2003 and commenced operations on that date. Our principal executive office is located at 6120 Windward Parkway, Suite 290, Alpharetta, Georgia 30005 and our telephone number is (678) 990-5740. Our website address is

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

[www.alimerasciences.com](http://www.alimerasciences.com). The information contained on, or that can be accessed through, our website is not part of this prospectus.



---

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

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.

**General**

Our authorized capital stock consists 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. 1,300,000 shares of preferred stock have been designated as Series A Convertible Preferred Stock.

**Common Stock**

As of November 1, 2012, there were 31,527,756 shares of common stock outstanding held of record by approximately 42 stockholders.

Holders of our common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of our common stock are fully paid and nonassessable.

The following summary of the terms of our common stock is subject to and qualified in its entirety by reference to our restated certificate of incorporation and bylaws, copies of which are on file with the SEC as exhibits to previous SEC filings. Please refer to the section entitled "Where You Can Find More Information" for directions on obtaining these documents.

*Voting Rights.* The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders, including, without limitation, the election of our Board of Directors. Our stockholders have no right to cumulate their votes in the election of directors.

*Dividends.* Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive ratably those dividends declared from time to time by the Board of Directors. Further, for so long as at least 37.5% of the shares of Series A Preferred Stock originally issued to the investors at the closing of our Series A Preferred Stock financing in October 2012 are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Preferred Stock declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (A) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Preferred Stock is made pursuant to the certificate of designation or (B) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with the implementation of a poison pill rights plan or similar plan by us.

*Rights Upon Liquidation.* Subject to preferences that may apply to shares of preferred stock outstanding at the time, in the event of liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in assets remaining after payment of liabilities.

*Transfer Agent and Registrar.* The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

*Listing.* Our common stock is listed on the NASDAQ Global Market under the symbol ALIM.

**Series A Preferred 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. On October 2, 2012, we filed a certificate of designation which designated 1,300,000 shares of our preferred stock as Series A Convertible Preferred Stock.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

*Conversion.* Each share of Series A Preferred Stock, including any shares of Series A Preferred Stock issued upon exercise of the warrants, is convertible into shares of the Company's common stock at any time at the option of the holder at the rate (conversion rate) equal to \$40.00 (original purchase price) divided by the then current conversion price (conversion price). The initial conversion price of \$2.91 of the Series A Preferred Stock is subject to adjustment based on the occurrence or non-occurrence of certain events, in addition to certain customary price-based anti-dilution adjustments. The conversion price will be adjusted pursuant to the first to occur of the following occurrences (such adjusted conversion price being referred to herein as the Final Guidance Price): (i) the then-effective conversion price shall be automatically increased by \$0.25 as of the date on which NICE issues final guidance (following the review of a Patient Access Scheme (as commonly used by NICE), if required) recommending ILUVIEN (a Positive Guidance), provided that such Positive Guidance is issued on or before June 30, 2013; (ii) the then-effective conversion price shall be automatically decreased by \$0.25 (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Preferred Stock) on July 1, 2013, if ILUVIEN has not received Positive Guidance on or before June 30, 2013; or (iii) the then-effective conversion price shall be automatically decreased by \$0.25 as of the date, on or prior to June 30, 2013, on which: (a) NICE issues final unappealable guidance (following the review of a Patient Access Scheme) failing to recommend ILUVIEN (a Negative Guidance) or (b) the Company ceases to seek NICE approval of ILUVIEN. For the avoidance of doubt with respect to subsection (iii), the issuance of a Final Appraisal Determination (as commonly used by NICE) by NICE prior to the review of a Patient Access Scheme is not final guidance for these purposes.

---

**Table of Contents**

In the event (i) we are acquired or (ii) the automatic conversion of the Series A Preferred Stock into common stock pursuant to the terms of the Certificate of Designation occurs, in each case prior to the determination of the Final Guidance Price, then the conversion price shall be \$2.91, subject to certain customary price-based anti-dilution adjustments. Any voluntary conversion by the holder of Series A Preferred Stock into common stock at any time prior to July 1, 2013 and the determination of the Final Guidance Price shall be at a conversion price of \$3.16, subject to certain customary price based anti-dilution adjustments. The adjustments to the conversion price for purposes of the price based anti-dilution adjustments shall be determined by reference to an assumed conversion price which does not take into account adjustments made in connection with the Final Guidance Price (i.e., for purposes of the anti-dilution provisions, \$2.91, shall be the initial assumed conversion price from which anti-dilution adjustments will be determined). The price-based anti-dilution adjustment for the Series A Preferred Stock is calculated on a weighted average basis and is restricted such that the this adjustment may not result in a conversion price less than \$1.00.

Each share of Series A Preferred Stock shall automatically be converted into shares of our common stock at the then-effective conversion price upon the occurrence of the later to occur of both (i) we receive and publicly announce the approval by the United States Food and Drug Administration of our New Drug Application for ILUVIEN and (ii) the date on which we consummate an equity financing transaction pursuant to which we sell to one or more third party investors either (a) shares of our common stock or (b) other equity securities that are convertible into shares of our common stock and that have rights, preference or privileges, senior to or on a parity with, the Series A Preferred Stock, in each case having an as-converted per share of common stock price of not less than \$10.00 (adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Preferred Stock) and that results in total gross proceeds to us of at least \$30,000,000. The Series A Preferred Stock is not convertible at our option.

All conversion prices and adjustments to the conversion price of the Series A Preferred Stock shall be appropriately adjusted in the event of stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Preferred Stock.

*Liquidation Preference.* In the event of a Liquidation Transaction, as defined below, holders of the Series A Preferred Stock will receive, before any proceeds are distributed to the holders of common stock or any other stock or equity security, a payment equal to the greater of (i) the original purchase price (as adjusted for stock dividends, splits, combinations and similar events with respect to the Series A Preferred Stock), plus any declared and unpaid dividends, per share of Series A Preferred Stock and (ii) the amount each holder of a share of Series A Preferred Stock would be entitled to receive all shares of Series A Preferred Stock been converted into shares of common stock at the then-effective conversion rate immediately prior to such Liquidation Transaction. Unless waived by the holders of at least 70% of the then outstanding shares of Series A Preferred Stock, voting together as a separate class, the following shall be deemed to constitute a Liquidation Transaction: (a) our acquisition by means of merger, consolidation, stock sale, tender offer, exchange offer or other form of corporate reorganization in which our outstanding shares are exchanged or sold, in one transaction or a series of related transactions, for cash, securities, property or other consideration issued, or caused to be issued, by the acquiring entity or its subsidiary, or any other person or group of affiliated persons and in which the holders of our capital stock hold less than a majority of the voting power of the surviving entity and (b) any sale, transfer, exclusive license or lease of all or substantially all of the properties or assets of us or our subsidiaries (each of such transactions in clause (a) and (b), together with our actual liquidation, dissolution or winding up, a Liquidation Transaction), provided that none of the following shall be deemed to constitute a Liquidation Transaction: (x) a transaction for which the sole purpose is to change the state of our incorporation, (y) a transaction for which the sole purpose is to create a holding company that will hold no assets other than our shares and that will have securities with rights, preferences, privileges and restrictions substantially similar to ours and that are owned in substantially the same proportions by the persons who held such of our securities, in each case immediately prior to such transaction or (z) our entry into a license transaction for the purpose of developing and/or commercializing one or more of our products, so long as such license transaction would not be reasonably considered to be a sale or license of all or substantially all of our assets.

*Voting Rights.* Except as otherwise set forth in the Certificate of Designation, the Series A Preferred Stock will vote together with the common stock on an as converted basis based on a deemed conversion price of \$2.95 (adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Preferred Stock).

## **Table of Contents**

In addition, for so long as at least 37.5% of the shares of Series A Preferred Stock issued to the selling stockholders at the closing of our Series A Stock financing are held by the initial selling stockholders or their affiliates, we may not without first obtaining approval of the holders of at least 70% of the then outstanding shares of Series A Preferred Stock, voting together as a separate class: (i) increase or decrease the authorized number of shares of Series A Preferred Stock; (ii) authorize, create, issue or obligate ourselves to issue (by reclassification, merger or otherwise) any security (or any class or series thereof) or any indebtedness, in each case that has any rights, preferences or privileges senior to, or on a parity with, the Series A Preferred Stock, or any security convertible into or exercisable for any such security or indebtedness (other than the issuance of (a) up to an aggregate of \$35,000,000 of indebtedness pursuant to our Credit Facility with Silicon Valley Bank and/or MidCap Financial, as the same may be amended, refinanced or resyndicated from time to time or (b) up to an aggregate of \$500,000 of indebtedness pursuant to operating, capital or equipment leases entered into in the ordinary course of business (such indebtedness being the Permitted Indebtedness)); (iii) amend our certificate of incorporation (including by filing any new certificate of designation or elimination) or the Certificate of Designation, in each case in a manner that adversely affects the rights, preference or privileges of the Series A Preferred Stock; (iv) redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of common stock or preferred stock; provided, however, that this restriction shall not apply to (a) the redemption of rights issued pursuant to any poison pill rights plan or similar plan we adopt after the closing of our Series A Preferred Stock financing or (b) the repurchases of stock from former employees, officers, directors or consultants who performed services for us in connection with the cessation of such employment or service pursuant to the terms of existing agreements with such individuals; (v) declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (a) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Preferred Stock is made pursuant to the Certificate of Designation or (b) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with our the implementation of a poison pill rights plan or similar plan; (vi) authorize or approve any increase to the number of aggregate shares of capital stock reserved for issuance pursuant to our stock option, stock purchase plans or other equity incentive plans such that the total aggregate number of shares issued under such plans and reserved for issuance under such plans (on an as-converted basis) exceeds the number of shares issued and reserved for issuance under such plans (on an as-converted basis) on the date of the closing of the Series A Preferred Stock financing by more than 20% (adjusted for stock splits, combinations, stock dividends, recapitalizations and the like), provided that any increases resulting solely from the annual increases resulting from the evergreen provisions of our equity incentive plans in effect on the date of the closing of the offering shall not be subject to this restriction and shall not be included for purposes of determining whether such 20% increase has occurred; (vii) issue stock or other equity securities of any of our subsidiaries (other than to us or another wholly-owned subsidiary) or declare or pay any dividend or other distribution of cash, shares or other assets or redemption or repurchase of shares of any subsidiary; or (viii) incur any secured indebtedness other than any Permitted Indebtedness.

In connection with the Series A Preferred Stock financing, our Board of Directors approved an amendment to our bylaws, effective as of October 2, 2012, to provide that the holders of Series A Preferred Stock may take any exclusive action required or permitted to be taken by the stockholders holding Series A Preferred Stock pursuant to the Certificate of Designation by written consent at any time.

*Dividends.* The Series A Preferred Stock does not accrue dividends. The holders of Series A Preferred Stock will be entitled to receive dividends and other distributions on a pari passu basis with the holders of our common stock on an as-converted basis.

*Redemption.* The Series A Preferred Stock is not redeemable.

The Certificate of Designation is filed as Exhibit 3.5 to the registration statement of which this prospectus forms a part. The foregoing description of the Certificate of Designation and the Series A Preferred Stock does not purport to be complete and is qualified in its entirety by reference to such exhibit.

### **Registration of the Underlying Common Stock**

We and the selling stockholders entered into a Registration Rights Agreement (Registration Rights Agreement) dated October 2, 2012, whereby we are required to file this registration statement pursuant to the Securities Act to register the shares of common stock issuable upon conversion of the Series A Preferred Stock issued and sold in the Series A Preferred Stock financing (Conversion Shares), and the shares of common stock issuable upon exercise of the Warrants or issuable upon conversion of the Series A Preferred Stock issuable upon exercise of the Warrants (Warrant Shares, and together with the Conversion Shares, Registrable Securities) for resale. The Registration Rights Agreement also contains provisions for demand registration rights, pursuant to which the selling stockholders may require us to register all or a portion of their Registrable Securities and offer them for resale in an underwritten offering, and piggyback registration rights pursuant to which the selling stockholders may include their Registrable Securities in any future registration statement we file, with certain exceptions as set forth in the Registration Rights Agreement. In addition, we agreed to use commercially reasonable efforts to keep the registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective, and to keep the registration statement and any related prospectuses or prospectus supplement free of any material misstatements or omissions, until the date on which we shall have obtained a written opinion of legal counsel reasonably satisfactory to the selling stockholders and addressed to us and the

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

selling stockholders to the effect that the Registrable Securities may be publicly offered for sale in the United States by the selling stockholders or any subsidiary of such selling stockholders without restriction as to manner of sale and amount of securities sold and without registration or other restriction under the Securities Act. The Registration Rights Agreement is filed as Exhibit 4.11 to the registration statement of which this prospectus forms a part. The foregoing description of the Registration Rights Agreement does not purport to be complete and is qualified in its entirety by reference to such exhibit.

### **Investor Representation on Our Board of Directors**

For as long as Sofinnova Venture Partners VIII, L.P., together with its affiliates (Sofinnova), continues to hold at least 50% of the shares of Series A Preferred Stock originally issued to Sofinnova at the closing of our Series A Preferred Stock financing (or shares of common stock issued upon conversion thereof), the holders of Series A Preferred Stock, voting as single class, shall be entitled to elect, at any election of our Class II Directors, one individual to serve as a Class II Director (Series A Director), who shall be designated by Sofinnova. The initial Series A Director, Garheng Kong, was appointed as of the closing of our Series A Preferred Stock financing.

---

**Table of Contents**

**Anti-Takeover Effects of Our Restated Certificate of Incorporation, Bylaws and Delaware Law**

Some provisions of Delaware law and our restated certificate of incorporation and bylaws could make the following transactions more difficult: our acquisition by means of a tender offer; our acquisition by means of a proxy contest or otherwise; or removal of our incumbent officers and directors.

Section 203 of the Delaware General Corporation Law is applicable to takeovers of Delaware corporations. Subject to exceptions enumerated in Section 203, Section 203 provides that a corporation shall not engage in any business combination with any interested stockholder for a three-year period following the date that the stockholder becomes an interested stockholder unless:

prior to that date, the Board of Directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, though some shares may be excluded from the calculation; and

on or subsequent to that date, the business combination is approved by the Board of Directors of the corporation and by the affirmative votes of holders of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder. Except as specified in Section 203, an interested stockholder is generally defined to include any person who, together with any affiliates or associates of that person, beneficially owns, directly or indirectly, 15% or more of the outstanding voting stock of the corporation, or is an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of the corporation, any time within three years immediately prior to the relevant date. Under certain circumstances, Section 203 makes it more difficult for an interested stockholder to effect various business combinations with a corporation for a three-year period, although the stockholders may elect not to be governed by this section, by adopting an amendment to the certificate of incorporation or bylaws, effective 12 months after adoption. Our restated certificate of incorporation and bylaws do not opt out from the restrictions imposed under Section 203. We anticipate that the provisions of Section 203 may encourage companies interested in acquiring us to negotiate in advance with the board because the stockholder approval requirement would be avoided if a majority of the directors then in office excluding an interested stockholder approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder. These provisions may have the effect of deterring hostile takeovers or delaying changes in control, which could depress the market price of our common stock and deprive stockholders of opportunities to realize a premium on shares of common stock held by them. Our Board of Directors waived the provisions of Section 203 with respect to the issuance of the Series A Preferred Stock and Warrants to selling stockholders in our Series A Preferred Stock financing.

In addition to our Board of Directors' ability to issue shares of preferred stock, our restated certificate of incorporation and bylaws contain provisions that may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our restated certificate of incorporation and bylaws:

authorize the issuance of blank check preferred stock that could be issued by our Board of Directors to thwart a takeover attempt;

do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the 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;

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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, other than action by the holders of the Series A Preferred Stock; 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.

Further, for so long as at least 37.5% of the shares of Series A Preferred Stock issued to the selling stockholders at the closing of our Series A Stock financing are held by the initial selling stockholders or their affiliates, we may not without first obtaining approval of the holders of at least 70% of the then outstanding shares of Series A Preferred Stock, voting together as a separate class:

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

---

## **Table of Contents**

amend our certificate of incorporation (including by filing any new certificate of designation or elimination) or the Certificate of Designation, in each case in a manner that adversely affects the rights, preference or privileges of the Series A Preferred Stock.

### **Warrants**

*Warrants issued to selling stockholders in our Series A Preferred Stock financing.* Each unit sold to the selling stockholders in the Series A Preferred Stock financing included a Warrant to purchase 0.30 shares of Series A Preferred Stock at an exercise price equal to \$44.00 per share. As of November 1, 2012, there were outstanding Warrants to purchase up to an aggregate of 300,000 shares of Series A Preferred Stock, which as of such date were voluntarily convertible into 3,797,468 shares of common stock. The Warrants may be exercised for cash or, if the fair market value of the underlying stock exceeds the exercise price, on a cashless net exercise basis. The Warrants are exercisable beginning on the original date of issuance and will expire on the earlier to occur of (i) immediately following the consummation of a sale of the Company (for cash or freely tradable securities), if the warrants are not exercised or exchanged at or prior to the consummation of such sale or (ii) October 2, 2017. The terms of the Warrants provide that they will automatically be exercised on a cashless basis prior to their expiration if the fair market value of the underlying stock exceeds the exercise price. At the election of the holder of a Warrant, the Warrant may be exercised for the number of shares of common stock then issuable upon conversion of the Series A Preferred Stock that would otherwise be issued upon such exercise at the then-effective conversion price. The exercise price and the number of shares issuable upon exercise of the Warrants are subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our Series A Preferred Stock, and also upon any distributions of assets, including cash, stock or other property to our stockholders. Prior to the exercise of any Warrants, holders of the Warrants will not have any of the rights of holders of the Series A Preferred Stock purchasable upon exercise, including the right to vote or to receive any payments of dividends on the stock purchasable upon exercise. The Warrants are filed as Exhibits 4.10.A, 4.10.B, 4.10.C, 4.10.D, 4.10.E to the registration statement of which this prospectus forms a part. The foregoing description of the Warrants does not purport to be complete and is qualified in its entirety by reference to such exhibits.

### **PLAN OF DISTRIBUTION**

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale or at negotiated prices.

If any of the selling stockholders are deemed an underwriter within the meaning of Section 2(11) of the Securities Act in connection with the resale of our common stock under this prospectus, any commissions received by such selling stockholders and any profit on the resale of the shares of our common stock (including the shares of common stock issuable upon the exercise and conversion to common stock of our Series A Preferred Stock and the Warrants, as applicable) sold by such security holders while acting as principals will be deemed to be underwriting discounts or commissions. Because it will have been deemed to be an underwriter within the meaning of Section 2(11) of the Security Act, such selling stockholders will be subject to prospectus delivery requirements under the Securities Act.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;



privately negotiated transactions;

short sales;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

---

## **Table of Contents**

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of the common stock issuable to them upon the exercise or conversion of the Series A Preferred Stock and the Warrants, as applicable, owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock issuable upon the exercise or conversion of the Series A Preferred Stock and the Warrants, as applicable, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the share of common stock issuable upon the exercise or conversion of the Series A Preferred Stock and the Warrants, as applicable, in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities, once issued, to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities that require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the Warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealer. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for purposes of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participated in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed to use commercially reasonable efforts to maintain the effectiveness of this registration statement until the earlier of (i) the five-year anniversary of the date of the Registration Rights Agreement or (ii) until all shares of common stock that may become issuable to the selling stockholders upon the exercise or conversion, as applicable, of the Series A Preferred Stock and Warrants are sold pursuant to this registration statement.

### **Blue Sky Restrictions on Resale**

If a selling stockholder wants to sell shares of our common stock under this prospectus in the United States, the selling stockholder will also need to comply with state securities laws, also known as Blue Sky laws, with regard to secondary sales. As a result, holders may not resell their shares of common stock in the United States without satisfying the applicable state securities law or qualifying for an exemption therefrom, including the exemptions provided under the U.S. National Securities Markets Improvement Act of 1996. The broker for a selling stockholder

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

will be able to advise a selling stockholder as to which states our common stock is exempt from registration with that state for secondary sales.

Any person who purchases shares of our common stock from a selling stockholder under this prospectus who then wants to sell such shares will also have to comply with Blue Sky laws regarding secondary sales. These restrictions and potential costs could be significant burdens to our stockholders seeking to effect resales of our common stock with in the United States.

---

**Table of Contents**

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

*The following discussion and analysis should be read in conjunction with our audited annual consolidated financial statements and the related notes that appear elsewhere in this prospectus. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this prospectus. For further information regarding forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements and Projections" elsewhere in this prospectus.*

**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 has received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain, for the treatment of vision impairment associated with diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN has not been approved by the FDA.

We submitted a New Drug Application (NDA) in June 2010 for the low dose of ILUVIEN in the U.S. with the U.S. Food and Drug Administration (FDA), followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain under the EU's Decentralized Procedure (DCP) in July 2010 with the United Kingdom acting as the Reference Member State (RMS). The RMS is responsible for coordinating the review and approval process between itself and the other involved countries, or Concerned Member States.

In November 2010, we received a Preliminary Assessment Report (PAR) from the RMS and in December 2010, we received a Complete Response Letter (CRL) from the FDA regarding our respective registration filings. The primary concerns expressed in both the PAR and the CRL centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of the data from our two Phase 3 pivotal clinical trials (collectively, the FAME<sup>TM</sup> Study) through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filings.

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

In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its then current form stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. At the time, the FDA indicated that we would need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. During the second quarter of 2012, we met with the FDA in an effort to gain a better understanding of the regulatory path for ILUVIEN in the U.S. Based upon this meeting, we plan to submit to the FDA a response to the second CRL to include additional analysis of the benefits and risks of ILUVIEN based upon clinical data available from the FAME Study.

After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a Final Assessment Report (FAR) from the United Kingdom Medicines Healthcare products Regulatory Agency (MHRA) indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the decentralized procedure was complete. Upon receipt of the FAR, we entered the national phase with each of these seven countries. During the national phase labeling in each country's local language is finalized. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients with chronic DME. ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France and Germany for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies.

We currently plan to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and are pursuing pricing and reimbursement in those countries. In July 2012, we received a letter from Germany's Federal Joint Committee indicating that the automatic obligation to submit a dossier on ILUVIEN, per the Arzneimittelmarkt-Neuordnungsgesetz law, would not be necessary, and that a benefit assessment would not be required. This allows us to launch ILUVIEN in Germany without price restriction. In August 2012, we received an appraisal consultation

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

document from the United Kingdom's National Institute for Health and Clinical Excellence (NICE) with a preliminary recommendation that ILUVIEN is not recommended given the cost of £5500 and other variables included in our submission to NICE. This document is not NICE's final guidance and the recommendation may change prior to NICE's final appraisal determination (FAD). We provided further comments on the draft appraisal and additional data in advance of the second appraisal meeting that was held in October 2012. We are currently awaiting additional feedback from NICE.

---

**Table of Contents**

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

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of September 30, 2012, we have accumulated a deficit of \$225.8 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

complete the clinical development and registration of ILUVIEN;

prepare for the anticipated commercial launch of ILUVIEN in the EU in early 2013, at the earliest;

continue to seek regulatory approval of ILUVIEN in the U.S. and other jurisdictions;

evaluate the use of ILUVIEN for the treatment of other diseases; and

advance the clinical development of other new product candidates either currently in our pipeline, or that we may license or acquire in the future.

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

As of September 30, 2012, we had approximately \$17.4 million in cash and cash equivalents.

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

On October 2, 2012, we closed our Series A Preferred Stock financing where we sold units consisting of in the aggregate 1,000,000 shares of our Series A Preferred Stock and the Warrants to purchase 300,000 shares of our Series A Preferred Stock for gross proceeds of \$40.0 million prior to the payment of related expenses.

In April 2012, we established a wholly-owned subsidiary in the United Kingdom, Alimera Sciences Limited, to facilitate transacting business in the EU. As of November 13, 2012 Alimera Sciences Limited had three employees.

We plan to proceed with the direct commercialization of ILUVIEN in Germany, the United Kingdom and France in 2013. We believe that we have sufficient funds available to fund our operations beyond the projected commercialization of ILUVIEN in these EU countries. We do not expect the generation of revenue until 2013, and therefore do not expect to have positive cash flow from operations until 2014. If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

**Our Agreement with pSivida US, Inc.**

In February 2005, we entered into an agreement with pSivida US, Inc. (pSivida) for the use of fluocinolone acetonide (FAC) in pSivida's proprietary delivery device. pSivida is a global drug delivery company committed to the biomedical sector and the development of drug delivery products. Our agreement with pSivida provides us with a worldwide exclusive license to develop and sell ILUVIEN, which consists of a tiny polyimide tube with membrane caps that is filled with FAC in a polyvinyl alcohol matrix for delivery to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis). This agreement also provides us with a worldwide non-exclusive license to develop and sell pSivida's proprietary delivery device to deliver other corticosteroids to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis) or to treat DME by delivering a compound to the back of the eye through a direct delivery method through an incision required for a 25-gauge or larger needle. We do not have the right to develop and sell pSivida's proprietary delivery device for indications for diseases outside of the eye or for the treatment of uveitis. Further, our agreement with pSivida permits pSivida to grant to any other party the right to use its intellectual property (i) to treat DME through an incision smaller than that required for a 25-gauge needle, unless using a corticosteroid delivered to the back of the eye, (ii) to deliver any compound outside the back of the eye unless it is to treat DME through an incision required for a 25-gauge or larger needle, or (iii) to deliver non-corticosteroids to the back of the eye, unless it is to treat DME through an incision required for a 25-gauge or larger needle.

## **Table of Contents**

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. In connection with this arrangement we are entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits. As of September 30, 2012 and December 31, 2011, pSivida owed us \$4,924,000 and \$4,064,000, respectively, in commercialization costs. Due to the uncertainty of future profits from ILUVIEN, we have fully reserved these amounts in the accompanying unaudited consolidated financial statements.

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

Total consideration to pSivida in connection with the execution of the March 2008 agreement was \$33.8 million, which consisted of a cash payment of \$12.0 million, the issuance of a \$15.0 million note payable, and the forgiveness of \$6.8 million in outstanding receivables. The \$15.0 million promissory note was repaid pursuant to its terms with the proceeds from our IPO. We will owe pSivida an additional milestone payment of \$25.0 million if ILUVIEN is approved by the FDA. If we were to enter into any sub-license of ILUVIEN, we must share 20% of net profits and 33% of any lump sum milestone payments received from a sub-licensee, as defined in the agreement, with pSivida.

## **Our Credit Facility**

### ***Term Loan Agreement***

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

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

If we repay Term Loan A prior to maturity, we must pay to the Lenders a prepayment fee equal to 1.0% of the total amount of principal then outstanding (subject to a 50% reduction in the event that the prepayment occurs in connection with an acquisition of us).

The weighted average interest rate of our notes payable to Silicon Valley Bank and MidCap Financial LLP approximates the rate at which we could obtain alternative financing; therefore, the carrying amount of the notes approximates their fair value.

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

On the Effective Date, we issued to the Lenders warrants to purchase an aggregate of up to 39,773 shares of our common stock. Each of the warrants is exercisable immediately, has a per-share exercise price of \$11.00 and has a term of 10 years. We estimated the fair value of warrants



## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

---

## **Table of Contents**

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

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

### ***Working Capital Revolver***

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

The Working Capital Revolver is a working capital-based revolving line of credit in an aggregate amount of up to the lesser of (i) \$20.0 million, or (ii) 85% of eligible domestic accounts receivable. As of September 30, 2012 and December 31, 2011, respectively, no amounts under the Working Capital Revolver were outstanding or available to us. We may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which we do not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to us.

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

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

### **Our Discontinued Non-Prescription Business**

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

## **Table of Contents**

### **Financial Operations Overview**

#### ***Revenue***

To date we have only generated revenue from our dry eye non-prescription product. From the launch of that product in September 2004 to its sale in July 2007, we generated \$4.4 million in net revenues. We do not expect to generate any significant additional revenue until after the anticipated EU commercial launch of ILUVIEN in 2013, or unless or until we obtain regulatory approval in additional jurisdictions of, and commercialize, our product candidates or in-license additional products that generate revenue. In addition to generating revenue from product sales, we intend to seek to generate revenue from other sources such as upfront fees, milestone payments in connection with collaborative or strategic relationships, and royalties resulting from the licensing of our product candidates and other intellectual property. We expect any revenue we generate will fluctuate from quarter to quarter as a result of the nature, timing and amount of any milestone payments we may receive from potential collaborative and strategic relationships, as well as revenue we may receive upon the sale of our products to the extent any are successfully commercialized.

#### ***Research and Development Expenses***

Substantially all of our research and development expenses incurred to date related to our continuing operations have been related to the development of ILUVIEN. In the event the FDA approves our NDA for ILUVIEN, we will owe an additional milestone payment of \$25.0 million to pSivida. We anticipate that we will incur additional research and development expenses in the future as we evaluate and possibly pursue the regulatory approval of ILUVIEN in additional jurisdictions, the development of ILUVIEN for additional indications, or develop additional product candidates. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

salaries and related expenses for personnel;

fees paid to consultants and contract research organizations (CRO) in conjunction with independently monitoring clinical trials and acquiring and evaluating data in conjunction with clinical trials, including all related fees such as investigator grants, patient screening, lab work and data compilation and statistical analysis;

costs incurred with third parties related to the establishment of a commercially viable manufacturing process for our product candidates;

costs related to production of clinical materials, including fees paid to contract manufacturers;

costs related to upfront and milestone payments under in-licensing agreements;

costs related to compliance with FDA, EU or other regulatory requirements;

consulting fees paid to third-parties involved in research and development activities; and

costs related to stock options or other stock-based compensation granted to personnel in development functions.

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

We expect that a large percentage of our research and development expenses in the future will be incurred in support of our current and future technical, preclinical and clinical development programs. These expenditures are subject to numerous uncertainties in terms of both their timing and total cost to completion. We expect to continue to develop stable formulations of our product candidates, test such formulations in preclinical studies for toxicology, safety and efficacy and to conduct clinical trials for each product candidate. We anticipate funding clinical trials ourselves, but we may engage collaboration partners at certain stages of clinical development. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain product candidates or programs in order to focus our resources on more promising product candidates or programs. Completion of clinical trials by us or our future collaborators may take several years or more, the length of time generally varying with the type, complexity, novelty and intended use of a product candidate. The costs of clinical trials may vary significantly over the life of a project owing to but not limited to the following:

the number of sites included in the trials;

the length of time required to enroll eligible patients;

the number of patients that participate in the trials;

the number of doses that patients receive;

the drop-out or discontinuation rates of patients;

---

**Table of Contents**

the duration of patient follow-up;

the phase of development the product candidate is in; and

the efficacy and safety profile of the product candidate.

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

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

***General and Administrative Expenses***

General and administrative expenses consist primarily of compensation for employees in executive and administrative functions, including finance, accounting and human resources. Other significant costs include facilities costs and professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents. We expect to continue to incur significant costs to comply with the corporate governance, internal control and similar requirements applicable to public companies.

***Marketing Expenses***

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

We expect significant increases in our marketing and selling expenses as we prepare for the commercialization of ILUVIEN in the EU. We plan to proceed with the direct commercialization of ILUVIEN in Germany, the United Kingdom and France in 2013. Currently we are engaged, with the assistance of local consultants, in the pricing and reimbursement process in these countries and are developing related market access plans. We have identified an Alimera European management team and, through outsourced third party providers, are developing an in country commercial infrastructure of approximately thirty people in management and the field combined including sales representatives, market access personnel and medical science liaisons.

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

severance costs related to this reduction in force in December of 2011 of which \$206,000 was payable at December 31, 2011. All amounts due at December 31, 2011 were paid to affected employees during the nine months ended September 30, 2012.

### ***Interest and Other Income***

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

---

**Table of Contents*****Interest Expense***

In October 2010, we drew the Initial Tranche of \$6.25 million on our term loan from Silicon Valley Bank and MidCap Financial LLP which accrues interest at the rate of 11.5% per annum and is payable monthly.

***Basic and Diluted Net Loss per Common Share***

We calculated net loss per share in accordance with ASC 260, *Earning Per Share*. We had a net loss for all periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive. Dilutive common stock equivalents would include the dilutive effect of convertible securities, common stock options, warrants for convertible securities and warrants for common stock equivalents. Potentially dilutive weighted average common stock equivalents totaled approximately 1,489,869, 9,131,451 and 22,149,592 for the years ended December 31, 2011, 2010 and 2009, respectively, approximately 951,793 and 1,530,555 for the three months ended September 30, 2012 and 2011, respectively, and 960,238 and 1,602,472 for the nine months ended September 30, 2012 and 2011, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods of net loss from continuing operations because of their anti-dilutive effect. Therefore, for the years ended December 31, 2011, 2010 and 2009 and for the three and nine months ended September 30, 2012, the weighted average shares used to calculate both basic and diluted loss per share are the same.

***Critical Accounting Policies and Estimates***

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

***Clinical Trial Prepaid and Accrued Expenses***

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

***Research and Development Costs***

Research and development expenditures are expensed as incurred, pursuant to ASC 730, *Research and Development*. Costs to license technology to be used in our research and development that have not reached technological feasibility, defined as FDA approval for our current product candidates, and have no alternative future use are expensed when incurred. Payments to licensors that relate to the achievement of preapproval development milestones are recorded as research and development expense when incurred.

***Stock-Based Compensation***

We account for our stock-based compensation in accordance with the provisions of ASC 718, *Compensation - Stock Compensation*, using the modified prospective application method. We recognize the grant date fair value as compensation cost of employee stock-based awards using the

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

straight-line method over the actual vesting period, adjusted for our estimates of forfeiture. Typically, we grant stock options with a requisite service period of four years from the grant date. We have elected to use the Black-Scholes option pricing model to determine the fair value of stock-based awards.

We concluded that this was the most appropriate method by which to value our share-based payment arrangements, but if any share-based payment instruments should be granted for which the Black-Scholes method does not meet the measurement objective as stated within ASC 718, we will utilize a more appropriate method for valuing that instrument. However, we do not believe that any instruments granted to date and accounted for under ASC 718 would require a method other than the Black-Scholes method.



**Table of Contents**

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 expected term of the option. For the calculation of expected volatility, because we lack significant company-specific historical and implied volatility information, we estimate our volatility by utilizing an average of volatilities of publicly traded companies, including our own, deemed similar to us in terms of product composition, stage of lifecycle, capitalization and scope of operations. We intend to continue to consistently apply this process using this same index until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

To estimate the expected term, we utilize the simplified method for plain vanilla options as discussed within the Securities and Exchange Commission's (SEC) Statement of Accounting Bulletin (SAB) 107. We believe that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method are true for us and for our share-based payment arrangements. We intend to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior will be more widely available.

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

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

Total stock-based compensation expense related to all our stock option awards for the three and nine months ended September 30, 2012 and 2011, respectively, was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(Dollars in thousands)			
Marketing	\$ 57	\$ 94	\$ 172	\$ 262
Research and development	92	98	277	285
General and administrative	193	225	687	869
Total employee option-based compensation expense	\$ 342	\$ 417	\$ 1,136	\$ 1,416

Per the terms of our 2004 and 2005 Option Plans (Plans), our Series A Preferred Stock financing constituted a change of control for the purposes of Plan vesting and as a result all unvested options under the Plans would become vested. As of September 30, 2012, there were 79,380 unvested options and \$196,000 of unrecognized compensation expense in connection with the 2004 and 2005 Plans, which will be recognized as expense in the fourth quarter of 2012.

**Restricted Stock Units**

In February 2012, we awarded 85,437 restricted stock units (RSUs), to our executive officers and employees at a grant date fair value of \$1.70 per RSU. A RSU is a stock award that entitles the holder to receive shares of our common stock as the award vests. The fair value of the RSUs was determined on the date of grant based on the closing price of our common stock on the date of grant, which equals the RSU's intrinsic value. The RSUs vested upon the receipt of marketing approval of ILUVIEN in four of the seven EU countries in which ILUVIEN was recommended for marketing authorization. During the second quarter of 2012, the United Kingdom, Austria and Portugal granted ILUVIEN marketing authorization and we recorded \$109,000 in compensation expense in connection with the RSUs. On July 18, 2012, France granted marketing authorization to ILUVIEN and, as a result, the RSUs became fully vested. During the three and nine months ended September 30, 2012, we recognized \$36,000 and \$145,000, respectively, in compensation expense in connection with the RSUs.



**Table of Contents****Income Taxes**

We recognize deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of our assets and liabilities in accordance with ASC 740, *Income Taxes*. We evaluate the positive and negative evidence bearing upon the realizability of our deferred tax assets on an annual basis. Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of our deferred tax assets due to our history of operating losses, a valuation allowance has been established against our deferred tax asset balances to reduce the net carrying value to an amount that is more likely than not to be realized. As a result we have fully reserved the deferred tax asset balances. The valuation allowances are based on our estimates of taxable income in the jurisdictions in which we operate and the period over which deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact our financial position and results of operations. Our deferred tax assets primarily consist of net operating loss (NOL) carry-forwards. At December 31, 2011 we had federal NOL carry-forwards of approximately \$120.4 million and state NOL carry-forwards of approximately \$103.8 million, respectively, that were available to reduce future income otherwise taxable. At September 30, 2012 we had federal NOL carry-forwards of approximately \$134.6 million and state NOL carry-forwards of approximately \$118.1 million, respectively, that were available to reduce future income otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2023 and 2031 and the state NOL carry-forwards will expire at various dates between 2020 and 2031. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of our company were to occur. In general, an ownership change occurs for purposes of Section 382 if there is a more than 50% change in ownership of a company over a 3-year testing period. We are currently evaluating whether a change in ownership occurred with respect to our Series A Preferred Stock financing.

In the event that we were to determine that we are able to realize any of our net deferred tax assets in the future, an adjustment to the valuation allowance would increase net income in the period such determination was made. We believe that the most significant uncertainty that will impact the determination of our valuation allowance will be our estimation of the extent and timing of future net income, if any.

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

**Results of Operations**

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

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

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

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

---

**Table of Contents**

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

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

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

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

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

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

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

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

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

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

**Table of Contents**

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

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

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

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

	Three Months Ended		Nine Months Ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
	(in thousands)			
RESEARCH AND DEVELOPMENT EXPENSES	\$ 2,199	\$ 2,224	\$ 5,636	\$ 5,732
GENERAL AND ADMINISTRATIVE EXPENSES	1,506	1,421	4,488	4,827
MARKETING EXPENSES	1,503	2,612	3,704	5,038
TOTAL OPERATING EXPENSES	5,208	6,257	13,828	15,597
INTEREST INCOME	1	1	3	15
INTEREST EXPENSE	(187)	(284)	(632)	(863)
NET LOSS	\$ (5,394)	\$ (6,540)	\$ (14,457)	\$ (16,445)

**Three Months ended September 30, 2012 Compared to the Three Months Ended September 30, 2011**

*Research and development expenses.* Research and development expenses were approximately \$2.2 million for each of the three month periods ended September 30, 2012, and 2011, respectively. While research and development expenses remained constant over each three month period, costs increased approximately \$700,000 during the three months ended September 30, 2012 primarily related to a consultant engaged to assist with the continued pursuit of approval of ILUVIEN in the U.S. This increase was offset primarily by decreases of \$290,000 in consulting expense related to our preparation for a previously anticipated FDA Advisory Board meeting and \$260,000 in technical development expenses as we approached the final stages of the development of the inserter for ILUVIEN, which expenses were incurred during the three months ended September 30, 2011.

*General and administrative expenses.* General and administrative expenses increased by approximately \$100,000, or 7.1%, to approximately \$1.5 million for the three months ended September 30, 2012 compared to approximately \$1.4 million for the three months ended September 30, 2011. The increase was primarily attributable to an increase of approximately \$130,000 in recruiting costs as we sought to add personnel in preparation of our European launch.

*Marketing expenses.* Marketing expenses decreased by approximately \$1.1 million, or 42.3%, to approximately \$1.5 million for the three months ended September 30, 2012 compared to approximately \$2.6 million for the three months ended September 30, 2011. The decrease was primarily attributable to a decrease of approximately \$2.1 million in costs associated with the previously expected commercial launch of ILUVIEN in the U.S., offset by an increase of \$1.1 million in costs attributable to our pre-launch activities in Europe.

*Interest expense.* Interest expense decreased by approximately \$90,000, or 32.1%, to approximately \$190,000 for the three months ended September 30, 2012 compared to approximately \$280,000 for the three months ended September 30, 2011. Interest expense for the three months ended September 30, 2012 and 2011, respectively, was incurred in connection with our Credit Facility with Silicon Valley Bank and MidCap Financial LLP. The decrease was primarily attributable to lower principal balances with both Silicon Valley Bank and MidCap Financial LLP as a result of amortization payments beginning August 2011.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

### *Nine Months Ended September 30, 2012 Compared to the Nine Months Ended September 30, 2011*

*Research and development expenses.* Research and development expenses decreased by approximately \$100,000, or 1.8%, to approximately \$5.6 million for the nine months ended September 30, 2012 compared to approximately \$5.7 million for the nine months ended September 30, 2011. The decrease was primarily attributable to decreases of approximately \$730,000 in costs associated with contracting with U.S. based medical science liaisons to engage with retina specialists in the study of ILUVIEN in preparation for the previously expected commercial launch of ILUVIEN in the U.S., \$550,000 in costs for technical development as we approached the final stages of the development of the inserter for ILUVIEN, \$360,000 in costs for consultants engaged to assist with preparing for a previously anticipated FDA Advisory Board meeting, \$350,000 in costs associated with the CROs of our FAME Study and \$160,000 in costs associated with our ancillary studies, offset by increases of approximately \$1.8 million in costs related to a consultant engaged to assist with the continued pursuit of approval of ILUVIEN in the U.S. and \$440,000 in costs related to the physician utilization study which is being conducted to assess the safety and utility of the commercial version of the ILUVIEN inserter.

*General and administrative expenses.* General and administrative expenses decreased by approximately \$300,000, or 6.3%, to approximately \$4.5 million for the nine months ended September 30, 2012 compared to approximately \$4.8 million for the nine months ended September 30, 2011. The decrease was primarily attributable to decreases of approximately \$280,000 in personnel costs relating to employees terminated in connection with our reduction in force in December 2011.

*Marketing expenses.* Marketing expenses decreased by approximately \$1.3 million, or 26.0%, to approximately \$3.7 million for the nine months ended September 30, 2012 compared to approximately \$5.0 million for the nine months ended September 30, 2011. The decrease was primarily attributable to a decrease of approximately \$3.2 million in costs associated with the previously expected commercial launch of ILUVIEN in the U.S., offset by an increase of \$1.8 million in costs attributable to our pre-launch activities in the EU.

*Interest expense.* Interest expense decreased by approximately \$230,000, or 26.7%, to approximately \$630,000 for the nine months ended September 30, 2012 compared to approximately \$860,000 for the nine months ended September 30, 2011. Interest expense for the nine months ended September 30, 2012 and 2011, respectively, was incurred in connection with our Credit Facility with Silicon Valley Bank and MidCap Financial LLP. The decrease was primarily attributable to lower principal balances with both Silicon Valley Bank and MidCap Financial LLP due to amortization payments beginning August 2011.



---

**Table of Contents*****Liquidity and Capital Resources***

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of \$225.8 million from our inception through September 30, 2012. Prior to our IPO in April 2010, we funded our operations through the private placement of common stock, preferred stock, warrants and convertible debt, as well as by the sale of certain assets of the non-prescription business in which we were previously engaged.

As of September 30, 2012, we had \$17.4 million in cash and cash equivalents. On October 2, 2012, we sold units consisting of an aggregate of 1,000,000 shares of our Series A Preferred Stock and warrants to purchase an additional 300,000 shares of Series A Preferred Stock in a private placement transaction for gross proceeds of \$40.0 million prior to the payment of related expenses.

As of December 31, 2011, we had approximately \$33.6 million in cash, cash equivalents and investments in marketable securities. We plan to proceed with the direct commercialization of ILUVIEN in the United Kingdom, France and Germany in 2013. We believe that we have sufficient funds available to fund our operations beyond the projected commercialization of ILUVIEN in these EU countries. We do not expect the generation of revenue until 2013, and therefore do not expect to have positive cash flow from operations until 2014. If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

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

For the nine months ended September 30, 2012, cash used in our operations of \$14.5 million was primarily due to our net loss of \$14.5 million offset by stock-based compensation and other non-cash expense of \$1.5 million. Further decreasing cash was a decrease in accounts payable, accrued expenses and other current liabilities of \$740,000, and increases in inventory and prepaid expenses and other current assets of \$880,000. The change in accounts payable, accrued expenses and other current liabilities was primarily due to decreases of approximately \$540,000 paid to the administrator of our U.S. reimbursement and patient assistance programs for a termination payment and final billing due to the suspension of our commercialization of ILUVIEN in the U.S., \$500,000 in amounts paid to our CROs, \$240,000 in amounts paid to our legal and professional accounting firms, and \$210,000 in severance payments made to terminated employees associated with our fourth quarter reduction in force and \$140,000 in amounts paid to vendors performing pharmacoeconomic studies to evaluate the pricing of ILUVIEN in the EU, offset by increases of approximately \$460,000 in amounts payable to our third party manufacturers of ILUVIEN for inventory and \$240,000 in amounts payable to vendors assisting us in growing our market presence in the EU as the expected launch of ILUVIEN in the EU approaches. The increases in inventory and prepaid expenses and other current assets were primarily due to increases of approximately \$670,000 for inventory and \$110,000 of prepaid insurance.

For the nine months ended September 30, 2011, cash used in our operations of \$16.1 million was primarily due to our net loss of \$16.4 million offset by stock-based compensation and other non-cash expense of \$1.9 million. Further decreasing cash was a decrease in accounts payable, accrued expenses and other current liabilities of \$1.5 million, and an increase in prepaid expenses and other current assets of \$160,000. The decrease in accounts payable, accrued expenses and other current liabilities was primarily due to decreases of \$1.4 million in amounts due to our clinical sites for the FAME Study and \$450,000 in amounts due to our CROs, offset by an increase of \$270,000 in amounts payable to third party professional services firms in connection with legal counsel and accounting and audit services and \$140,000 to our third party reading center for the analysis of retinal images. The increase in prepaid expenses and other current assets was primarily due to advanced payments made in connection with participation in industry tradeshow and events.

For the twelve months ended December 31, 2011, cash used in our continuing operations of \$20.7 million was primarily due to our net loss from continuing operations of \$22.5 million decreased by non-cash charges of \$1.9 million for stock compensation expense, and \$130,000 for depreciation and amortization expense. Further decreasing cash in continuing operations was a decrease in accounts payable, accrued liabilities and other current liabilities of \$1.0 million offset by a decrease in prepaid and other current assets of \$390,000. The decrease in accounts payable, accrued expenses and other current liabilities was primarily due to decreases of \$1.1 million payable to the investigators in our FAME Study and ancillary clinical studies, \$210,000 of amounts payable to providers of corporate communications and medical marketing services for pre-launch activities and \$180,000 in amounts payable to our CROs, offset by increases of \$220,000 in amounts payable to our vendors associated with the establishment of our managed care programs, \$150,000 of amounts payable to vendors performing pharmacoeconomic studies

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

to evaluate the pricing of ILUVIEN in the U.S. and EU and \$100,000 in employee expenses that were not paid until 2012. The decrease in prepaid and other current assets was primarily due to decreases of \$240,000 in cash receivable for the U.S. government's Qualifying Therapeutic Discovery Project Tax Credit and \$200,000 in interest receivable on our investments in marketable securities.

**Table of Contents**

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

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

For the nine months ended September 30, 2012 and September 30, 2011, net cash provided by our investing activities was approximately \$490,000 and \$25.7 million, respectively, which was primarily due to the maturities of investments.

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

	Years Ended December 31,		
	2011	2010	2009
	(In thousands)		
Continuing Operations	\$ 25,720	\$ (26,460)	\$ (65)
Discontinued Operations		4,000	
<b>Total</b>	<b>\$ 25,720</b>	<b>\$ (22,460)</b>	<b>\$ (65)</b>

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

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

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

For the nine months ended September 30, 2012, cash used by financing activities was \$1.7 million, which was primarily due to payments of principal on our notes payable to Silicon Valley Bank and MidCap Financial LLP.

For the nine months ended September 30, 2011, cash provided by financing activities was \$17,000. This was primarily due to proceeds of \$340,000 from the exercise of stock options and common stock warrants and from the purchase of common stock under our employee stock purchase plan, offset by \$270,000 in principal payments to Silicon Valley Bank and MidCap Financial.

**Table of Contents**

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

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

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

**Contractual Obligations and Commitments**

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

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

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

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

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

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

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

\$110,000, respectively, are included in outsourced services payable.

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

---

## **Table of Contents**

In February 2012, we engaged a consultant in connection with our efforts to obtain the approval of ILUVIEN from the FDA. During the three and nine months ended September 30, 2012, respectively, we recorded charges of \$700,000 and \$1.8 million pertaining to consulting fees related to our agreement with this consultant. We expect to record an additional \$1.7 million in charges in connection with this agreement through September 30, 2013. In addition, we have agreed to pay the consultant \$2.0 million, if, and only if, the FDA approves our NDA for ILUVIEN.

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in the table above.

### **Off-Balance Sheet Arrangements**

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

### **New Accounting Pronouncements**

In May 2011, the FASB amended the FASB Accounting Standards Codification to converge the fair value measurement guidance in U.S. GAAP and International Financial Reporting Standards. Some of the amendments clarify the application of existing fair value measurement requirements, while other amendments change particular principles in fair value measurement guidance. In addition, the amendments require additional fair value disclosures. The amendments are effective for fiscal years beginning after December 15, 2011 and should be applied prospectively. We do not believe the adoption of these amendments will have a material impact on our financial position or results of operations.

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

### **Qualitative and Quantitative Disclosures About Market Risk**

We are exposed to market risk related to changes in interest rates. As of December 31, 2011, we had approximately \$33.6 million in cash, cash equivalents and investments in marketable securities. As of September 30, 2012, we had approximately \$17.4 million in cash and cash equivalents. On October 2, 2012, we sold units consisting of an aggregate of 1,000,000 shares of our Series A Preferred and warrants to purchase an additional 300,000 shares of Series A Preferred in a private placement transaction for gross proceeds of \$40.0 million prior to the payment of related expenses. Our interest income is exposed to market risk primarily due to changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

Our interest expense is exposed to market risk primarily due to the variability of interest on our revolving loan agreement which is calculated as the prime rate plus 2.50% (with a rate floor of 6.50%). As of December 31, 2011 and September 30, 2012, no amounts under the Working Capital Revolver were outstanding or available to us.

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

**Table of Contents****DIRECTORS AND EXECUTIVE OFFICERS**

The following table sets forth certain information about our executive officers and directors, including their ages and positions as of September 30, 2012.

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
C. Daniel Myers	58	President, Chief Executive Officer and Director
Richard S. Eiswirth, Jr.	44	Chief Financial Officer
Kenneth Green, Ph.D.	54	Senior Vice President and Chief Scientific Officer
Susan Caballa	68	Senior Vice President, Regulatory and Medical Affairs
David Holland	49	Vice President of Marketing
Philip R. Tracy(1)	70	Chairman of the Board of Directors
Mark J. Brooks(2)	46	Director
Brian K. Halak, Ph.D.(1)(2)	41	Director
Glen Bradley Ph.D (3)	69	Director
Calvin W. Roberts, M.D.(3)	60	Director
James R. Largent(1)(2)	62	Director
Peter J. Pizzo, III(3)	46	Director
Garheng Kong, M.D., Ph.D.(4)	37	Director

- (1) Member of the Nominating/Corporate Governance Committee
- (2) Member of the Compensation Committee
- (3) Member of the Audit Committee
- (4) Dr. Kong was appointed as a member of our Board of Directors on October 2, 2012

**Executive Officers**

Our executive officers are currently elected by our board of directors on an annual basis and serve until their successors are duly elected and qualified, or until their earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

*C. Daniel Myers* is one of our co-founders and has served as our Chief Executive Officer and as a director since the founding of our Company in 2003. Before founding our Company, Mr. Myers was an initial employee of Novartis Ophthalmics (formerly CIBA Vision Ophthalmics) and served as its Vice President of Sales and Marketing from 1991 to 1997 and as President from 1997 to 2003. Mr. Myers holds a B.S. in Industrial Management from Georgia Institute of Technology. Our Board of Directors believes that Mr. Myers should serve as a director of the Company, in light of its business and structure, because in addition to his valuable contributions to our Company in recent years, Mr. Myers has over 30 years of ophthalmic pharmaceutical experience, including 15 years in the role of president or chief executive officer. Mr. Myers previously served as a director of Ocular Therapeutix, Inc.

*Richard S. Eiswirth* has served as Chief Financial Officer of our Company since October 2005 and as Chief Operating Officer since August 2010. From 2003 to 2005, Mr. Eiswirth served as founding partner of Brand Ignition Group, 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 previously served as chairman, audit committee chairman and member of the compensation committee of Jones Soda Co., a Seattle, Washington based beverage company, and as 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 Bachelor's 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 V.P. 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.



## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

*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 J&J 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 served as the Vice President of Marketing since the founding of our Company in 2003 through August 2010 when he was appointed the Senior Vice President of Sales and Marketing. 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 of Procter and Gamble. Mr. Holland holds an A.B. in Politics from Princeton University.

**Table of Contents****Directors**

Our board of directors is currently comprised of nine (9) directors divided into three equal classes with staggered three-year terms. The term of office of our Class I directors, C. Daniel Myers, Calvin W. Roberts, M.D. and James R. Largent, will expire at the 2014 annual meeting of stockholders. The term of office of our Class II directors, Philip R. Tracy, Glen Bradley, Ph.D. and Garheng Kong, M.D., Ph.D., will expire at the 2015 annual meeting of stockholders. The term of office of our Class III directors, Brian K. Halak, Ph.D., Mark J. Brooks and Peter J. Pizzo, III, will expire at the 2013 annual meeting of stockholders. There are no family relationships among any of our directors or executive officers.

*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: Carticapt Medical, Cortria Corporation, Esprit Pharma, Inc., Fenway Pharmaceuticals, GI Dynamics, Inc., Immune Control, Inc., Oceana Therapeutic, Inc., Opherion, Inc., Tobira Therapeutics, Inc., Vanda Pharmaceuticals, and Zyga Technology.

*Glen Bradley, Ph.D., M.B.A.* has been a member of our Board of Directors since 2011. Dr. Bradley served as the Chief Executive Officer of CIBA Vision Corporation, the eye care unit of Novartis, A.G., or CIBA Vision, from 1990 to January 2003. Since 2003, Dr. Bradley has acted as a consultant to various medical device and ophthalmic drug companies. Dr. Bradley served in the positions of President and CEO from 1986 to 1989 for CIBA Vision, the United States operations of the CIBA Vision Group. Prior to CIBA Vision, he served in senior management positions in the Agricultural, Plastics & Additives and Electronic Equipment Groups of CIBA-Geigy Corporation. Dr. Bradley has been Chairman of the Board of Directors at REFOCUS Group Inc., since March 2003. He serves as a Director of Intuity Medical, Inc. He has previously held board positions with Spectra Physics, Summit Technology, Biofisica, AerovectRx, e-Dr and Biocure. He served as Chairman of the Contact Lens Institute. Dr. Bradley holds a bachelor's degree in chemical engineering from Mississippi State University, a Ph.D. in chemical engineering from Louisiana State University, an MBA in business and finance from the University of Connecticut and is a graduate of the Advanced Management Program at Harvard Business School. Our Board of Directors believes that Dr. Bradley should serve as a director of the Company, in light of its business and structure, because of his significant knowledge, experience, and financial expertise in the ophthalmic industry.

## **Table of Contents**

*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' 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.

*James R. Largent* has been a member of our Board of Directors since 2011. Mr. Largent has worked extensively within the medical industry. He most recently served as a medical and pharmaceutical consultant, including work with U.S. ophthalmic device company, Eyeonics Inc. While there, he led the lobbying effort that resulted in the 2005 landmark decision by the Centers for Medicare & Medicaid Services (CMS) to allow for patient shared billing for premium presbyopia-correcting intraocular lenses. Also in his role as a consultant, he assisted a multinational pharmaceutical and medical device company in the evaluation of strategic targets. Prior to this, Mr. Largent served in various senior management positions at Allergan, Inc., including as vice president of strategic planning where he fostered licensing deals to build product pipelines. Earlier in his career, he was vice president of strategic marketing at Allergan Medical Optics, Inc. Mr. Largent also held positions of increasing responsibility in the marketing and sales departments at Allergan and Pharmacia Ophthalmics. In addition to serving on Alimera's Board, Mr. Largent is on the Board of Directors of Tear Science, Inc., a privately held developer of diagnostic and therapeutic devices for the treatment of patients with dry eye disease. Mr. Largent earned a B.A. in chemistry and an M.B.A., both from the University of California, Irvine.

*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 Carticcept 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.

*Garheng Kong, M.D., Ph.D.* has been a member of our Board of Directors since October 2012. Dr. Kong has been a general partner at Sofinnova Ventures, a venture capital firm focused on life sciences, since 2010. From 2000 to 2010, he was at Intersouth Partners, a venture capital firm, most recently as a general partner, where he was a founding investor or board member for various life sciences ventures, several of which were acquired by large pharmaceutical companies. Dr. Kong has served on the Board of Directors of Cemptra, Inc. since September 2006 and as chairman of its board since November 2008. Dr. Kong has served on the Board of Directors of SARcode BioScience, Inc., a private biopharmaceutical company, since 2011 and on the board of Histogenics Corporation, a private biotechnology company, since 2012 where he also serves as the chairman of the board. Dr. Kong holds a B.S. in chemical engineering and biological sciences from Stanford University. He holds an M.D., Ph.D. in biomedical engineering and M.B.A. from Duke University. Among other experience, qualifications, attributes and skills, Dr. Kong's knowledge and experience in the venture capital industry and his medical training led to the conclusion of our Board of Directors that he should serve as a director of us in light of our business and structure.

## **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, or 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.

**Table of Contents****Board 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 current 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. Copies of each charter are posted on our website at <http://www.alimerasciences.com> under the Investor Relations section. The inclusion of our website address in this proxy statement does not include or incorporate by reference the information on our website into this proxy statement.

The following table provides membership and meeting information for each of the committees of the Board of Directors during the year ended December 31, 2011:

<b>Committee</b>	<b>Chairman</b>	<b>Members</b>	<b>Number of Meetings in 2011</b>
Audit Committee	Peter J. Pizzo, III	Calvin W. Roberts, M.D.(1) Anders D. Hove, M.D.(2) Glen Bradley, Ph.D. (3)	6
Compensation Committee	Brian K. Halak, Ph.D.	Mark J. Brooks Anders D. Hove, M.D. (2) Bryce Youngren (4) James R. Largent (5)	9
Nominating/Corporate Governance Committee	Philip R. Tracy	Brian K. Halak, Ph.D. Bryce Youngren (4) James R. Largent (5)	1

- (1) Resigned as a member of the audit committee in June 2012 and has been replaced by Mark Brooks as of June 2012.
- (2) Resigned as a director and member of the audit committee and compensation committee in April 2011.
- (3) Appointed as a director and a member of the audit committee in April 2011.
- (4) Replaced Dr. Hove as a member of the compensation committee in April 2011; resigned as a director and member of the compensation committee and nominating/corporate governance committee in August 2011.
- (5) Appointed as a director in July 2011 and a member of the compensation committee and the nominating/corporate governance committee in August 2011.

The primary responsibilities of each committee are described below.

**Audit Committee**

Our audit committee currently consists of Peter J. Pizzo, III, Glen Bradley, Ph.D. and Mark J. Brooks. Mr. Pizzo serves as the chairman of the audit committee. Our Board of Directors annually reviews the NASDAQ listing standards definition of independence for audit committee members and has determined that all current members of our audit committee are independent (as independence is currently defined in

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

applicable NASDAQ listing standards and Rule 10A-3 promulgated under the Exchange Act).

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. Our audit committee monitors compliance with our Code of Business Conduct policy. 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. Related party transactions will be approved by our audit committee before we enter into them, in accordance with the applicable rules of NASDAQ.

Both our independent registered public accounting firm and internal financial personnel regularly meet with, and have unrestricted access to, the audit committee.

## **Table of Contents**

### ***Compensation Committee***

Our compensation committee currently consists of Mark J. Brooks, Brian K. Halak, Ph.D. and James R. Largent. Dr. Halak serves as chairman of the compensation committee. Our Board of Directors has determined that Mr. Brooks, Dr. Halak and Mr. Largent satisfy the independence requirements of the NASDAQ and the SEC rules and regulations for directors. 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.

The compensation committee makes recommendations to the Board of Directors and reviews and approves our compensation policies and all forms of compensation to be provided to our directors and executive officers, including, among other things, annual salaries, bonuses, and equity incentive awards and other incentive compensation arrangements. In addition, our compensation committee will administer our equity incentive and employee stock purchase plans, including granting stock options or awarding restricted stock units to our directors and executive officers. 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, Ph.D., Philip R. Tracy and James R. Largent. Mr. Tracy serves as chairman of the nominating/corporate governance committee.

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. In evaluating potential nominees to the Board of Directors, the nominating/corporate governance committee considers a wide variety of qualifications, attributes and other factors and recognizes that a diversity of viewpoints and practical experience can enhance the effectiveness of our Board of Directors. Accordingly, as part of its evaluation of each candidate, the nominating/corporate governance committee takes into account that candidate's background, experience, qualifications, attributes and skills that may complement, supplement or duplicate those of other prospective candidates and current 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 of Directors concerning corporate governance matters. Our nominating/corporate governance committee has not adopted a policy regarding the consideration of diversity in identifying director nominees.

### **Compensation Committee Interlocks and Insider Participation**

As noted above, the compensation committee of our Board of Directors currently consists of Mark J. Brooks, Brian K. Halak, Ph.D. and James R. Largent. 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.

### **Board Meetings and Attendance**

Our Board of Directors held fourteen (14) meetings in 2011. In 2011, each member of the Board of Directors attended 75% or more of the aggregate of (i) the total number of board meetings held during the period of such member's service and (ii) the total number of meetings of committees on which such member served, during the period of such member's service.

### **Director Attendance at Annual Meetings of Stockholders**

Directors are encouraged, but not required, to attend our annual stockholder meetings. All of our directors attended our last annual meeting.

### **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.



---

## **Table of Contents**

### **Risk Oversight**

Our Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board of Directors performs this oversight role by using several different levels of review. In connection with its reviews of the operations and corporate functions of our Company, our Board of Directors addresses the primary risks associated with those operations and corporate functions. In addition, our Board of Directors reviews the risks associated with our Company's business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our board committees also oversees the management of our Company's risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Financial Officer reports to the audit committee with respect to risk management and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its risk management role, our audit committee meets privately with representatives from our independent registered public accounting firm and our Chief Financial Officer. The audit committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks and reports to our Board of Directors regarding these activities.

### **Employee Compensation Risks**

As part of its oversight of our Company's executive compensation program, our compensation committee considers the impact of the program, and the incentives created by the compensation awards that it administers, on our Company's risk profile. In addition, the compensation committee reviews all of our Company's compensation policies and procedures, including the incentives that they create and factors that may reduce the likelihood of excessive risk taking, to determine whether they present a significant risk to our Company. The compensation committee has determined that, for all employees, our Company's compensation programs are not reasonably likely to have a material adverse effect on our Company.

### **Code of Business Conduct**

Our Board of Directors has adopted a code of ethics and business conduct that applies to all of our employees, executive officers (including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions) and directors. The full text of our code of ethics and business conduct is posted on our website at [www.alimerasciences.com](http://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 at the same location on our website identified above and also in a Current Report on Form 8-K, as required, within four business days following the date of such amendment or waiver. The inclusion of our website address in this proxy statement does not include or incorporate by reference the information on our website into this proxy statement.

### **Limitation of Liability and Indemnification**

We have entered into indemnification agreements with each of our directors and executive officers. The agreements provide that we will indemnify each of our directors and executive officers against any and all expenses incurred by that director or executive officer because of his or her status as one of our directors or executive officers, 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;



## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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 in the future 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.

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 executive officers and we are authorized to purchase directors' and officers' liability insurance, which we currently maintain to cover our directors and executive officers.

**Table of Contents****Communications to the Board of Directors**

Stockholders interested in communicating with the independent directors regarding their concerns or issues may address correspondence to a particular director, or to the independent directors generally, in care of Alimera Sciences, Inc., 6120 Windward Parkway, Suite 290, Alpharetta, Georgia 30005, Attn: Secretary of the Company. The Secretary of the Company has the authority to disregard any inappropriate communications or to take other appropriate actions with respect to any inappropriate communications. If deemed an appropriate communication, the Secretary of the Company will forward it, depending on the subject matter, to the chairman of the Board of Directors, chairman of a committee of the Board of Directors, the full Board of Directors or a particular director, as appropriate.

**Director Compensation**

In October 2009, our Board of Directors adopted a compensation program for outside directors, which became effective upon the consummation of our initial public offering in April 2010. Pursuant to this program, each member of our Board of Directors who is not our employee receives a \$20,000 annual cash retainer, other than the chairman of our Board of Directors who receives a \$25,000 annual cash retainer. The chairman of the audit committee receives an additional annual retainer of \$7,500, and the chairman of each other committee receives an additional annual retainer of \$3,500. Each other non-employee director serving as a member of a committee receives an additional annual retainer of \$2,000 for service on that committee. All retainer fees are paid in four quarterly payments.

Each new non-employee director 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, which vests and becomes 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. Following each annual meeting, the non-employee directors will be granted an option for 7,500 shares of our common stock, which will be vested and exercisable in full on the date of grant. However, a non-employee director who receives an option to purchase 20,000 shares in connection with joining the Board of Directors will not also receive the annual option to purchase 7,500 shares in the same calendar year.

Each option granted under our non-employee director compensation program that is not fully vested will become fully vested upon a change in control of our Company and if the non-employee director's service terminates due to death. All options granted to the non-employee directors have an exercise price equal to the fair market value of our common stock on the date of the grant.

In 2011, Hewitt Associates recommended to the compensation committee that the annual retainer paid and the annual equity grant awarded to our non-employee directors be increased to better align with the median of the compensation of the directors of the Company's group of peer companies. However, the compensation committee decided not to make any changes to the compensation of the Board of Directors at such time.

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

**Director Compensation Table for Year Ended December 31, 2011**

The following table sets forth information regarding compensation earned by each of our non-employee directors during the fiscal year ended December 31, 2011:

Name(1)	Fees Earned or	Option Awards	Total (\$)
	Paid in Cash (\$)	(\$)(2)	
Glen Bradley, Ph.D. (3)	\$ 15,400	\$ 120,712	\$ 136,112
Mark J. Brooks (4)	22,000	39,109	61,109
Brian K. Halak, Ph.D. (4)	25,500	39,109	64,609
Anders D. Hove, M.D.(4) (5)	12,000		12,000
James R. Largent (6)	10,956	124,802	135,758
Peter J. Pizzo, III	27,500	39,109	66,609
Calvin W. Roberts, M.D.	22,000	39,109	61,109
Philip R. Tracy	28,500	39,109	67,609
Bryce Youngren (4)	18,000	39,109	57,109

- (1) Mr. Myers was not eligible in 2011 to receive any compensation from us for service as a director pursuant to our non-employee director compensation plan because Mr. Myers is a Company employee. Dr. Kong was not a director of the Company in 2011.
- (2) The amounts reported in this column represent the aggregate grant date fair value of option awards computed in accordance with FASB ASC Topic 718. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. See Note 12 of the Notes to the Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2011 for a discussion of our assumptions in determining the ASC 718 values of our option awards.
- (3) Dr. Bradley was appointed to the Board of Directors effective April 18, 2011.

**Table of Contents**

- (4) Fees earned by Mr. Brooks, Dr. Halak, Dr. Hove and Mr. Youngren were paid to the management companies of the venture capital funds affiliated with these directors.
- (5) Dr. Hove resigned as a member of the Board of Directors effective April 18, 2011.
- (6) Mr. Largent was appointed to the Board of Directors effective July 28, 2011.
- (7) Mr. Youngren resigned as a member of the Board of Directors effective August 26, 2011.

The following table sets forth information regarding outstanding option awards held by each of our non-employee directors as of December 31, 2011:

Name	Option awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Glen Bradley, Ph.D. (1)		20,000	7.97	April 18, 2021(3)
Mark J. Brooks	2,812	4,688	11.00	April 27, 2020(4)
	7,500		7.53	June 8, 2021(5)
Brian K. Halak, Ph.D.	2,812	4,688	11.00	April 27, 2020(4)
	7,500		7.53	June 8, 2021(5)
James R. Largent (2)		20,000	8.47	July 28, 2021(6)
Peter J. Pizzo, III	7,500	12,500	11.00	April 27, 2020(4)
	7,500		7.53	June 8, 2021(5)
Calvin W. Roberts, M.D.	8,824		1.33	December 14, 2013(5)
	4,412		3.88	June 25, 2015(5)
	4,412		4.02	June 16, 2016(5)
	2,812	4,688	11.00	April 27, 2020(4)
	7,500		7.53	June 8, 2021(5)
Philip R. Tracy	2,812	4,688	11.00	April 27, 2020(4)
	7,500		7.53	June 8, 2021(5)

- (1) Dr. Bradley was appointed to the Board of Directors effective April 18, 2011.
- (2) Mr. Largent was appointed to the Board of Directors effective July 28, 2011.
- (3) Exercisable with respect to 25% of the shares of stock which are subject to this option on April 18, 2012 (Initial Vesting Date), provided the optionee provides continuous service to Alimera through the Initial Vesting Date; and the remainder of the shares of stock which are subject to this option shall vest in equal increments quarterly over three years beginning on the date three months from such Initial Vesting Date, provided optionee provides continuous service to Alimera through the last day of each quarterly period.
- (4) Exercisable with respect to 25% of the shares of stock which are subject to this option on April 27, 2011 (Initial Vesting Date), provided the optionee provides continuous service to Alimera through the Initial Vesting Date; and the remainder of the shares of stock which are subject to this option shall vest in equal increments quarterly over three years beginning on the date three months from such Initial Vesting Date, provided optionee provides continuous service to Alimera through the last day of each quarterly period.
- (5) Exercisable with respect to 100% of the shares of stock which are subject to this option as of the date of grant.
- (6) Exercisable with respect to 25% of the shares of stock which are subject to this option on July 28, 2012 (Initial Vesting Date), provided the optionee provides continuous service to Alimera through the Initial Vesting Date; and the remainder of the shares of stock which are subject to this option shall vest in equal increments quarterly over three years beginning on the date three months from such Initial Vesting Date, provided optionee provides continuous service to Alimera through the last day of each quarterly period.

**EXECUTIVE COMPENSATION****Compensation Discussion and Analysis**

This section discusses our executive compensation policies 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 named executive officers and offers perspective on the data presented in the tables and narrative that follow.



---

## **Table of Contents**

### ***Executive Summary of 2011 Executive Compensation Program***

The following provides a brief overview of the more detailed disclosure set forth in this Compensation Discussion and Analysis.

2011 was a challenging year for our Company. Although certain of our 2011 corporate goals and our named executive officers' individual objectives were satisfied or partially met, such as the amendment of our credit facility, the completion of the analysis of the 36-month data from our FAME Study, the resubmission of our NDA in response to the Complete Response Letter (CRL) received from the U.S. Food and Drug Administration (FDA) in late 2010 relating to our New Drug Application (NDA) for ILUVIEN in the treatment of diabetic macular edema and the continued development and execution of our commercialization strategy in the European Union, we received a second CRL from the FDA stating that our NDA was not approvable in its then current form in November 2011.

In the fourth quarter of 2010, prior to the receipt of the initial CRL, the compensation committee increased the 2011 base salary and target bonuses for our named executive officers based on the committee's revised compensation philosophy discussed in detail below.

In February 2012, due primarily to the receipt of the second CRL, although certain of the corporate and individual goals under the 2011 annual incentive compensation program were fully or partially achieved, the compensation committee utilized the discretion reserved to it under our cash bonus plan, to reduce the annual incentive bonus for each of the named executive officers by 50% of the amount which would otherwise have been awarded.

No equity grants were made to our named executive officers in 2011.

### ***Compensation 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 our executive officers and 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 our executive officers, attract and retain highly qualified executive officers, motivate the performance of our executive officers towards, and reward the achievement of, clearly defined corporate goals, and align our executive officers' long-term interests with those of our stockholders. To that end, our executive officers' compensation has four primary components: (1) base compensation or salary, (2) annual incentive compensation or bonus, (3) long-term incentive compensation in the form of stock option or other equity awards and (4) certain cash and equity award vesting acceleration benefits in the event of an executive officer's termination without cause, or the executive officer's decision to terminate his or her employment for good reason after a change in control. In addition, we provide our executive officers a variety of benefits that are available generally to all salaried employees, including the right to participate in our employee stock purchase plan and 401(k) plan.

We review the total compensation of our executive officers when making compensation decisions. We aim to (1) provide overall compensation, when targeted levels of performance are achieved, which allows us to attract and retain highly qualified executive officers and (2) emphasize at-risk equity compensation over annual cash compensation to retain executive officers and align a substantial portion of their compensation with long-term stockholders' interests. Our annual cash incentives and our equity awards are intended to be 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. As discussed below, in the fourth quarter of 2010, the compensation committee determined that our named executive officers' targeted overall compensation should be at or near the 50<sup>th</sup> percentile of our peer group companies with a greater emphasis placed on long-term compensation.

We historically determined the appropriate level for each compensation component based in part, but not exclusively, on a review of various survey and publicly available compensation data, our view of internal equity and consistency, our overall performance and other considerations we deemed relevant. For annual compensation reviews we evaluated each executive officer's performance, looked to industry trends in compensation levels and generally sought to ensure that compensation is appropriate for an executive's level of responsibility and for promotion of future performance. Under the compensation committee's revised compensation philosophy, our goal is to continue to make a greater percentage of an executive'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 equity awards.

We do not have stock ownership guidelines for our executive officers, because the compensation committee is satisfied that stock and option holdings among our 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 that stock ownership guidelines are rare in development-stage biopharmaceutical companies, which means that ownership requirements would put us at a competitive disadvantage when recruiting and retaining high-quality executives. Under our trading policy, we prohibit all hedging or short sales involving our securities by our executive officers and employees.

#### *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 reviews the performance of our management in achieving corporate objectives and aims 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 annually reviews the performance of each executive officer. Our Chief Executive Officer, as the manager of the executive team, assesses our executive officers' contributions to the corporate goals and makes a recommendation to the compensation committee with respect to any merit increase in salary, cash bonus and equity 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 equity award.

## **Table of Contents**

### ***Compensation Consultant***

Prior to the third quarter of 2010, the compensation committee had not engaged a compensation consultant for advice on matters related to compensation for executive officers, other key employees and non-employee directors. In July 2010, the compensation committee determined that, in light of Company's initial public offering, it would engage an executive compensation consultant to review the compensation of the Company's executives and advise the compensation committee with respect to any recommended changes to such compensation. The compensation committee engaged Hewitt Associates LLC in the third quarter of 2010 to provide advice in connection with our 2011 executive compensation program. As described in detail below, the compensation committee utilized Hewitt Associates' recommendations as part of its decision-making process for setting the named executive officers' 2011 base salary and target bonus.

### ***Peer Group***

In late 2007, the compensation committee identified a group of peer companies to use to prepare an analysis of competitive compensation data. The compensation committee continues to review and revise the peer group periodically to ensure that it reflects companies similar to us in size and development stage. Our peer group utilized to prepare data in connection with 2011 compensation decisions, which is listed below, was suggested by Hewitt Associates and approved by the compensation committee in late 2010, based on a review of biopharmaceutical companies that were similar to us in market capitalization, development stage, size, revenues and business model. Our peer group companies consisted of:

Affymax Inc.	Ista Pharmaceuticals Inc.
Allos Therapeutics Inc.	Momenta Pharmaceuticals Inc.
Amag Pharmaceuticals Inc.	Optimer Pharmaceuticals Inc.
Arena Pharmaceuticals Inc.	Orexigen Therapeutics Inc.
Aveo Pharmaceuticals Inc.	Rigel Pharmaceuticals Inc.
Cadence Pharmaceuticals Inc.	Trius Pharmaceuticals Inc.
Inspire Pharmaceuticals Inc.	Xenoport Inc.
Ironwood Pharmaceuticals Inc.	

This peer group differs greatly from the group of companies whose executive officer compensation was reviewed by the compensation committee in connection with its 2010 compensation decisions, with only Cadence Pharmaceuticals and Orexigen Therapeutics being included in both groups. This change was substantially due to the fact that our 2011 peer group of companies was suggested by Hewitt Associates rather than independently picked by our compensation committee.

### ***Revised Compensation Philosophy***

Prior to the fourth quarter of 2010, as our compensation committee made decisions with respect to compensation for individual executive officers and for the Company's compensation programs in general, it relied upon the peer group or survey data to understand where the Company's compensation practices fall relative to its competitors, to identify individual executive officers whose compensation seems out of step with other Company officers or similar officers at peer group or similar companies, and as a way of staying current with market practices. Historically, the compensation committee had not specifically benchmarked or targeted a particular level of compensation with respect to total compensation or to any individual component of compensation and the objective peer group or survey market data was one of the numerous factors the compensation committee used as part of its decision making process.

In the fourth quarter of 2010, the compensation committee determined that it would revise its compensation philosophy and begin targeting the compensation of our executive officers based on the compensation provided to executives in similar positions at our peer group companies. The compensation committee decided to begin targeting overall compensation at or near the 50th percentile of our peer group companies while continuing to follow its historical philosophy of placing greater emphasis on long-term compensation in an effort to align our executive officers interests with those of our stockholders. As such, the compensation committee decided to begin setting our named executive officers' base salary at or near the 25th percentile of that provided at our peer group, annual incentive compensation at or near the 50th percentile and long-term incentive compensation in such a manner that the executive's total annual compensation would be at or near the 50th percentile of the Company's peer group. The compensation committee did not resolve to always set executive compensation components at the exact levels derived from its analysis of the peer group data. The compensation committee determined that our executive compensation program should remain flexible. As



## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

such, at times the compensation committee may decide to use the peer group data as merely a reference point and base the decision on other factors, including, but not limited to, the compensation committee's view of internal equity and consistency, the individual experience and judgment of the members of the committee, information it receives from management, individual performance, the committee's judgment of the current state of the Company's business, the small size of our executive team and the need to tailor each executive's compensation to retain and motivate that executive officer. The compensation committee believes this practice will allow us to retain and attract executive talent while maintaining the desired emphasis on long-term incentives aligned with stockholders. In certain circumstances in which an executive officer is uniquely critical to our success or due to the intensely competitive market for highly qualified employees in our industry, the compensation committee expects that it may deviate from this new approach. The compensation committee utilized this new approach in November of 2010 when it set our executive officers' 2011 base salaries and target bonuses.

**Table of Contents**

The compensation committee will continue to review the method utilized for executive compensation decisions on an ongoing basis.

***Principal Elements of Compensation***

**Base Salaries.** Base salaries are intended 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. 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 by a comparison to our then current peer group.

Salary for our Chief Executive Officer and the other executive officers was historically established based on the underlying scope of their respective responsibilities, taking into account, among other things, competitive market compensation data. We review base salaries for the executive officers annually near the end of each year, and our Chief Executive Officer proposes salary adjustments (other than for himself) 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.

In November 2010, as part of the annual compensation review and implementation of the compensation committee's revised compensation philosophy, the compensation committee reviewed the peer group analysis prepared by Hewitt Associates, its compensation consultant. Following this review, the compensation committee determined to increase the 2011 base salaries for our named executive officers to an amount that equaled the 25<sup>th</sup> percentile of base salary provided to similarly situated executives at our peer group companies. The compensation committee believed the increases were merited based on, among other considerations, information the compensation committee received from management, individual executive performance, the then current state of the Company's business and its prospects, the small size of our executive team, the expected long-term contributions of the named executive officers as the company continues to develop and the need to tailor each executive's compensation to retain and motivate that executive. The 2011 25<sup>th</sup> percentile base salaries of similarly situated executives at our peer group companies, the base salary of our named executive officers following the increase and the percentage increase from their respective 2010 base salaries were:

	<b>2011 Base Salary (1)</b>	<b>% Increase from 2010 Base Salary</b>
C. Daniel Myers	\$ 431,650	17.4%
Richard S. Eiswirth	\$ 311,383	4.1%
Kenneth Green, Ph.D.	\$ 294,228	8.8%
Susan Caballa	\$ 253,499	6.5%
David Holland	\$ 285,634	4.6%

- (1) The 2011 base salaries of our executive officers is equal to 25<sup>th</sup> percentile of the base salaries of similarly situated employees at our peer group companies.

**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 should increase stockholder value. Historically and for 2011, annual incentive awards were determined 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.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

An aggregate target bonus, which includes the potential subjective or discretionary bonus, was set for each executive officer based in part on our review of our peer group and is stated in terms of a percentage of the executive officer's annualized base salary for the year. In November 2010, as part of the annual compensation review, the compensation committee increased the aggregate target bonus for our Chief Executive Officer from 40% of his annualized base salary in 2010 to 55% in 2011 and the aggregate target bonus for each of our other named executive officers from 25% of their respective annualized base salary in 2010 to 40% in 2011. The increase in the aggregate target bonus percentage was in connection with the compensation committee's implementation of its revised compensation philosophy. Our Chief Executive Officer's and other named executive officer's aggregate target annual bonus percentage was set slightly above the average target at the 25<sup>th</sup> percentile of our peer group companies of 50% for chief executive officers and 36% to 39% for executive officers in comparable positions at our peer group companies due to the progress of our clinical programs through November 2010.

**Table of Contents**

Historically and for 2011, the annual performance goals, both corporate and individual, were established each year and were clearly communicated to the respective executive officer and were objectively measurable. Early each year, our Chief Executive Officer proposed a set of corporate performance objectives and proposed percentage weights to be allocated to each goal, with higher weights given to those goals that we believed would have a greater impact on our value and/or were more challenging to achieve within the time frame specified. The compensation committee evaluated the goals and weightings and made a recommendation to the Board of Directors for approval. The individual goals of our Chief Executive Officer and other named executive officers were established in a manner intended to align their performance objectives with, and support the achievement of, our corporate performance goals. Our Chief Executive Officer proposed 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 executive officers were determined individually by the Chief Executive Officer and the specific named executive and then approved by the compensation committee.

Historically and in 2011, at the end of each year, our Chief Executive Officer assessed his and the named executive officers' achievement of their individual performance goals for the year, and recommended a percentage payout for each individual for the 50% of the aggregate target bonus that was allocated to individual performance goals. The compensation committee accepted and approved that percentage as is, or adjusted it to the extent the compensation committee deemed appropriate. Our Chief Executive Officer and his management team also assessed our achievement of corporate performance goals, and recommended a percentage payout for the 25% of the aggregate target bonus that was allocated to corporate performance goals. The compensation committee accepted and approved that percentage as is, or adjusted it to the extent the compensation committee deemed appropriate. The remaining 25% of the aggregate target bonus was determined at the discretion of the compensation committee. The compensation committee evaluated subjective criteria, including, but not limited to, its assessment of the management team's stewardship of our Company, contributions to improving stockholder value and strategic planning for long-term goals. Our compensation committee believed that partial or over achievement of both corporate and individual goals is possible. In addition, pursuant to our cash bonus plan, the compensation committee has the flexibility and power to adjust an executive officer's annual incentive compensation up or down as it determines.

**2011 Annual Incentive Compensation.** With input from our Chief Executive Officer, our compensation committee approved corporate and individual performance goal achievement for each of our named executive officers. In February 2012, our compensation committee reviewed the recommendations of our Chief Executive Officer with respect to the achievement of our 2011 corporate goals and the 2011 individual goals of our named executive officers. Due primarily to our receipt of the second CRL and its effects on the Company, the compensation committee determined that all of our named executive officers should be paid bonuses substantially below the amount that otherwise would have been awarded based on the achievement of the individual and corporate goals. Although certain 2011 corporate goals and a majority of our named executive officer's individual goals were satisfied or partially achieved, the compensation committee exercised its discretion to reduce each named executive officer's aggregate annual incentive cash bonus that would have otherwise been awarded by 50%.

**2011 Corporate Goals.** For 2011, the corporate goals component of the annual performance goals under our Incentive Compensation Bonus Plan, which accounted for 25% of the amount of aggregate 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:

<b>Corporate Goals (Results Achieved)</b>	<b>Weighted Percentage</b>	<b>Weighted Percentage Achievement</b>
Obtain FDA approval of ILUVIEN NDA ( <i>We received a second CRL from the FDA in December of 2011 indicating that the NDA for ILUVIEN was not approvable in its then current form.</i> )	35%	0%
Consummate first sale of ILUVIEN following FDA regulatory approval ( <i>The Commercial launch of ILUVIEN did not occur in 2011.</i> )	20%	0%
Minimize the Company's cash burn and maintain compliance with 2011 budget approved by the Board of Directors ( <i>Our monthly cash burn rate was adjusted relative to business conditions resulting in cash positions higher than Board of Director approved targets.</i> )	20%	20%
Execute on ILUVIEN commercial strategy in the European Union ( <i>We conducted discussions and negotiations with potential strategic partners regarding the commercialization of ILUVIEN in the European Union. We identified and engaged a third party to</i> )	25%	25%

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

*assist the Company in assessing the market landscape, developing a pricing and reimbursement strategy in Europe and preparing of health economics and outcomes research models and product dossiers.)*

<b>Total</b>	100%	45%
--------------	------	-----

**Table of Contents**

*2011 Individual Goals.* The individual goals component under our Incentive Compensation Bonus Plan for our named executive officers was 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 deemed appropriate. Our Chief Executive Officer made recommendations to our compensation committee as to the degree to which those named executive officers have satisfied their individual goals. For 2011, the individual goals, which accounted for 50% of the amount of aggregate 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:

<b>Daniel Myers Individual Goals (Results Achieved)</b>	<b>Weighted Percentage</b>	<b>Re-Allocated Weighted Percentage Achievement</b>	<b>Re-Allocated Weighted Percentage Achievement</b>
Assure response to first CRL is submitted to FDA in a timely manner pursuant to the timeline approved by the Board of Directors ( <i>Our response to the 2010 CRL was submitted in May 2011.</i> )	20%	26%	26%
Oversee coordination of FDA advisory committee meeting resulting in a positive panel vote ( <i>This target was not applicable because no advisory committee was requested by the FDA.</i> ) (1)	25%	N/A	N/A
Execute amendment with Silicon Valley Bank and MidCap Financial LLP, the lenders under our credit facility, to extend availability of second tranche drawdown until December 31, 2011 ( <i>Our credit facility was amended in May of 2011 to extend the availability of the second tranche to December 31, 2011 and increase the amount from \$6.25 million to \$11 million. Additionally, the maturity dates of our term loan and revolving credit facility were extended from October 2013 to April 2014. The compensation committee determined that Mr. Myers over achieved on this goal because of the increased size of the facility and the extended maturity date.</i> )	10%	14%	17%
Consummate first sale of ILUVIEN following FDA regulatory approval (The commercial launch of ILUVIEN did not occur in 2011.)	25%	33%	0%
Establish, present to the Board of Directors and execute on Company's ILUVIEN commercial strategy in the European Union based on the regulatory path and timing ( <i>We conducted discussions and negotiations with potential strategic partners regarding the commercialization of ILUVIEN in the European Union. We identified and engaged a third party to assist the Company in assessing the market landscape, developing a pricing and reimbursement strategy in Europe and the preparation of health economics and outcomes research models and product dossiers.</i> )	20%	27%	27%
<b>Total</b>	100%	100%	70%

- (1) Due to the fact that the FDA did not request an advisory committee meeting, the compensation committee determined to cancel this individual goal and reallocate the weighted percentages pro rata amongst the remaining targets.

**Table of Contents**

	Weighted Percentage	Weighted Percentage Achievement
<b>Richard Eiswirth's Individual Goals (Results Achieved)</b>		
Execute amendment with Silicon Valley Bank and MidCap Financial LLP, the lenders under our credit facility, to extend availability of second tranche drawdown until December 31, 2011 <i>(Our credit facility was amended in May of 2011 to extend the availability of the second tranche to December 31, 2011 and increase the amount from \$6.25 million to \$11 million. Additionally, the maturity dates of our term loan and revolving credit facility were extended from October 2013 to April 2014. The compensation committee determined that Mr. Eiswirth over achieved on this goal because of the increased size of the facility and the extended maturity date.)</i>	25%	30%
Lead effort to file shelf registration statement on Form S-3 with the SEC in accordance with the timelines established by our Board of Directors <i>(A shelf registration statement was filed with the SEC in May 2011.)</i>	15%	15%
Enhance, test and maintain our Company's internal control over financial reporting in accordance with Section 404 of the Sarbanes Oxley Act of 2002 <i>(Our finance department, at the direction of Mr. Eiswirth, identified key risks, documented key controls and developed testing methodologies to support management's assertions in our annual report on Form 10-K for the year ended December 31, 2011. No material weaknesses were identified.)</i>	20%	20%
Timely completion of manufacturing of commercial batches of ILUVIEN <i>(Commercial batches were not completed in accordance with the timeline established by our Board of Directors. However, our compensation committee acknowledged that Mr. Eiswirth had taken on additional responsibility for the manufacturing of ILUVIEN from the quality assurance team in February of 2011 and supervised numerous redesigns of the ILUVIEN inserter and its manufacturing processes in determining to give him credit for partial achievement of this goal.)</i>	15%	10%
Establish and implement third party logistics and distributor relationships in preparation of U.S. ILUVIEN commercial launch <i>(We contracted with a third party logistic provider and negotiated agreements with four specialty distributors in 2011. We delayed executing definitive agreements with the specialty distributors in order to mitigate unnecessary start-up fees in advance of ILUVIEN's PDUFA date.)</i>	15%	15%
Establish, present to the Board of Directors and execute on Company's ILUVIEN commercial strategy in the European Union based on the regulatory path and timing <i>(We conducted discussions and negotiations with potential strategic partners regarding the commercialization of ILUVIEN in the European Union. We identified and engaged a third party to assist the Company in assessing the market landscape, developing a pricing and reimbursement strategy in Europe and the preparation of health economics and outcomes research models and product dossiers.)</i>	10%	10%
<b>Total</b>	<b>100%</b>	<b>100%</b>

**Table of Contents**

<b>Kenneth Green s Individual Goals (Results Achieved)</b>	<b>Weighted Percentage</b>	<b>Re-Allocated Weighted Percentage Achievement</b>	<b>Re-Allocated Weighted Percentage Achievement</b>
Submit response to first CRL to FDA in a timely manner pursuant to the timeline approved by the Board of Directors ( <i>Our response to the 2010 CRL was submitted in May 2011.</i> )	25%	33%	33%
Submit response to the preliminary assessment report issued by the United Kingdom Medicines and Healthcare Products Regulatory Agency (UK MHRA) pursuant to the timeline approved by the Board of Directors. ( <i>The draft response to the preliminary assessment report was submitted in September 2011 and the final response was submitted in November 2011.</i> )	25%	33%	33%
Represent the Company and present at FDA advisory committee meeting resulting in a positive panel vote ( <i>This target was not applicable because no advisory committee was requested by the FDA.</i> ) (1)	25%	N/A	N/A
Manage 2011 clinical budget approved by the Board of Directors and maintain material compliance with the approved budget ( <i>2011 spending was controlled within budget.</i> )	10%	13%	13%
Manage ongoing phase II clinical studies, and produce prototype of delivery system for NADPH oxidase lead ( <i>Although Dr. Green managed the ongoing phase II clinical studies in a satisfactory manner, we determined that NADPH oxidase inhibitors licensed from Emory University were not viable for drug delivery.</i> )	15%	21%	5%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>84%</b>

- (1) Due to the fact that the FDA did not request an advisory committee meeting, the compensation committee determined to cancel this individual goal and reallocate the weighted percentages pro rata amongst the remaining targets.

<b>Susan Caballa s Individual Goals (Results Achieved)</b>	<b>Weighted Percentage</b>	<b>Weighted Percentage Achievement</b>
Collaborate with the Company s third party manufactures to obtain good manufacturing practice, or GMP, status. Review and approve documents for pre-approval inspection of their facilities and resolve any GMP issues at such facilities ( <i>In 2011, two of our third party manufacturers previously noted in the 2010 CRL as being out of compliance with cGMP, received notification that their deficiencies had been resolved and their respective facilities were acceptable.</i> )	10%	10%
Draft and submit responses to technical section of the 2010 CRL in a timely manner pursuant to the timeline approved by the Board of Directors ( <i>Our response to the 2010 CRL was submitted in May 2011.</i> )	30%	30%
Manage the Company s activities relating to the regulatory approval process in the European Union for ILUVIEN. Write technical sections to the draft response to the preliminary assessment report issued by the UK MHRA. Timely submit final response to the UK MHRA ( <i>The draft response to the preliminary assessment report was submitted in September 2011 and the final response was submitted in November 2011</i> )	20%	20%
Manage and coordinate the Company s preparation for a potential FDA advisory committee meeting and represent the Company at any such meeting ( <i>The Company completed preliminary activities and preparation for a potential advisory committee meeting, however the FDA did not request an advisory committee meeting.</i> )	20%	20%
	5%	0%



Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Review and approve information materials in connection with first commercial production batches <i>(All documents were reviewed and approved in preparation for production, however commercial batches were not produced in accordance with the timeline approved by the Board of Directors.)</i>		
Manage amounts budgeted by the Board of Directors in the 2011 budget relating to regulatory, medical and technical affairs, and maintain material compliance with the approved budget <i>(2011 spending was controlled within budget.)</i>	5%	5%
<b>Total</b>	100%	95%

**Table of Contents**

	Weighted Percentage	Weighted Percentage Achievement
<b>Dave Holland's Individual Goals (Results Achieved)</b>		
Achieve ILUVIEN specified sales target in 2011, as adjusted based on timing of U.S. commercial launch of ILUVIEN ( <i>Sales targets were not met since the commercial launch of ILUVIEN did not occur due to receipt of the 2011 CRL. However, the compensation committee acknowledged that our sales and marketing group, led by Mr. Holland, was sufficiently prepared to meet the sales target in 2011, and credited him for partial achievement of this goal.</i> )	30%	15%
Interview and hire region director and sales representative positions in territory in a manner timely enough to permit the completion of such employees required sales training prior to commercial launch of ILUVIEN (Prior to the receipt of the 2011 CRL, we had filled the necessary positions contingent upon FDA approval of ILUVIEN and developed the sales training programs for the planned commercial launch.)	20%	20%
Prepare and present to the Board of Directors a marketing plan to support ILUVIEN prior, during and after the previously anticipated commercial launch ( <i>Our Board of Directors approved the proposed marketing plan prior to the receipt of the second CRL.</i> )	10%	10%
Develop scientific messaging presentations and conduct speaker's training program prior to commercial launch. Arrange for the Company to have podium presence at 9 key retinal meetings during 2011 ( <i>During 2011, ILUVIEN data was discussed in 16 podium presentations and displayed on 2 posters at meetings of various retinal groups. Scientific Communication Advisory Boards were executed in the U.S. and European Union.</i> )	15%	15%
Ensure managed markets support, such as patient support program, reimbursement hotline, coding applications and managed care team, are in place in time for U.S. commercial launch of ILUVIEN ( <i>Our managed markets personnel were hired and market access and patient assistance programs were developed in 2011. In addition, coding applications were prepared with submission pending agreement with the FDA regarding product labeling.</i> )	15%	15%
Establish, present to the Board of Directors and execute on Company's ILUVIEN commercial strategy in the European Union based on the regulatory path and timing ( <i>Mr. Holland assisted with and participated in discussions and negotiations with potential strategic partners regarding the commercialization of ILUVIEN in the European Union. Mr. Holland managed a third party engaged to assist the Company in assessing the market landscape, developing a pricing and reimbursement strategy in Europe and the preparation of health economics and outcomes research models and product dossiers.</i> )	10%	10%
<b>Total</b>	<b>100%</b>	<b>85%</b>

**Table of Contents**

*2011 Discretionary Bonus.* The remaining 25% of the aggregate bonus potential for each of our named executive officers was awarded in the discretion of our compensation committee. This portion of the bonus is not considered a non-equity incentive plan award. Based on the compensation committee's consideration of the achievements, as well as disappointments which occurred during 2011 at both a corporate and individual level, the compensation committee exercised its discretion to award each of our named executive officers only 20% of the potential discretionary bonus, or 5% of their respective aggregate bonus potential. Although our Company was very disappointed with the receipt of the second CRL, the compensation committee acknowledged the effort exerted by our named executive officers over the course of the year and their achievement of a significant portion of their 2011 individual goals.

In February 2012, our compensation committee met to discuss the annual incentive compensation to be awarded to our named executive officers in connection with the satisfaction of the 2011 corporate goals, satisfaction of the named executive officers individual goals, and the 2011 discretionary or subjective bonus. Based primarily on our receipt of the second CRL and its effects on our Company, our compensation committee utilized the discretion reserved to it under our Incentive Compensation Bonus Plan to reduce the bonus that otherwise would have been paid to our named executive officers by 50%. The table below sets forth the 2011 target bonus for each of our named executive officers, the amount otherwise awardable to such officers based on satisfaction of the Company's 2011 corporate goals, satisfaction of the named executive officers individual goals, and the 2011 discretionary bonus and the amount actually paid to such officers following the 50% reduction applied to the bonus by the compensation committee.

Name	Aggregate Target (1)	Pre-Reduction Bonus	Actual Payout Following 50% Reduction
C. Daniel Myers	\$ 237,408	\$ 118,110	\$ 59,055
Richard S. Eiswirth	\$ 124,553	\$ 82,517	\$ 41,258
Kenneth Green, Ph.D.	\$ 117,691	\$ 66,790	\$ 33,395
Susan Caballa	\$ 101,340	\$ 63,121	\$ 31,561
David Holland	\$ 114,254	\$ 67,124	\$ 33,562

(1) Includes the objective and subjective portion of the aggregate target bonus.

See the columns titled "Bonus" and "Non-Equity Incentive Compensation" in the 2011 Summary Compensation Table for additional information related to the performance bonuses earned by our named executive officers.

*Long-Term Incentive Compensation.* We utilize equity awards for our long-term equity compensation to ensure that our executive officers have a continuing stake in our long-term success. To date, our long-term incentive awards have primarily been in the form of options to purchase our common stock. 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, these options will have value to our executive officers only if the market price of our common stock increases after the date of grant.

Prior to our IPO, our Board of Directors 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. Since becoming a public company, we have and intend to continue to grant equity awards at fair market value (the closing price of our common stock on the NASDAQ Global Market) on the date that the grant occurs. We anticipate granting equity awards to our executive officers on an annual 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. Typically, our initial stock option grants to new executives vest at the rate of 25% after the first year of service, with the remainder vesting ratably over the subsequent 36 months and our stock option grants to continuing executives vest in equally monthly installments over a four year period. Historically, the compensation committee determined the size of the grant based in part on its review of peer group and other publicly available data. Subsequent stock option grants to our named executive officers vest monthly over a four year period.

---

## **Table of Contents**

Under the compensation committee's revised compensation philosophy, the goal is to set long-term incentive compensation in such a manner that the executive's total annual compensation would be at or near the 50th percentile of the amounts provided by the Company's peer group to similarly situated executives. However, due to the fact that our named executive officers were granted options to purchase shares of our common stock in November 2010 and our receipt of the first CRL in December 2010, the compensation committee determined not to make any equity grants to our named executive officers during 2011.

The compensation committee plans to consider future equity awards for executive officers annually based upon recommendations from our Chief Executive Officer and in comparison to their current 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.

### ***Severance and Change in Control***

Each of our named executive officers 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, in the event of change of control, each executive will receive 12 months of additional vesting for any stock options that are outstanding and unvested as of the date of such transaction. In addition, 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 or her employment for good reason within 12 months of a change of control. See "Employment Agreements with our Executive Officers" and "Estimated Benefits and Payments Upon Termination of Employment" 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.

No material changes were made to these benefits in 2011.

### ***Other Benefits***

Our 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, our employee stock purchase plan 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. However, we expect to implement a clawback policy in accordance with the requirements of the Dodd-Frank Act and the regulations that will be issued under that act. We elected to wait until the SEC issues guidance about the proper form of a clawback policy in order to ensure that we implement a fully compliant policy at one time, rather than implementing a policy this year that may require amendment next year after the SEC regulations are released.

### ***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 compensation that meets certain requirements. All grants of options under our 2010 Equity Incentive Plan are intended to qualify for the exemption. Grants of restricted shares or stock units under our 2010 Equity Incentive Plan may

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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 executive 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.

**Table of Contents**

We account for equity compensation paid to our employees under the rules of FASB ASC Topic 718, 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.

**Stockholder Advisory Vote on Executive Compensation**

At our 2012 annual meeting of stockholders, approximately 99.7% of the shares voted were in favor of the compensation of our named executive officers as disclosed in the proxy statement for the 2011 annual meeting of stockholders, including the Compensation Discussion and Analysis, the 2011 Summary Compensation Table and other related tables and disclosures. Our compensation committee believes that the vote results confirm its view that our compensation programs are appropriate on an absolute and relative basis. The committee will consider the outcome of the stockholder advisory vote on executive compensation each year as it makes future compensation decisions. Our stockholder advisory vote on executive compensation is submitted to our stockholders on an annual basis.

**Report of the Compensation Committee<sup>1</sup>**

We, as members of the compensation committee of the Board of Directors, have reviewed and discussed the Compensation Discussion and Analysis contained in this proxy statement with management. Based on such review and discussion, we have recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this proxy statement and incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

SUBMITTED BY THE COMPENSATION

COMMITTEE OF THE BOARD OF DIRECTORS

Brian K. Halak, Ph.D. (Chairman)

Mark J. Brooks

James Largent

1 The material in this report shall not be deemed to be (i) soliciting material, (ii) filed with the SEC, (iii) subject to Regulations 14A or 14C of the Exchange Act, and/or (iv) subject to the liabilities of Section 18 of the Exchange Act. This report shall not be deemed incorporated by reference into any of our other filings under the Exchange Act or the Securities Act of 1933, as amended, except to the extent the Company specifically incorporates it by reference into such filing.

**2011 Summary Compensation Table**

The following table summarizes the compensation that we paid to our Chief Executive Officer, Chief Financial Officer and each of our three other most highly compensated executive officers during the year ended December 31, 2011. We refer to these executive officers in this proxy statement as our named executive officers.

Name and Principal Position	Year	Salary (\$)	Bonus \$(1)	Option Awards \$(2)	Non-Equity Incentive	All Other	Total (\$)
					Plan Compensation \$(3)	Compensation \$(4)	
C. Daniel Myers Chief Executive Officer	2011	\$ 431,650	\$ 5,935(5)	\$	\$ 53,120(5)	\$ 1,852	\$ 492,557(8)
	2010	367,744	33,097(6)	833,216	86,052(6)	1,764	1,321,873
	2009	353,600	35,360	365,380	108,909	1,721	864,970
Richard S. Eiswirth Chief Operating Officer	2011	\$ 311,383	\$ 3,114(5)	\$	\$ 38,144(5)	\$ 6,352	\$ 358,993(8)
	2010	274,560	15,444(6)	584,310	45,302(6)	6,264	925,880

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

and Chief Financial Officer	2009	249,600	15,600(7)	97,690	48,048(7)	6,221	417,159
Kenneth Green, Ph.D.	2011	\$ 294,228	\$ 2,942(5)	\$	\$ 30,453(5)	\$ 6,352	\$ 333,975(8)
Senior Vice President,	2010	270,400	15,210(6)	463,458	41,405(6)	6,264	796,737
Scientific Affairs and Chief Scientific Officer	2009	260,000	16,250(7)	126,652	50,050(7)	6,221	459,173
Susan Caballa	2011	\$ 253,499	\$ 2,535(5)	\$	\$ 29,026(5)	\$ 6,352	\$ 291,412(8)
Senior Vice President,	2010	237,952	13,385(6)	337,719	35,247(6)	6,246	630,549
Regulatory and Medical Affairs	2009	228,880	14,300	83,995	43,186	6,174	376,455
David Holland	2011	\$ 285,634	\$ 2,856(5)	\$	\$ 30,706(5)	\$ 6,352	\$ 325,548(8)
Senior Vice President, Sales and Marketing	2010	244,608	13,759(6)	376,068	41,278(6)	6,218	681,931
	2009	218,400	13,650(7)	94,513	42,042(7)	6,128	374,733

**Table of Contents**

- (1) The amounts set forth in this column represent the subjective portion of our annual bonus awards paid to the named executive officers based on the Board of Directors' approval. See Compensation Discussion and Analysis above for further discussion of this discretionary bonus.
- (2) The amounts reported in this column represent the aggregate grant date fair value of option awards computed in accordance with FASB ASC Topic 718. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. See Note 12 of the Notes to the Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2011 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.
- (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 February 2012, but earned for fiscal year 2011.
- (6) Represents amount paid in January 2011, but earned for fiscal year 2010.
- (7) Represents amount paid in January 2010, but earned for fiscal year 2009.
- (8) In 2011, 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	88%	1%	11%
Richard S. Eiswirth	87%	1%	11%
Kenneth Green, Ph.D.	88%	1%	9%
Susan Caballa	87%	1%	10%
David Holland	88%	1%	9%

**Grants of Plan-Based Awards in 2011**

The following table sets forth each non-equity incentive plan-based award granted to our named executive officers during the year ended December 31, 2011. There were no equity incentive plan awards granted to our named executive officers during the year ended December 31, 2011.

Name	Estimated Future Payouts Under Non-Equity Incentive Plan Awards (1)		
	Threshold (\$)	Target (\$)	Maximum (\$)
C. Daniel Myers	(2)	\$ 178,055.63	(3)
Richard S. Eiswirth	(2)	93,414.90	(3)
Kenneth Green, Ph.D.	(2)	88,268.40	(3)
Susan Caballa	(2)	76,049.70	(3)
David Holland	(2)	85,690.20	(3)

- (1) Represents bonus payable to executives based on personal and corporate targets as defined in our Incentive Compensation Bonus Plan and approved by the Board of Directors. This amount does not include the discretionary portion of the executive's aggregate target bonus amount.
- (2) No threshold amount is included because the Incentive Bonus Compensation Plan does not provide for a minimum non-zero payout amount.
- (3) No maximum amount is included because the Incentive Bonus Compensation Plan does not provide for maximum payout amounts in the event of over achievement of both corporate and individual goals.





**Table of Contents****Outstanding Equity Awards as of December 31, 2011**

The following table sets forth information regarding each option held by each of our named executive officers as of December 31, 2011. The vesting applicable to each outstanding option is described in the footnotes to the table below. For a description of the acceleration of vesting provisions applicable to the options held by our named executive officers, please see the section titled "Estimated Benefits and Payments Upon Termination of Employment" below.

Name	Initial Vesting Date(1)	Option Awards		Option Exercise Price (\$)	Option Expiration Date
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		
C. Daniel Myers	7/7/2005	22,775		\$ 2.04	7/7/2014
	11/22/2006	55,147		1.33	10/12/2016
	12/13/2008	177,883		1.40	12/13/2017
	3/20/2009	150,100	10,007	2.42	3/20/2018
	8/25/2010	14,797	11,509	4.02	8/25/2019
	12/22/2010	39,925	39,926	4.02	8/25/2019
	12/3/2010(2)	26,320	70,865	11.15	11/3/2020
Richard S. Eiswirth	10/31/2006	13,625		2.04	10/31/2015
	10/31/2006	96,669		1.33	1/1/2016
	11/22/2007	51,471		1.33	10/12/2016
	12/13/2008	33,094		1.40	12/13/2017
	3/20/2009	43,450	2,897	2.42	3/20/2018
	6/25/2009	25,735	3,676	3.88	6/25/2018
	8/25/2010	3,955	3,078	4.02	8/25/2019
	12/22/2010	10,675	10,675	4.02	8/25/2019
12/3/2010(2)	18,457	49,696	11.15	11/3/2020	
Kenneth Green, Ph.D.	8/2/2005	73,529		2.04	8/2/2014
	1/3/2006	14,706		2.04	1/1/2015
	11/22/2006	44,118		1.33	1/1/2016
	11/22/2006	36,177		1.33	10/12/2016
	11/22/2007	8,031		1.33	10/12/2016
	3/1/2008	58,824		1.40	3/1/2017
	12/13/2008	26,077		1.40	12/13/2017
	3/20/2009	63,200	4,214	2.42	3/20/2018
	8/25/2010	5,128	3,990	4.02	8/25/2019
	12/22/2010	13,839	13,839	4.02	8/25/2019
	12/3/2010(2)	14,640	39,417	11.15	11/3/2020
Susan Caballa	7/7/2005	8,931		2.04	7/4/2014
	2/18/2006	20,480		2.04	2/18/2015
	11/22/2006	44,118		1.33	1/1/2016
	11/22/2006	44,118		1.33	10/12/2016
	3/1/2008	14,706		1.40	3/1/2017
	12/13/2008	3,682		1.40	12/13/2017
	3/20/2009	43,450	2,897	2.42	3/20/2018
	8/25/2010	3,418	2,660	4.02	8/25/2019
	12/22/2010	9,224	9,225	4.02	8/25/2019
	12/3/2010(2)	10,668	28,723	11.15	11/3/2020
David Holland	7/7/2005	26,795		2.04	7/7/2014
	11/22/2006	33,088		1.33	1/1/2016
	11/22/2006	33,088		1.33	10/12/2016
	12/13/2008	1,954		1.40	12/13/2017

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

3/20/2009	47,400	3,160	2.42	3/20/2018
8/25/2010	3,846	2,993	4.02	8/25/2019
12/22/2010	10,379	10,380	4.02	8/25/2019
12/3/2010(2)	11,879	31,985	11.15	11/3/2020

- (1) Unless otherwise set forth below, 25% 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.
- (2) Vests in 48 equal monthly installments over a four year period beginning on the Initial Vesting Date.

**Table of Contents****Option Exercises and Stock Vested During 2011**

The following table shows the number of shares acquired by named executive officers upon option exercises during the year ended December 31, 2011.

Name	Option Awards	
	Number of shares acquired on exercise (#)	Value realized on exercise \$(1)
C. Daniel Myers	55,147	\$ 349,081
Kenneth Green, Ph.D.	21,969	146,533

(1) The value realized is based on the fair market value of our Common Stock on the date of exercise minus the exercise price. The amounts set forth do not necessarily reflect proceeds actually received by the executive officer.

There were no shares of restricted stock, restricted stock units or other equity subject to vesting held by our named executive officers during 2011 other than options to purchase our common stock.

**Employment Agreements with Our Executive Officers**

We have entered into employment agreements with each of our named executive officers. The employment agreements provide for a starting base salary and a potential annual bonus, which is subject to adjustment by our Board of Directors from time to time. In addition, each of the agreements provides that if we terminate the named executive officer's employment without cause or if he or she resigns for good reason, the named executive officer is entitled to one year of his or her base salary at the rate in effect at the time of his termination paid in 12 equal monthly installments. The named executive officer will also be entitled to the portion of his or her bonus earned up until termination. In addition, the named executive officer is entitled to reimbursement of his or her premiums for medical insurance coverage under COBRA for 12 months after the date of termination or until the named executive officer is eligible to be covered under a medical insurance plan by a subsequent employer. The employment agreements also provide for acceleration of any unvested options held by our named executive officers in the event of a change of control. Under these provisions, in the event of change of control, each executive will receive 12 months of additional vesting for any stock options that are outstanding and unvested as of the date of such transaction. In addition, 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 or her employment for good reason within 12 months of a change of control.

The following table sets forth the base salary and potential bonus of each of our named executive officers under their respective employment agreements at January 1, 2011 and 2012, respectively.

Name	Base Salary (\$)	Potential Bonus (\$)
C. Daniel Myers	431,650	\$ 237,408
Richard S. Eiswirth	311,383	124,553
Kenneth Green, Ph.D.	294,228	117,691
Susan Caballa	253,499	101,400
David Holland	285,634	114,254

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. For purposes of option acceleration, "good reason" is defined in all applicable 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****Estimated Benefits and Payments Upon Termination of Employment**

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 our Company as described above, as if each officer's employment terminated as of December 31, 2011, the last business day of the 2011 fiscal year.

Name	Benefit	Termination		
		Voluntary Resignation or Termination for Cause	without Cause or for Good Reason Prior to Change in Control	without Cause or for Good Reason after Change in Control
<i>C. Daniel Myers</i>				
	Salary	\$ 0	\$ 431,650	\$ 431,650
	Bonus	0	237,408(1)	237,408(1)
	Benefit Continuation	0	14,714	14,714
	Accrued Vacation(2)	1,897	1,897	1,897
	Accelerated Vesting			0(3)
	<i>Total value</i>	\$ 1,897	\$ 685,669	\$ 685,669
<i>Richard S. Eiswirth</i>				
	Salary	\$ 0	\$ 311,383	\$ 311,383
	Bonus	0	124,553(1)	124,553(1)
	Benefit Continuation	0	22,174	22,174
	Accrued Vacation(2)	11,090	11,090	11,090
	Accelerated Vesting			0(3)
	<i>Total value</i>	\$ 11,090	\$ 469,200	\$ 469,200
<i>Kenneth Green, Ph.D.</i>				
	Salary	\$ 0	\$ 294,228	\$ 294,228
	Bonus	0	117,691(2)	117,691(1)
	Benefit Continuation	0	22,174	22,174
	Accrued Vacation(2)	16,928	16,928	16,928
	Accelerated Vesting			(3)
	<i>Total value</i>	\$ 16,928	\$ 451,021	\$ 451,021
<i>Susan Caballa</i>				
	Salary	\$ 0	\$ 253,499	\$ 253,499
	Bonus	0	101,400(1)	101,400(1)
	Benefit Continuation	0	15,250	15,250
	Accrued Vacation(2)	11,807	11,807	11,807
	Accelerated Vesting			0(3)
	<i>Total value</i>	\$ 11,807	\$ 381,956	\$ 381,965
<i>David Holland</i>				
	Salary	\$ 0	\$ 285,634	\$ 285,634
	Bonus	0	114,254(1)	114,254(1)

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Benefit Continuation	0	22,174	22,174
Accrued Vacation(2)	11,738	11,738	11,738
Accelerated Vesting			0(3)
<i>Total value</i>	\$ 11,738	\$ 433,800	\$ 433,800

- (1) Represents aggregate target bonus, including objective and subjective portion, for 2011. Bonus payments in the year of termination would be based on the actual earned bonus and may be less than the aggregate target bonus.
- (2) Based on each executive officer's base salary in effect at the end of 2011 and the number of accrued but unused vacation days at the end of 2011.
- (3) The value of option acceleration was zero because the exercise price per share of the accelerated options was greater than the \$1.25 closing market price of shares of the Company's common stock on December 30, 2011 (the last trading day in fiscal 2011) and the exercise price of the option.

**Table of Contents****SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS****Equity Compensation Plan Information**

Our executive officers, directors and all of our employees are allowed to participate in our equity incentive plans. We believe that providing them with the ability to participate in such plans provides them with a further incentive towards ensuring our success and accomplishing our corporate goals.

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

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

- (1) Of these shares, 580,398 were subject to options then outstanding under the 2010 Plan, 1,691,120 were subject to options then outstanding under the 2005 Plan and 335,928 were subject to options then outstanding under the 2004 Plan.
- (2) Represents 2,642,526 shares of common stock available for issuance under our 2010 Plan and 472,512 shares of common stock available for issuance under our ESPP. No shares are available for future issuance under the 2005 Plan or 2004 Plan. In addition, our 2010 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year equal to the least of: (1) 2,000,000 shares of our common stock; (2) 4% of the shares of common stock outstanding at that time; and (3) such other amount as our Board of Directors may determine. On January 1, 2012, an additional 1,257,095 shares became available for future issuance under our 2010 Plan in accordance with the annual increase. In addition, our ESPP provides for annual increases in the number of shares available for issuance thereunder equal to such number of shares necessary to restore the number of shares reserved thereunder to 494,422 shares of our common stock. As such, on January 1, 2012, an additional 21,910 shares became available for future issuance under our ESPP. These additional shares from the annual increase under the 2010 Plan and the ESPP are not included in the table above.

**Beneficial Ownership of Common Stock**

The following table provides information concerning beneficial ownership of our common stock as of November 1, 2012, by:

each stockholder, or group of affiliated stockholders, known to us to beneficially own more than 5% of our outstanding common stock;

each of our named executive officers;



each of our directors; and

all of our current executive officers and directors as a group.

The table below is based upon information supplied by directors, executive officers and principal stockholders and Schedule 13Gs and 13Ds filed with the SEC through November 1, 2012.

For purposes of the table below, we deem shares of common stock subject to options or warrants (assuming conversion or exercise (as the case may be) of all Series A Preferred Stock and Warrants held by the selling stockholders) that are currently exercisable or exercisable within 60 days of November 1, 2012 and common stock subject to restricted stock unit awards that will vest within 60 days of November 1, 2012 to be outstanding based on the number of shares of common stock issuable upon exercise or conversion, as applicable, (assuming conversion or exercise (as the case may be) of all Series A Preferred Stock and Warrants held by the selling stockholders) of such securities and to be beneficially owned by the person holding the options, warrants or restricted stock unit award (assuming conversion or exercise (as the case may be) of all Series A Preferred Stock and Warrants held by the selling stockholders) for the purpose of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The table assumes conversion price of \$3.16 for the Series A Preferred Stock, which is the current conversion price applicable to voluntary conversion of such securities. Except as otherwise noted, the persons or entities in this table have sole voting and investing power with respect to all of the shares of common stock beneficially owned by them, subject to community property laws, where applicable.

**Table of Contents**

The percentage ownership is based upon 31,527,756 shares of common stock outstanding as of November 1, 2012.

<b>Name and Address of Beneficial Owner(1)</b>	<b>Number of Shares Beneficially Owned(2)</b>	<b>Percentage of Shares Beneficially Owned</b>
<b>5% Stockholders (other than our executive officers and directors)</b>		
BAVP, LP 950 Tower Lane, Suite 700 Foster City, California 94404	4,863,094(3)	15.4%
Domain Associates, L.L.C. One Palmer Square Princeton, New Jersey 08542	4,189,427(4)	13.3%
Intersouth Partners 406 Blackwell Street, Suite 200 Durham, North Carolina 27701	4,877,480(5)	15.5%
Polaris Venture Partners 1000 Winter Street, Suite 3350 Waltham, Massachusetts 02451	3,308,355(6)	10.5%
Columbia Wanger Asset Management, LLC 227 West Monroe Street, Suite 3000 Chicago, IL 60606	2,513,680(7)	8.0%
Palo Alto Investors, LLC 470 University Avenue Palo Alto, California 94301	13,508,401(8)	32.6%
Sofinnova Venture Partners VIII, L.P. 2800 Sand Hill Road, Suite 150 Menlo Park, California 94025	4,113,924(9)	11.5%
Growth Equity Opportunities Fund III, LLC New Enterprise Associates 1954 Greenspring Drive, Suite 600 Timonium, MD 21093	2,468,354(10)	7.3%

<b>Name and Address of Beneficial Owner(1)</b>	<b>Number of Share Beneficially Owned</b>	<b>Percentage of Shares Beneficially Owned</b>
<b>Directors and Named Executive Officers</b>		
Glen Bradley, Ph.D.	15,000(11)	*
Mark J. Brooks	4,882,781(12)	15.5%
Susan Caballa	307,657(13)	1.0%
Richard S. Eiswirth	373,553(14)	1.2%
Kenneth Green, Ph.D.	412,509(15)	1.3%
Brian K. Halak, Ph.D.	4,209,114(16)	13.3%
David Holland	331,446(17)	1.0%
Garheng Kong, M.D., Ph.D.	4,113,924(18)	11.5%
James R. Largent	13,750(19)	*

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

C. Daniel Myers	735,889(20)	2.3%
Peter J. Pizzo, III	30,000(21)	*
Calvin W. Roberts, M.D.	445,276(22)	1.4%
Philip R. Tracy	4,897,167(23)	15.5%
<b>All current directors and executive officers as a group (13 persons)</b>	<b>21,067,916(24)</b>	<b>55.2%</b>

**Table of Contents**

\* Represents beneficial ownership of less than one percent of our outstanding common stock.

- (1) Unless otherwise indicated, the address for each beneficial owner is c/o Alimera Sciences, Inc., 6120 Windward Parkway, Suite 290, Alpharetta, Georgia 30005.
- (2) Pursuant to the terms of the Series A Preferred Stock, the Series A Preferred Stock will vote together with our common stock on an as converted basis based on a deemed conversion price of \$2.95 (adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Preferred Stock). As such, as of November 1, 2012, assuming all of the outstanding Warrants to purchase Series A Preferred Stock were exercised in full for cash, such entities and individuals would be entitled to vote the following number of shares of our common stock at any meeting of our stockholders:

<b>Beneficial Owner</b>	<b>Voting Power</b>	<b>Percentage of Voting Power</b>
BAVP, LP	4,863,094	15.4%
Domain Associates, L.L.C.	4,189,427	13.3%
Intersouth Partners	4,877,480	15.5%
Polaris Venture Partners	3,308,355	10.5%
Columbia Wanger Asset Management, LLC	2,513,680	8.0%
Palo Alto Investors, LLC	14,211,255	34.1%
Sofinnova Venture Partners VIII, L.P.	4,406,779	12.3%
Growth Equity Opportunities Fund III, LLC	2,644,037	7.7%
Glen Bradley, Ph.D.	15,000	*
Mark J. Brooks	4,882,781	15.5%
Susan Caballa	307,657	1.0%
Richard S. Eiswirth	373,553	1.2%
Kenneth Green, Ph.D.	412,509	1.3%
Brian K. Halak, Ph.D.	4,209,114	13.3%
David Holland	331,446	1.0%
Garheng Kong, M.D., Ph.D.	4,406,779	12.3%
James R. Largent	13,750	*
C. Daniel Myers	735,889	2.3%
Peter J. Pizzo, III	30,000	*
Calvin W. Roberts, M.D.	445,276	1.4%
Philip R. Tracy	4,897,167	15.5%
<b>Total</b>	<b>21,067,916</b>	<b>55.5%</b>

**Table of Contents**

- (3) 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.
- (4) Represents 4,129,773 shares held by Domain Partners VI, L.P. and 40,790 shares held by DP VI Associates, L.P. and 18,864 shares held by One Palmer Square Associates VI, L.L.C. 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, Ph.D., 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.
- (5) Represents 73,590 shares held by Intersouth Associates V, L.P.; 1,605,743 shares held by Intersouth Partners V, L.P.; 2,053,381 shares held by Intersouth Partners VI, L.P.; and 1,144,766 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 Associates 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.
- (6) Represents 3,247,811 shares held by Polaris Venture Partners IV, L.P. and 60,544 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.
- (7) The shares reported herein include shares held by Columbia Acorn Trust (CAT), a Massachusetts business trust that is advised by the reporting person. CAT holds 6.9% of the outstanding shares of common stock.
- (8) Represents 1,103,988 shares held by Micro Cap Partners, L.P. (Micro Cap), 5,021,120 shares held by Palo Alto Healthcare Master Fund, L.P. (Healthcare Master) and 7,383,293 shares held by Palo Alto Healthcare Master Fund II, L.P. (Healthcare Master II). Includes 353,797 shares of common stock issuable upon voluntary conversion and exercise, as applicable, of the Series A Preferred Stock and Warrants held by Micro Cap, 3,804,557 shares of common stock issuable upon voluntary conversion and exercise, as applicable, of the Series A Preferred Stock and Warrants held by Healthcare Master and 5,715,063 shares of common stock issuable upon voluntary conversion and exercise, as applicable, of Series A Preferred Stock and Warrants held by Healthcare Master II. In the event that the conversion price of the Series A Preferred Stock is adjusted, the aggregate number of shares of common stock issuable upon conversion and exercise, as applicable, of the Series A Preferred Stock and Warrants held by Micro Cap, Healthcare Master I and Healthcare Master II would be:

Stockholder	\$2.66 conversion price	\$2.91 conversion price
Micro Cap	1,170,492	1,134,383
Healthcare Master	5,736,262	5,347,972
Healthcare Master II	8,457,553	7,874,278
Total	15,364,307	14,356,633

Palo Alto Investors, Inc. (PAI Corp) is the manager of Palo Alto Investors, LLC (PAI LLC). William Leland Edwards is the controlling shareholder of PAI Corp. Dr. Anthony Joonkyoo Yun is the President of PAI LLC and PAI Corp. PAI LLC, PAI Corp, Mr. Edwards and Dr. Yun filed Schedule 13G jointly, but not as members of a group, and each of them expressly disclaims membership in a group. Each of PAI LLC, PAI Corp, Mr. Edwards and Dr. Yun disclaims beneficial ownership of the shares except to the extent of their respective pecuniary interest therein. In addition, Healthcare Master II should not be construed as a member of a group, and it disclaims that it is a beneficial owner. PAI LLC is a registered investment adviser and is the general partner and investment adviser of Healthcare Master II and other investment limited partnerships, and is the investment adviser to other investment funds. PAI LLC's clients have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, the shares. No individual client, other than Healthcare Master II, separately holds more than five percent of the outstanding shares of the Company.

- (9) The securities are owned directly by Sofinnova Venture Partners VIII, L.P. (SVP VIII). Sofinnova Management VIII, L.L.C. (SM VIII), the general partner of SVP VIII, and Garheng Kong, Michael Powell, and James I. Healy, the managing members of SM VIII, may be deemed to have shared voting and dispositive power over the shares owned by SVP VIII. Such persons and entities disclaim beneficial ownership over the shares owned by SVP VIII except to the extent of any pecuniary interest therein.

In the event that the conversion price of the Series A Preferred Stock is adjusted, the aggregate number of shares of common stock issuable upon conversion and exercise, as applicable, of the Series A Preferred Stock and Warrants would be:

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

\$2.66 conversion price  
4,887,218

\$2.91 conversion price  
4,467,353

**Table of Contents**

- (10) The securities are owned directly by Growth Equity Opportunities Fund III, LLC (GEO). New Enterprise Associates 14, L.P. (NEA 14), which is the sole member of GEO; NEA Partners 14, L.P. (NEA Partners 14), which is the sole general partner of NEA 14; NEA 14 GP, LTD (NEA 14 GP), which is the sole general partner of NEA Partners 14; and Michael James Barrett, Peter J. Barris, Forest Baskett, Ryan D. Drant, Anthony A. Florence, Jr., Patrick J. Kerins, Krishna S. Kolluri, David M. Mott, Scott D. Sandell, Peter W. Sonsini, Ravi Viswanathan and Harry R. Weller (collectively, the Directors). The Directors are the individual directors of NEA 14 GP. GEO, NEA 14, NEA Partners 14, NEA 14 GP and the Directors are sometimes referred to collectively herein as the Reporting Persons. Each Reporting Person disclaims beneficial ownership of such shares of common stock except for the shares, if any, such Reporting Person holds of record.

In the event that the conversion price of the Series A Preferred Stock is adjusted, the aggregate number of shares of common stock issuable upon conversion and exercise, as applicable, of Series A Preferred Stock and Warrants would be:

\$2.66 conversion price	\$2.91 conversion price
2,932,330	2,680,412

- (11) Includes 15,000 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 12,500 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (12) 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 (2) above, except to the extent of his pecuniary interest therein. Includes 19,687 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 2,813 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (13) Includes 234,171 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 97,129 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (14) Includes 363,254 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 243,899 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (15) Includes 404,989 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 149,740 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (16) 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 (3) above, except to the extent of his pecuniary interest therein. Includes 19,687 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 2,813 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (17) Includes 205,080 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 116,867 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (18) Dr. Kong is affiliated with SVP VIII. Dr. Kong disclaims beneficial ownership of the shares held by the entities affiliated with SVP VIII referenced in footnote (9) above, except to the extent of his pecuniary interest therein. Includes 0 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 20,000 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (19) Includes 13,750 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 13,750 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (20) Includes 610,289 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 403,965 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012. Includes 125,600 shares held in joint tenancy with Mr. Myers spouse and pledged or held in a margin account with a brokerage firm.

**Table of Contents**

- (21) Includes 27,500 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 7,500 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (22) Includes 37,335 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012, 39,706 shares issuable upon exercise of warrants exercisable within 60 days of November 1, 2012, 40,587 shares held by Calvin W. Roberts MD PC Pension Plan and 60,200 shares held in trust with indirect ownership. Mr. Roberts disclaims beneficial ownership of the share held in trust. Excludes 2,813 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (23) 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 (4) above, except to the extent of his pecuniary interest therein. Includes 19,687 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012. Excludes 2,813 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.
- (24) Includes 1,970,429 shares issuable upon exercise of options exercisable within 60 days of November 1, 2012, 39,706 shares issuable upon a warrant exercisable within 60 days of November 1, 2012, 40,587 shares held by Calvin W. Roberts MD PC Pension Plan, 60,200 shares held in trust with indirect ownership, which Mr. Roberts disclaims beneficial ownership thereof and 144,764 shares held in joint tenancy by an executive and his spouse and pledged or held in a margin account with a brokerage firm. Excludes 1,056,602 shares of common stock subject to options that are not exercisable within 60 days of November 1, 2012.

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

In addition to the compensation arrangements with directors and executive officers described elsewhere in this proxy statement, the following is a description of transactions since January 1, 2011, in which we have been a participant, in which the amount involved exceeded or will exceed \$120,000 and in which any of our directors, executive officers, beneficial holders of more than 5% of our capital stock, or entities affiliated with them, had or will have a direct or indirect material interest.

All of the transactions set forth below were approved by a majority of our Board of Directors, including a majority of the independent and disinterested members of our 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 directors, executive officers and principal stockholders and their affiliates are approved by a majority of the members of our Board of Directors, including a majority of the independent and disinterested members of our 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 A Preferred Stock Financing.* On October 2, 2012, we sold an aggregate of 1,000,000 units comprised of 1,000,000 shares of our Series A Preferred Stock and Warrants exercisable for up to an aggregate of 300,000 shares of our Series A Preferred Stock at an exercise price of \$44.00 per share for gross proceeds of \$40.0 million prior to the payment of related expenses. The units were issued to various investors, including entities affiliated with Palo Alto Investors, LLC (Palo Alto), Sofinnova Venture Partners VIII, L.P. (Sofinnova) and Growth Equity Opportunities Fund III, LLC (GEOF). Additionally, Garheng Kong, M.D., Ph.D., one of our directors, serves as a member of the general partner of Sofinnova. 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.

*Registration Rights Agreement.* In connection with our Series A Preferred Stock financing, we entered into a registration rights agreement with Palo Alto, Sofinnova and GEOF dated October 2, 2012. The agreement provides that Palo Alto, Sofinnova and GEOF have certain registration rights relating to the registration of the Company's common stock under certain circumstances set forth in the agreement.

*Stock Option Awards.* See [Corporate Governance](#), [Director Compensation](#) and [Executive Compensation](#) for additional information regarding stock options and equity awards granted to our directors and named executive officers.





---

**Table of Contents**

**SELLING RESTRICTIONS**

**Notice to Prospective Investors in the Dubai International Financial Centre**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

**Notice to Prospective Investors in the European Economic Area**

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Member State it has not made and will not make an offer of securities to the public in that Member State, except that it may, with effect from and including such date, make an offer of securities to the public in that Member State:

- (a) at any time to legal entities which are 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;
- (b) at any time to any legal entity which 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; or
- (c) at any time in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of the above, the expression an offer of securities to the public in relation to any securities in any 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 for the securities, as the same 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 that Member State.

**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.

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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'épargne*).

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*.

## **Table of Contents**

### **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 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;

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

- (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.

---

## **Table of Contents**

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 securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

### **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 (SFA), (ii) to a relevant person, 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.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) 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 (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) 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 may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the company, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the shares.

---

**Table of Contents**

**Notice to Prospective Investors in the United Kingdom**

This prospectus and any other material in relation to the shares described herein 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 Prospective Directive ( "qualified investors" ) that also (i) have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, (ii) who fall within Article 49(2)(a) to (d) of the Order or (iii) to whom it may otherwise lawfully be communicated (all such persons together being referred to as "relevant persons" ). The shares are only available to, and any invitation, offer or agreement to purchase or otherwise acquire such shares will be engaged in only with, relevant persons. 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 person in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this prospectus 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 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 shares of common stock offered by this prospectus will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP.

**EXPERTS**

The financial statements of Alimera Sciences, Inc. as of December 31, 2010 and 2011, 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.

**CHANGE IN INDEPENDENT ACCOUNTANTS**

On August 23, 2012, the audit committee of our Board of Directors dismissed Deloitte & Touche LLP as our independent registered public accounting firm, effective as of August 23, 2012. Deloitte & Touche LLP's report on our financial statements for the fiscal years ended December 31, 2011 and 2010 contained an explanatory paragraph regarding our ability to continue as a going concern. Other than such statement, no report of Deloitte & Touche LLP on our financial statements for either of the fiscal years ended December 31, 2011 and 2010 contained an adverse opinion or disclaimer of opinion, or was qualified or modified as to uncertainty, audit scope or accounting principles. During the fiscal years ended December 31, 2011 and 2010 and through August 23, 2012, there were no disagreement(s) with Deloitte & Touche LLP on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of Deloitte & Touche LLP, would have caused Deloitte & Touche LLP to make reference to the subject matter of the disagreement in connection with its reports on our consolidated financial statements.

On August 23, 2012, the audit committee of our Board of Directors approved the engagement of Grant Thornton LLP as our independent registered public accounting firm, subject to Grant Thornton LLP's acceptance of such engagement. On August 27, 2012, we formally engaged Grant Thornton LLP as our independent registered public accounting firm.

**DISCLOSURE OF COMMISSION POSITION ON**

**INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

The Delaware General Corporation Law and our certificate of incorporation and bylaws provide for indemnification of our directors and officers for liabilities and expenses that they may incur in such capacities. In general, directors and officers are indemnified with respect to actions taken in good faith in a manner reasonably believed to be in, or not opposed to, the best interests of our company, and with respect to any criminal action or proceeding, actions that the indemnitee had no reasonable cause to believe were unlawful.



---

## **Table of Contents**

We have also entered into identification agreements with our directors and executive officers. These identification agreements generally require us to pay, on behalf of each director and officer party thereto, all amounts that he or she is or becomes legally obligated to pay because of any claim or claims made against him or her because of any act or omission which he or she commits or suffers while acting in his or her capacity as our director and/or officer and because of his or her being a director and/or officer. Under the Delaware General Corporation Law, absent an identification agreement or a provision in a corporation's bylaws or certificate of incorporation, indemnification of a director or officer is discretionary rather than mandatory (except in the case of a proceeding in which a director or officer is successful on the merits).

We currently maintain a directors' and officers' liability insurance policy.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to such directors, officers or controlling persons pursuant to the foregoing provisions, or otherwise, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

### **WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). You can inspect and copy these reports, proxy statements and other information at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. The SEC also maintains a web site that contains reports, proxy and information statements and other information regarding issuers, such as Alimera Sciences, Inc. (<http://www.sec.gov>). Our web site is located at <http://www.alimerasciences.com>. The information contained on our website is not part of this prospectus.

### **DOCUMENTS INCORPORATED BY REFERENCE**

The SEC allows us to incorporate by reference information into this document. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be a part of this document, except for any information superseded by information that is included directly in this document or incorporated by reference subsequent to the date of this document.

This prospectus incorporates by reference the documents listed below:

Our Annual Report on Form 10-K for the year ended December 31, 2011;

Quarterly Reports on Form 10-Q for the quarters ended March 31, 2012, June 30, 2012 and September 30, 2012;

Our Current Reports on Form 8-K and 8-K/A filed with the SEC on February 28, 2012, March 2, 2012, March 8, 2012, March 27, 2012, May 11, 2012, June 15, 2012, July 18, 2012, August 9, 2012, August 28, 2012, September 21, 2012, October 2, 2012, November 7, 2012 and November 8, 2012 (other than any portions thereof deemed furnished and not filed);

Proxy Statements on Schedule 14A filed with the SEC on April 30, 2012, August 24, 2012 and September 24, 2012; and

The description of our common stock contained on Form 8-A, filed with the SEC on April 19, 2010, including any amendments or reports filed for the purpose of updating the description.

You may request a copy of these filings, at no cost, by writing or calling us at the following:

Alimera Sciences, Inc.

6120 Windward Parkway, Suite 290

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Alpharetta, Georgia 30005

Attn: Secretary of the Company

Copies of the documents incorporated by reference may also be found on our website at [www.alimerasciences.com](http://www.alimerasciences.com) (information, other than these documents, contained on our website is not a part of this prospectus).

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
Audited Financial Statements as of December 31, 2011 and 2010 and for the years ended December 31, 2011, 2010, and 2009:	
<u>Balance Sheets</u>	F-3
<u>Statements of Operations</u>	F-4
<u>Statements of Changes in Stockholders' Equity (Deficit)</u>	F-5
<u>Statements of Cash Flows</u>	F-6
<u>Notes to Financial Statements</u>	F-7
Unaudited Interim Condensed Consolidated Financial Statements:	
<u>Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011</u>	F-21
<u>Consolidated Statements of Operations for the three and nine months ended September 30, 2012 and 2011</u>	F-22
<u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and 2011</u>	F-23
<u>Notes to Consolidated Financial Statements</u>	F-24

**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, 2011 and 2010, and the related statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

As described in Note 4, the accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company's recurring net losses, negative cash flow from operations, accumulated deficit, and current lack of a commercial product raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 4. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Deloitte & Touche LLP

Atlanta, Georgia

March 30, 2012

**Table of Contents****ALIMERA SCIENCES, INC.****BALANCE SHEETS****AS OF DECEMBER 31, 2011 AND 2010**

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

See Notes to Financial Statements.

Table of Contents

## ALIMERA SCIENCES, INC.

## STATEMENTS OF OPERATIONS

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

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

See Notes to Financial Statements.

**Table of Contents****ALIMERA SCIENCES, INC.****STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)****FOR THE YEARS ENDED DECEMBER 31, 2011, 2010, AND 2009**

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Series C-1 Preferred Warrants	Common Warrants	Accumulated Deficit	Total
(In thousands, except share data)							
BALANCE December 31, 2008	1,490,113	51	3,474		58	(119,470)	(115,887)
Redeemable preferred stock accretion and dividends						(7,848)	(7,848)
Issuance of common stock	92,351	3	458				461
Exercise of stock options	3,860		6				6
Exercise of common stock warrants	12,247		31				31
Retirement of common stock warrants			1		(1)		
Issuance of series C-1 preferred stock warrants				1,472			1,472
Accretion of series C-1 preferred stock beneficial conversion feature (Note 11)			355			(355)	
Stock compensation expense			511				511
Net loss						(44,218)	(44,218)
BALANCE December 31, 2009	1,598,571	54	4,836	1,472	57	(171,891)	(165,472)
Redeemable preferred stock accretion and dividends						(3,104)	(3,104)
Issuance of common stock	29,421,942	256	192,707				192,963
Issuance of common warrants (Note 9)					366		366
Exercise of stock options	44,499	1	93				94
Exercise of common stock warrants	190,941	2	618		(8)		612
Exercise of series C-1 preferred stock warrants				(1,472)			(1,472)
IPO costs			(2,282)				(2,282)
Elimination of preferred stock conversion feature upon conversion of preferred stock to common stock (Note 11)			36,528				36,528
Stock compensation expense			838				838
Net loss						(13,859)	(13,859)
BALANCE December 31, 2010	31,255,953	\$ 313	\$ 233,338	\$	\$ 415	\$ (188,854)	\$ 45,212
Issuance of common stock	21,910		154				154
Exercise of stock options	144,787	1	235				236
Exercise of common stock warrants	4,705		19				19
Stock compensation expense			1,873				1,873
Net loss						(22,516)	(22,516)
BALANCE December 31, 2011	31,427,355	\$ 314	\$ 235,619	\$	\$ 415	\$ (211,370)	\$ 24,978

See Notes to Financial Statements.

**Table of Contents****ALIMERA SCIENCES, INC.****STATEMENTS OF CASH FLOWS****FOR THE YEARS ENDED DECEMBER 31, 2011, 2010, AND 2009**

	Years Ended December 31,		
	2011	2010	2009
	(In thousands)		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (22,516)	\$ (13,859)	\$ (44,218)
Income from discontinued operations (Note 3)		(4,000)	
Change in fair value of preferred stock conversion feature		(3,644)	23,142
Gain from early extinguishment of debt		(1,343)	
Depreciation and amortization	133	194	1,098
Stock compensation expense and other	1,873	957	551
Amortization of deferred financing costs and debt discount	286	73	
Unrealized investment (loss) gain	(2)	2	
Noncash research and development expense (Note 8)			300
<b>Changes in assets and liabilities:</b>			
Prepaid expenses and other current assets	386	(566)	591
Accounts payable	271	391	183
Accrued expenses and other current liabilities	(1,275)	(258)	705
Other long-term liabilities	128		153
Net cash used in operating activities of continuing operations	(20,716)	(22,053)	(17,495)
Net cash used in operating activities of discontinued operations			(43)
Net cash used in operating activities	(20,716)	(22,053)	(17,538)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of investments		(39,927)	
Proceeds from maturities of investments	25,830	13,595	
Purchases of property and equipment	(110)	(128)	(65)
Net cash provided by (used in) investing activities of continuing operations	25,720	(26,460)	(65)
Net cash provided by investing activities of discontinued operations (Note 3)		4,000	
Net cash provided by (used in) investing activities	25,720	(22,460)	(65)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from sale of Series C-1 preferred stock net		9,997	4,897
Proceeds from exercise of stock options	236	94	7
Proceeds from exercise of common stock warrants	19	613	31
Proceeds from sale of common stock	154	68,470	
Payment of common stock offering costs		(1,942)	(339)
Proceeds from issuance of notes payable (Note 9)		6,250	
Payment of debt issuance costs (Note 9)	(50)	(305)	
Repayment of pSivida note payable (Note 7)		(15,000)	
Payment of principal on note payable	(758)		
Payments on capital lease obligations	(11)	(8)	(10)
Net cash (used in) provided by financing activities	(410)	68,169	4,586



Edgar Filing: ALIMERA SCIENCES INC - Form S-1

NET INCREASE (DECREASE) IN CASH	4,594	23,656	(13,017)
CASH Beginning of period	28,514	4,858	17,875
CASH End of period	\$ 33,108	\$ 28,514	\$ 4,858
<b>SUPPLEMENTAL DISCLOSURES:</b>			
Cash paid for interest	\$ 656	\$ 681	\$ 1,200
<b>Supplemental schedule of noncash investing and financing activities:</b>			
Reclassification of fair value of preferred stock conversion feature to additional paid-in capital	\$	\$ 36,528	\$
IPO issuance costs charged to equity	\$	\$ 3,994	\$
Notes payable issuance costs charged to equity (Note 9)	\$	\$ 366	\$
Property and equipment acquired under capital leases	\$	\$ 36	\$
Common stock issued for research and development expense (Note 8)	\$	\$	\$ 300

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

See Notes to Financial Statements.

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**1. NATURE OF OPERATIONS**

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

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<sup>®</sup>, which is being developed for the treatment of diabetic macular edema (DME). DME is a disease of the retina which affects individuals with diabetes and can lead to severe vision loss and blindness.

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

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

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

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

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

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

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

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

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

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

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

F-7

---

## **Table of Contents**

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

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

Income tax positions are considered for uncertainty in accordance with ASC 740-10. The provisions of ASC 740-10 were effective beginning January 1, 2008, but the Company early adopted effective January 1, 2007. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position; therefore, no ASC 740-10 liabilities have been recorded. The Company's adoption of ASC 740-10 did not result in a cumulative effect adjustment to retained earnings. The Company will recognize accrued interest and penalties related to unrecognized tax benefits, if any, as interest expense and income tax expense, respectively, in the statements of operations.

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

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

**Stock-Based Compensation** The Company has stock option plans which provide for grants of stock options to employees and directors to purchase shares of the Company's common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. Compensation cost is recognized for all share-based awards granted subsequent to January 1, 2005 based on the grant date fair value in accordance with the provisions of ASC 718, *Compensation - Stock Compensation*. The fair values for the options are estimated at the dates of grant using a Black-Scholes option-pricing model.

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

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

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

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

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

	Years Ended December 31,		
	2011	2010	2009
Series A preferred stock and convertible accrued dividends		2,245,484	7,005,145
Series B preferred stock		2,291,242	7,147,894
Series C preferred stock		1,861,457	5,807,112
Series C-1 preferred stock		888,298	339,408
Series C-1 preferred stock warrants		42,426	678,820
Common stock warrants	26,313	97,757	45,297
Stock options	1,463,556	1,704,787	1,125,916
Total	1,489,869	9,131,451	22,149,592

F-8

**Table of Contents**

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

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

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

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

**3. DISCONTINUED OPERATIONS**

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

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

**4. FACTORS AFFECTING OPERATIONS**

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

**Table of Contents**

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

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

**5. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following:

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

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

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

**6. ACCRUED EXPENSES**

Accrued expenses consisted of the following:

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

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

F-10



---

**Table of Contents**

**7. PSIVIDA AGREEMENT**

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

pay \$12.0 million to pSivida upon the execution of the March 2008 agreement;

issue a \$15.0 million promissory note to pSivida;

forgive all outstanding development payments, penalties and interest as of the effective date of the March 2008 agreement, which totaled \$6.8 million;

continue responsibility for regulatory, clinical, preclinical, manufacturing, marketing and sales for the remaining development and commercialization of the products;

assume all financial responsibility for the development of the products and assume 80% of the commercialization costs of the products (instead of 50% as provided under the February 2005 agreement); and

make an additional milestone payment of \$25.0 million after the first product under the March 2008 agreement has been approved by the FDA.

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

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

Upon commercialization of ILUVIEN, the Company must share 20% of net profits and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined by the agreement, with pSivida. In connection with this arrangement the Company is entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits. As of December 31, 2011 and 2010, the Company was owed \$4,064,000 and \$2,224,000, respectively, in commercialization costs. Due to the uncertainty of future net profits, the Company has fully reserved these amounts in the accompanying financial statements.

**8. LICENSE AGREEMENTS**

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

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

F-11

## **Table of Contents**

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

## **9. TERM AND REVOLVING LOAN AGREEMENT**

### *Term Loan*

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

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

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

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

On the Effective Date, the Company issued to the Lenders warrants to purchase an aggregate of up to 39,773 shares of the Company's common stock. Each of the warrants is exercisable immediately, has a per-share exercise price of \$11.00 and has a term of 10 years. The Company estimated the fair value of warrants granted using the Black-Scholes option pricing model. The aggregate fair value of the warrants was estimated to be \$389,000. The Company allocated a portion of the proceeds from the Term Loan Agreement to the warrants in accordance with ASC 470-20-25-2, *Debt Instruments with Detachable Warrants*. As a result, the Company recorded a discount of \$366,000 which is being amortized to interest expense using the effective interest method. The Lenders will have certain registration rights with respect to the shares of common stock issuable upon exercise of all of their warrants. The Company paid to the Lenders an upfront fee of \$62,500 on the Effective Date and an additional fee of \$50,000 in connection with the Term Loan Modification. In accordance with ASC 470-50-40-17, *Debt Modifications and Extinguishments*, the Company is amortizing the unamortized discount on Term Loan A and the \$50,000 modification fee over the remaining term of Term Loan A, as modified. The Lenders also hold warrants to purchase an aggregate of up to 69,999 shares of the Company's common stock, which were exercisable only if Term Loan B had been advanced to the Company. Each of these warrants has a per share exercise price of \$11.00 and a term of 10 years. In addition, the Lenders would have had certain registration rights with respect to the shares of common stock issuable upon exercise of all of their warrants.

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

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

F-12

**Table of Contents***Working Capital Revolver*

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

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

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

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

**10. COMMITMENTS AND CONTINGENCIES**

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

<b>Years Ending December 31</b>	
2012	\$ 2,462
2013	2,273
2014	757
Total	\$ 5,492

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

*Operating Leases* The Company leases office space and equipment under noncancelable agreements accounted for as operating leases. The leases generally require that the Company pay taxes, maintenance, and insurance. Management expects that in the normal course of business, leases that expire will be renewed or replaced by other leases. In December 2011, the Company signed an extension of its lease for office space through December 31, 2012. The Company's future minimum payments under this operating lease from December 31, 2011 to December 31, 2012 are \$267,000.

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

*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.

F-13

**Table of Contents**

At December 31, 2011, a schedule by year of future minimum payments under capital leases, together with the present value of minimum lease payments, is as follows (in thousands):

<b>Years Ending December 31</b>	
2012	\$ 13
2013	6
<b>Total</b>	<b>19</b>
Less amount representing interest	(1)
<b>Present value of minimum lease payments</b>	<b>18</b>
Less current portion	(12)
<b>Noncurrent portion</b>	<b>\$ 6</b>

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

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In thousands)</b>	
Office equipment	\$ 36	\$ 60
Less accumulated amortization	(19)	(32)
<b>Total</b>	<b>\$ 17</b>	<b>\$ 28</b>

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

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

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

In February 2010, the Company entered into an agreement with a third party manufacturer for the manufacture of the ILUVIEN insert, the assembly of the ILUVIEN applicator and packaging of the completed ILUVIEN commercial product. The Company is responsible for supplying the ILUVIEN applicator and the active pharmaceutical ingredient. In accordance with the terms of the agreement, the Company must order at least 80% of the ILUVIEN units required in the U.S., Canada and the EU from the third party manufacturer for an initial term of six years. The agreement has an initial six year term and will automatically renew for successive one year periods unless either party delivers written notice of non-renewal to the other at least 12 months prior to the end of the then current term.

In March 2011, the Company entered into an agreement with a CRO for clinical and data management services to be performed in connection with a physician utilization study which is being conducted to assess the safety and utility of the commercial version of the ILUVIEN applicator. In accordance with the terms of the agreement, the Company will incur approximately \$2,100,000 in costs with the CRO through 2012. For the

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

year ended December 31, 2011, the Company incurred \$670,000 of expense associated with this agreement. At December 31, 2011, \$657,000 is included in outsourced services payable.

*Employment Agreements* The Company is party to employment agreements with five executives. The agreements generally provide for annual salaries, bonuses, and benefits and for the at-will employment of such executives. Effective January 1, 2012 and 2011, the salaries ranged from \$254,000 to \$432,000, respectively. If any of the agreements are terminated by the Company without cause, or by the employee for good reason, as defined in the agreements, the Company will be liable for one year of salary and benefits. Certain other employees have general employment contracts which include stipulations regarding confidentiality, Company property, and miscellaneous items.

F-14



---

**Table of Contents**

**11. PREFERRED STOCK**

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

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

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

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

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

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

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

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

**12. OPTIONS**

The Company has stock option and stock incentive plans which provide for grants of shares to employees and grants of options to employees and directors to purchase shares of the Company's common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. Options granted to employees typically become exercisable over a four-year vesting period and have a 10-year term. Options granted to directors typically vest immediately and have a 5-year term.

As of December 31, 2011, the Company was authorized to grant under the Company's plans up to 2,642,526 shares under the 2010 Equity Incentive Plan. Upon the exercise of stock options, the Company may issue the required shares out of authorized but unissued common stock or

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

out of treasury stock at management's discretion.

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

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

**Table of Contents**

The following table provides additional information related to outstanding stock options, fully vested stock options, and stock options expected to vest as of December 31, 2011:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value (In thousands)
Outstanding	2,607,446	\$ 3.88	6.14 years	\$
Exercisable	2,058,585	2.74	5.54 years	
Expected to vest	532,303	8.28	8.42 years	

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

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

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

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

The Company's 2010 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year equal to the least of: (1) 2,000,000 shares of our common stock; (2) 4% of the shares of common stock outstanding at that time; and (3) such other amount as our Board of Directors may determine. On January 1, 2012, an additional 1,257,094 shares became available for future issuance under the 2010 Plan. These additional shares from the annual increase under the 2010 Plan are not included in the foregoing discussion.

**Table of Contents**

The following table summarizes outstanding and exercisable options at December 31, 2011:

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

**13. COMMON STOCK WARRANTS**

The Company has issued warrants to purchase common stock to various members of the Board of Directors, third-parties for services, and lenders. Total warrants to purchase common stock issued and outstanding were 82,715 and 87,420 at December 31, 2011 and 2010, respectively, at exercise prices ranging from \$1.70 to \$11.00 per share. The warrants are exercisable for a period of seven to ten years from the issuance date.

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

**14. INCOME TAXES**

The components of the income tax benefit were as follows:

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

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Income tax benefit	\$	\$	\$
--------------------	----	----	----

F-17

**Table of Contents**

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

Income tax positions are considered for uncertainty in accordance with ASC 740-10. The Company believes that its income tax filing positions and deductions are more likely than not of being sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position; therefore, no ASC 740-10 liabilities and no related penalties and interest have been recorded. Tax years since 2003 remain subject to examination in Georgia, Tennessee, and on the federal level. The Company does not anticipate any material changes to its uncertain tax positions within the next 12 months.

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

At December 31, 2011 and 2010, the Company had federal net operating loss (NOL) carry-forwards of approximately \$120,353,000 and \$97,813,000 and state NOL carry-forwards of approximately \$103,815,000, and \$80,995,000 respectively, that are available to reduce future income unless otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2023 and 2031 and the state NOL carry-forwards will expire at various dates between 2020 and 2031.

NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of the Company were to occur. The Company periodically evaluates its NOL carry-forwards and whether certain changes in ownership, including its IPO, have occurred that would limit the Company's ability to utilize a portion of its NOL carry-forwards. If it is determined that significant ownership changes have occurred since the Company generated its NOL carry-forwards, it may be subject to annual limitations on the use of these NOL carry-forwards under Internal Revenue Code (IRC), Section 382 (or comparable provisions of state law). The Company has not performed a formal analysis of its NOLs in connection with IRC Section 382.

Net deferred tax assets (liabilities) were as follows:

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

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

	Years Ended December 31,					
	2011		2010		2009	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax benefit at statutory rate	\$ (7,655)	34.0%	\$ (4,712)	34.0%	\$ (15,035)	34.0%
State tax net of federal benefit	(892)	4.0	(549)	4.0	(1,751)	4.0
Permanent items	379	(1.7)	(1,166)	8.4	8,938	(20.2)

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Change in state deferred tax rate						
Other	(205)	0.9	20		425	(1.0)
Increase in valuation allowance	8,373	(37.2)	6,407	(46.4)	7,423	(16.8)
Total tax expense	\$	%	\$	%	\$	%

F-18

**Table of Contents****15. FAIR VALUE**

The Company adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (ASC 820), effective January 1, 2008. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the exit price) in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. The hierarchy of those valuation approaches is broken down into three levels based on the reliability of inputs as follows:

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

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

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

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

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

	Level 1	December 31, 2010		Total
		Level 2	Level 3	
(In thousands)				
<b>Assets:</b>				
Cash equivalents(1)	\$ 27,393	\$	\$	\$ 27,393
Investments in marketable debt securities(2)		26,330		26,330
Assets measured at fair value	\$ 27,393	\$ 26,330	\$	\$ 53,723

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

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





**Table of Contents****16. EMPLOYEE BENEFIT PLANS**

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

In April 2010, the Company established an Employee Stock Purchase Plan (the "Purchase Plan"). Under the Company's Purchase Plan, eligible employees can participate and purchase common stock semi-annually through accumulated payroll deductions. The Purchase Plan is administered by the Company's Board of Directors or a committee appointed by the Company's Board of Directors. Under the Purchase Plan eligible employees may purchase stock at 85% of the lower of the fair market value of a share of Common Stock on the offering date or the exercise date. The Purchase Plan provides for two 6-month purchase periods generally starting on the first trading day on or after October 31 and April 30 of each year. Eligible employees may contribute up to 15% of their eligible compensation. A participant may purchase a maximum of 2,500 shares of common stock per purchase period. The value of the shares purchased in any calendar year may not exceed \$25,000.

The Purchase Plan was effective upon the completion of the Company's IPO, at which time a total of 494,422 shares of the Company's common stock were made available for sale. As of January 1 of each year, starting in 2011, the reserve will automatically be restored to the original level. A total of 21,910 and 8,246 shares of the Company's common shares were acquired through the Purchase Plan during the year ended December 31, 2011 and 2010, respectively. As such, on January 1, 2012 and 2011, respectively, an additional 21,910 and 8,246 shares became available for future issuance under the Purchase Plan. In accordance with ASC 718-50, the ability to purchase stock at 85% of the lower of the fair market value of a share of Common Stock on the offering date or the exercise date represents an option. The Company estimates the fair value of such options at the inception of each offering period using the Black-Scholes valuation model. In connection with the Purchase Plan, the Company recorded \$66,000 and \$43,000 of compensation expense for the years ended December 31, 2011 and 2010, respectively.

**17. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

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

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

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

- (1) Net loss per common stockholder is computed independently for each of the quarters presented. Therefore the sum of the quarterly net loss per share will not necessarily equal the total for the year.
- (2) The unaudited quarterly results of operations for the quarter ended December 31, 2011, includes \$401,000 of personnel and severance costs related to our work force reduction (Note 6) which took place in December of 2011.



**Table of Contents****UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****ALIMERA SCIENCES, INC.****CONSOLIDATED BALANCE SHEETS**

	September 30, 2012	December 31, 2011
	(In thousands, except share and per share data)	
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 17,355	\$ 33,108
Investments in marketable securities		500
Prepaid expenses and other current assets	1,549	692
Inventory (Note 4)	671	
Deferred financing costs	119	201
Total current assets	19,694	34,501
PROPERTY AND EQUIPMENT at cost less accumulated depreciation	132	197
<b>TOTAL ASSETS</b>	<b>\$ 19,826</b>	<b>\$ 34,698</b>
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 1,702	\$ 1,948
Accrued expenses (Note 5)	2,252	1,638
Outsourced services payable	161	658
Notes payable (Note 7)	2,462	2,462
Capital lease obligations	9	12
Total current liabilities	6,586	6,718
<b>LONG-TERM LIABILITIES:</b>		
Notes payable, net of discount less current portion (Note 7)	1,250	2,868
Other long-term liabilities	193	134
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS EQUITY:</b>		
Preferred stock, \$.01 par value 10,000,000 shares authorized and no shares issued and outstanding at September 30, 2012 and at December 31, 2011 (Note 12)		
Common stock, \$.01 par value 100,000,000 shares authorized and 31,498,502 shares issued and outstanding at September 30, 2012 and 100,000,000 shares authorized and 31,427,355 shares issued and outstanding at December 31, 2011	315	314
Additional paid-in capital	236,894	235,619
Common stock warrants	415	415
Accumulated deficit	(225,827)	(211,370)
<b>TOTAL STOCKHOLDERS EQUITY</b>	<b>11,797</b>	<b>24,978</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS EQUITY</b>	<b>\$ 19,826</b>	<b>\$ 34,698</b>

See Notes to Consolidated Financial Statements.

**Table of Contents****ALIMERA SCIENCES, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands, except share and per share data)			
RESEARCH AND DEVELOPMENT EXPENSES	\$ 2,199	\$ 2,224	\$ 5,636	\$ 5,732
GENERAL AND ADMINISTRATIVE EXPENSES	1,506	1,421	4,488	4,827
MARKETING EXPENSES	1,503	2,612	3,704	5,038
OPERATING EXPENSES	5,208	6,257	13,828	15,597
INTEREST INCOME	1	1	3	15
INTEREST EXPENSE	(187)	(284)	(632)	(863)
NET LOSS	\$ (5,394)	\$ (6,540)	\$ (14,457)	\$ (16,445)
NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS Basic and diluted	\$ (0.17)	\$ (0.21)	\$ (0.46)	\$ (0.52)
WEIGHTED-AVERAGE SHARES OUTSTANDING Basic and diluted	31,465,752	31,396,517	31,443,568	31,342,752

See Notes to Consolidated Financial Statements.

**Table of Contents****ALIMERA SCIENCES, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Nine Months Ended September 30, 2012      2011 (In thousands)</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (14,457)	\$ (16,445)
Depreciation and amortization	80	106
Stock compensation expense	1,245	1,478
Amortization of deferred financing costs and debt discount	169	318
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(204)	(158)
Inventory	(671)	
Accounts payable	(854)	273
Accrued expenses and other current liabilities	117	(1,720)
Other long-term liabilities	65	
Net cash used in operating activities	(14,510)	(16,148)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Proceeds from maturities of investments	500	25,828
Purchases of property and equipment	(15)	(104)
Net cash provided by investing activities	485	25,724
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercises of stock options		210
Proceeds from exercise of common stock warrants		19
Payment of principal on note payable	(1,705)	(265)
Proceeds from sale of common stock	28	111
Payment of preferred stock issuance costs (Note 12)	(42)	
Payment of debt modification costs		(50)
Payments on capital lease obligations	(9)	(8)
Net cash (used in) provided by financing activities	(1,728)	17
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(15,753)	9,593
CASH AND CASH EQUIVALENTS    Beginning of period	33,108	28,514
CASH AND CASH EQUIVALENTS    End of period	\$ 17,355	\$ 38,107
<b>SUPPLEMENTAL DISCLOSURES</b>		
Cash paid for interest	\$ 413	\$ 508

There were no income tax or dividend payments made for the nine months ended September 30, 2012 and 2011.

See Notes to Consolidated Financial Statements.



---

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of Operations**

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

The Company is presently focused on diseases affecting the back of the eye, or retina, because the Company's management believes these diseases are not well treated with current therapies and represent a significant market opportunity. The Company's most advanced product candidate is ILUVIEN<sup>®</sup>, which has received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain, for the treatment of vision impairment associated with diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness.

The Company submitted a New Drug Application (NDA) in June 2010 for the low dose of ILUVIEN in the U.S. with the U.S. Food and Drug Administration (FDA), followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain under the European Union's (EU) Decentralized Procedure (DCP) in July 2010, with the United Kingdom acting as the Reference Member State (RMS). The RMS is responsible for coordinating the review and approval process between itself and the other involved countries, or Concerned Member States.

In November 2010, the Company received a Preliminary Assessment Report (PAR) from the RMS and in December 2010, it received a Complete Response Letter (CRL) from the FDA regarding its respective registration filings. The primary concerns expressed in both the PAR and the CRL centered on the benefits of ILUVIEN in treating DME patients versus the risk of its side effects. Upon further analysis of data from the Company's two Phase 3 pivotal clinical trials (collectively, the FAME<sup>M</sup> Study) through its final readout at month 36, the Company determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in its original filings.

The Company submitted its response to the CRL to the FDA in May 2011, including additional safety and efficacy data through the final readout at month 36 of the FAME Study with an emphasis on the chronic DME subgroup. In July 2011, the Company submitted a draft response to the PAR to the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), the regulatory body in the RMS, which included a similar data package.

In November 2011, the FDA issued a second CRL to communicate that the NDA could not be approved in its then current form stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. In its second CRL, the FDA indicated that the Company would need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. During the second quarter of 2012, the Company met with the FDA in an effort to gain a better understanding of the regulatory path for ILUVIEN in the U.S. Based upon this meeting, the Company plans to submit to the FDA a response to the second CRL to include additional analysis of the benefits and risks of ILUVIEN based upon clinical data available from the FAME Study.

After meetings and discussions with the MHRA, the Company finalized and submitted its response to the PAR to the MHRA in November 2011. In February 2012, the Company received a Final Assessment Report (FAR) from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the DCP was complete. Upon receipt of the FAR, the Company entered the national phase with each of these seven countries. During the national phase, labeling in each country's local language is finalized. As part of the approval process in these countries, the Company has committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients with chronic DME. ILUVIEN has received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies.

The Company currently plans to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and is pursuing pricing and reimbursement in those countries. In July 2012, the Company received a letter from Germany's Federal Joint Committee indicating that the automatic obligation to submit a dossier on ILUVIEN, per the Arzneimittelmarkt-Neuordnungsgesetz law, would not be necessary, and that a benefit assessment would not be required. This allows the Company to launch ILUVIEN in Germany without price restriction. In August 2012,



## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

the Company received an appraisal consultation document from the United Kingdom's National Institute for Health and Clinical Excellence (NICE) with a preliminary recommendation that ILUVIEN is not recommended given the cost of £5500 and other variables included in the Company's submission to NICE. This document is not NICE's final guidance and the recommendation may change prior to NICE's final appraisal determination. The Company provided further comments on the draft appraisal and additional data in advance of the second appraisal meeting that was held in October 2012. The Company is currently awaiting additional feedback from NICE.

F-24

---

**Table of Contents****ALIMERA SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In April 2012, the Company established a wholly-owned subsidiary in the United Kingdom, Alimera Sciences Limited, to facilitate transacting business in the EU. Since its inception there have been no employees of Alimera Sciences Limited. As of September 30, 2012 Alimera Sciences Limited had no employees. Alimera Sciences Limited expects to hire approximately three employees prior to the end of the year ending December 31, 2012.

**2. Basis of Presentation**

The Company and its wholly-owned subsidiary have prepared the accompanying unaudited interim condensed consolidated financial statements and notes thereto in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and the instructions to Form 10-Q and Article 10-01 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary to present fairly the Company's interim financial information.

The accompanying unaudited interim condensed consolidated financial statements and related notes should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2011 and related notes included in the Company's Annual Report on Form 10-K, which was filed with the SEC on March 30, 2012. The financial results for any interim period are not necessarily indicative of the expected financial results for the full year.

*Recent Accounting Pronouncements* In May 2011, the FASB amended the FASB Accounting Standards Codification to converge the fair value measurement guidance in U.S. GAAP and International Financial Reporting Standards. Some of the amendments clarify the application of existing fair value measurement requirements, while other amendments change particular principles in fair value measurement guidance. In addition, the amendments require additional fair value disclosures. The amendments are effective for fiscal years beginning after December 15, 2011 and should be applied prospectively. The Company does not believe the adoption of these amendments has had a material impact on its financial position or results of operations.

**3. Factors Affecting Operations**

To date the Company has incurred recurring losses, negative cash flow from operations, and has accumulated a deficit of \$225,827,000 from the Company's inception through September 30, 2012. As of September 30, 2012, the Company had approximately \$17,355,000 in cash and cash equivalents. On October 2, 2012, the Company closed its preferred stock financing in which it sold units consisting of 1,000,000 shares of its Series A Convertible Preferred Stock (Series A Preferred Stock) and warrants to purchase 300,000 shares of Series A Preferred Stock for gross proceeds of \$40,000,000, prior to the payment of approximately \$650,000 of related issuance costs (Note 12). In October 2010, the Company obtained a \$32,500,000 senior secured credit facility (Credit Facility) to help fund its working capital requirements (Note 7). The Credit Facility consisted of a \$20,000,000 working capital revolver and a \$12,500,000 term loan. The lenders have advanced \$6,250,000 under the term loan. In May 2011, the Credit Facility was amended to increase the term loan to \$17,250,000, the remaining \$11,000,000 of which would have been advanced following FDA approval of ILUVIEN, but no later than December 31, 2011. As a result of the issuance of the second CRL by the FDA in November 2011 regarding the NDA for ILUVIEN, the remaining \$11,000,000 is no longer available to the Company. Additionally, the Company may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which the Company would not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to the Company. On February 6, 2012, the Company received a letter from the lenders stating that they reserve the right to assert that the occurrence of certain events, including the issuance of the second CRL and a decrease in the market value of the Company's public equity securities, may represent a material impairment of the value of the collateral under the loan agreements. To date, the lenders have not made such an assertion, and in the opinion of management a material impairment of the value of the collateral has not occurred.

The Company plans to proceed with the direct commercialization of ILUVIEN in Germany, the United Kingdom and France in 2013. The Company believes that it has sufficient funds available to fund its operations beyond the projected commercialization of ILUVIEN in these EU countries. The Company does not expect the generation of revenue until 2013, and therefore does not expect to have positive cash flow from operations until 2014. If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, the Company may adjust its commercial plans so that it can continue to operate with its existing cash resources or seek to raise additional financing.



**Table of Contents****ALIMERA SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Inventory**

Inventory is stated at the lower of cost or market (net realizable value). Inventory consisted of the following:

	September 30, 2012	December 31, 2011
	(In thousands)	
Component parts (1)	\$ 102	\$
Work-in-process (2)	569	
Finished goods		
Total inventory	\$ 671	\$

- (1) Component parts at September 30, 2012 consisted of manufactured components of the ILUVIEN inserter.  
 (2) Work-in-process at September 30, 2012 consisted of completed units of ILUVIEN that are undergoing, but have not completed, quality assurance testing as required by regulatory authorities.

**5. Accrued Expenses**

Accrued expenses consisted of the following:

	September 30, 2012	December 31, 2011
	(In thousands)	
Accrued clinical investigator expenses	\$ 821	\$ 788
Accrued severance expenses (1)		206
Accrued other compensation expenses	772	621
Accrued preferred stock issuance costs (Note 12)	608	
Other accrued expenses	51	23
Total accrued expenses	\$ 2,252	\$ 1,638

- (1) In connection with the FDA's CRL issued to the Company in November 2011 (Note 1), management and the board of directors of the Company approved a reduction in force pursuant to which the Company terminated the employment of 11 employees. The affected employees were notified in December 2011. The Company incurred \$401,000 of severance expense in December 2011 in connection with the reduction in force of which \$206,000 was payable at December 31, 2011. All amounts due at December 31, 2011 were paid to affected employees during the nine months ended September 30, 2012.

**6. pSivida Agreement**

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

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Company also agreed to:

pay \$12.0 million to pSivida upon the execution of the March 2008 agreement;

issue a \$15.0 million promissory note to pSivida (which was subsequently repaid in full in April 2010);

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 agreement prior to being amended and restated); and

make an additional milestone payment of \$25.0 million after the first product under the March 2008 agreement has been approved by the FDA.

F-26

**Table of Contents****ALIMERA SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

Upon commercialization of ILUVIEN, the Company must share 20% of net profits and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined by the agreement, with pSivida. In connection with this arrangement the Company is entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits. As of September 30, 2012 and December 31, 2011, pSivida owed the Company \$4,924,000 and \$4,064,000, respectively, in commercialization costs. Due to the uncertainty of future profits from ILUVIEN, the Company has fully reserved these amounts in the accompanying unaudited consolidated financial statements.

**7. Term Loan and Working Capital Revolver***Term Loan*

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

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

If the Company repays Term Loan A prior to maturity, the Company must pay to the Lenders a prepayment fee equal to 1.0% of the total amount of principal then outstanding (subject to a 50% reduction in the event that the prepayment occurs in connection with an acquisition of the Company).

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

On the Effective Date, the Company issued to the Lenders warrants to purchase an aggregate of up to 39,773 shares of the Company's common stock. Each of the warrants is exercisable immediately, has a per-share exercise price of \$11.00 and has a term of 10 years. The Company estimated the fair value of warrants granted using the Black-Scholes option pricing model. The aggregate fair value of the warrants was estimated to be \$389,000. The Company allocated a portion of the proceeds from the Term Loan Agreement to the warrants in accordance with ASC 470-20-25-2, Debt Instruments with Detachable Warrants. As a result, the Company recorded a discount of \$366,000 which is being

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

amortized to interest expense using the effective interest method. The Lenders will have certain registration rights with respect to the shares of common stock issuable upon exercise of all of their warrants. The Company paid to the Lenders an upfront fee of \$62,500 on the Effective Date and an additional fee of \$50,000 in connection with the Term Loan Modification. In accordance with ASC 470-50-40-17, Debt Modifications and Extinguishments, the Company is amortizing the deferred financing costs on Term Loan A and the \$50,000 modification fee over the remaining term of Term Loan A, as modified. The Lenders also hold warrants to purchase an aggregate of up to 69,999 shares of the Company's common stock, which would have been exercisable only if Term Loan B had been advanced to the Company. As a result of the issuance of the second CRL by the FDA in November 2011 (Note 1), the Company did not draw down Term Loan B by December 31, 2011 and the ability to draw down Term Loan B expired. Consequently, the warrants issued to the Lenders in connection with Term Loan B are not exercisable.

F-27

---

**Table of Contents****ALIMERA SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

The weighted average interest rate of the Company's notes payable to Silicon Valley Bank and MidCap Financial LLP approximates the rate at which the Company could obtain alternative financing; therefore, the carrying amount of the notes approximates their fair value.

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

*Working Capital Revolver*

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

The Working Capital Revolver is a working capital-based revolving line of credit in an aggregate amount of up to the lesser of (i) \$20,000,000, or (ii) 85% of eligible domestic accounts receivable. As of September 30, 2012 and December 31, 2011, respectively, no amounts under the Working Capital Revolver were outstanding or available to the Company. The Company may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which it does not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to the Company.

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

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

**8. Loss Per Share (EPS)**

Basic EPS is calculated in accordance with ASC 260, *Earnings per Share*, by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated in accordance with ASC 260 by adjusting weighted average common shares outstanding for the dilutive effect of common stock options, warrants, convertible preferred stock and accrued but unpaid convertible preferred stock dividends. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive. Weighted average common stock equivalents 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:



Edgar Filing: ALIMERA SCIENCES INC - Form S-1

	Three Months Ended		Nine Months ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Common stock warrants	3,555	28,086	3,584	29,366
Stock options	948,238	1,502,469	956,654	1,573,106
Total potentially dilutive securities	951,793	1,530,555	960,238	1,602,472

F-28

**Table of Contents****ALIMERA SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. Stock Options**

During the three months ended September 30, 2012 and 2011, the Company recorded compensation expense related to stock options of approximately \$342,000 and \$417,000, respectively. During the nine months ended September 30, 2012 and 2011, the Company recorded compensation expense related to stock options of approximately \$1,136,000 and \$1,416,000, respectively. As of September 30, 2012, the total unrecognized compensation cost related to non-vested stock options granted was \$2,590,000 and is expected to be recognized over a weighted average period of 2.09 years. The following table presents a summary of stock option transactions for the three and nine months ended September 30, 2012 and 2011:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012		2011		2012		2011	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options at beginning of period	3,698,019	\$ 3.17	2,677,474	\$ 3.98	2,607,446	\$ 3.88	2,741,985	\$ 3.81
Grants			90,000	7.95	1,127,500	1.71	155,000	7.83
Forfeitures	(9,146)	6.91			(46,073)	8.32	(7,500)	11.00
Exercises	(2,245)	1.33	(10,000)	2.04	(2,245)	1.33	(132,011)	1.59
Options at end of period	3,686,628	3.16	2,757,474	4.11	3,686,628	3.16	2,757,474	4.11
Weighted average per share fair value of options granted during the period	\$		\$	5.81	\$	1.33	\$	5.67

The following table provides additional information as of September 30, 2012:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
(In thousands)				
Outstanding	3,686,628	\$ 3.16	6.58 years	\$ 2,404
Exercisable	2,386,634	2.94	5.29 years	1,524
Expected to vest	941,265	4.06	8.84 years	575

The following table provides additional information as of December 31, 2011:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
(In thousands)				
Outstanding	2,607,446	\$ 3.88	6.14 years	\$

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Exercisable	2,058,585	2.74	5.54 years
Expected to vest	532,303	8.28	8.42 years

Per the terms of the Company's 2004 and 2005 Option Plans (Plans), the Company's preferred stock financing (Note 12) constituted a change of control for the purposes of Plan vesting and as a result all unvested options under the Plans became vested. As of September 30, 2012 there were 79,380 unvested options and \$196,000 of unrecognized compensation expense in connection with the 2004 and 2005 Plans, which will be recognized as expense in the fourth quarter of 2012.

F-29

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Restricted Stock Units*

In February 2012, the Company awarded 85,447 restricted stock units (RSUs), to executive officers and employees at a grant date fair value of \$1.70 per RSU. A RSU is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of the RSUs was determined on the date of grant based on the closing price of the Company's common stock on the date of grant, which equals the RSU's intrinsic value. The RSUs were to vest upon the receipt of marketing authorization of ILUVIEN in four of the seven EU countries in which ILUVIEN is recommended for marketing authorization (Note 1). During the second quarter of 2012, the United Kingdom, Austria and Portugal granted ILUVIEN marketing authorization and the Company recorded \$109,000 in compensation expense in connection with the RSUs. On July 18, 2012, France granted marketing authorization to ILUVIEN and, as a result, the RSUs became fully vested. During the three and nine months ended September 30, 2012, the Company recognized \$36,000 and \$145,000, respectively, in compensation expense in connection with the RSUs.

**10. Income Taxes**

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

Income tax positions are considered for uncertainty in accordance with ASC 740-10. The Company believes that its income tax filing positions and deductions are more likely than not of being sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position; therefore, no ASC 740-10 liabilities and no related penalties and interest have been recorded. Tax years since 2003 remain subject to examination in Georgia, Tennessee, and on the federal level. The Company does not anticipate any material changes to its uncertain tax positions within the next 12 months.

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

At September 30, 2012 and December 31, 2011, the Company had federal net operating loss (NOL) carry-forwards of approximately \$134,609,000 and \$120,353,000 and state NOL carry-forwards of approximately \$118,071,000 and \$103,815,000 respectively, that are available to reduce future income unless otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2023 and 2031 and the state NOL carry-forwards will expire at various dates between 2020 and 2031.

NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of the Company were to occur. In general, an ownership change occurs for purposes of Section 382 if there is a more than 50% change in ownership over a 3-year testing period. The Company is currently evaluating whether a change in ownership occurred with respect to the preferred stock financing in October 2012.

**Table of Contents****ALIMERA SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Fair Value**

The Company adopted ASC 820, *Fair Value Measurements and Disclosures*, 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 observable contractual prices for the underlying financial instrument, as well as other relevant economic measures.

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

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

	Level 1	September 30, 2012		Total
		Level 2	Level 3	
(In thousands)				
Cash equivalents (1)	\$ 16,941	\$	\$	\$ 16,941
Assets measured at fair value	\$ 16,941	\$	\$	\$ 16,941
	Level 1	December 31, 2011		Total
		Level 2	Level 3	
(In thousands)				
Cash equivalents (1)	\$ 32,438	\$	\$	\$ 32,438
Investments in marketable debt securities (2)		500		500
Assets measured at fair value	\$ 32,438	\$ 500	\$	\$ 32,938

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

(2) Valuations are based on quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly. These prices include broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

Pricing sources include industry standard data providers, security master files from large financial institutions, and other third party sources which are input into a distribution-curve-based algorithm to determine a daily market value. This creates a consensus price or a weighted average price for each security.

F-31

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. Subsequent Events**

*Preferred Stock Financing*

On October 2, 2012, the Company closed its preferred stock financing in which it sold units consisting of 1,000,000 shares of Series A Preferred Stock and warrants to purchase 300,000 shares of Series A Preferred Stock for gross proceeds of \$40,000,000, prior to the payment of approximately \$650,000 of related issuance costs. The powers, preferences and rights of the Series A Preferred Stock are set forth in the certificate of designation filed by the Company with the Secretary of State of the State of Delaware on October 1, 2012. Each share of Series A Preferred Stock, including any shares of Series A Preferred Stock issued upon exercise of the warrants, is convertible into shares of the Company's common stock at any time at the option of the holder at the rate equal to \$40.00 divided by the then current conversion price (conversion price). The initial conversion price of \$2.91 of the Series A Preferred Stock is subject to adjustment to \$3.16 or \$2.66 (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Preferred Stock) based on the occurrence or non-occurrence of certain events relating to guidance from NICE regarding ILUVIEN, in addition to certain customary price based anti-dilution adjustments. Each share of Series A Preferred Stock shall automatically be converted into shares of common stock at the then-effective conversion price upon the occurrence of the later to occur of both (i) the Company receives and publicly announces the approval by the FDA of the Company's NDA for ILUVIEN and (ii) the date on which the Company consummates an equity financing transaction pursuant to which the Company sells to one or more third party investors either (a) shares of common stock or (b) other equity securities that are convertible into shares of common stock and that have rights, preference or privileges, senior to or on a parity with, the Series A Preferred Stock, in each case having an as-converted per share of common stock price of not less than \$10.00 and that results in total gross proceeds to the Company of at least \$30,000,000.

Each unit sold in the preferred stock financing included a warrant to purchase 0.30 shares of Series A Preferred Stock at an exercise price equal to \$44.00 per share. At the election of the holder of a warrant, the warrant may be exercised for the number of shares of common stock then issuable upon conversion of the Series A Preferred Stock that would otherwise be issued upon such exercise at the then-effective conversion price.

Table of Contents

**19,548,871 Shares of Common Stock**

**ALIMERA SCIENCES, INC.**

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is correct only as of the date of this prospectus, regardless of the time of the delivery of this prospectus or the sale of these securities.



**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth all costs and expenses to be incurred by the registrant in connection with the preparation and filing of this registration statement. All amounts shown are estimates except for the SEC registration fee. The registrant will pay all expenses in connection with the distribution of the shares of common stock being registered hereby, except for the fees and expenses of any counsel and other advisors that any selling stockholder may employ to represent them in connection with the offering and any brokerage or underwriting discounts or commissions paid to broker-dealers in connection with the sale of the shares.

	<b>Amount to be Paid by Registrant</b>
SEC Registration Fee	\$ 6,133
Legal Fees and Expenses	\$ 25,000
Accounting Fees and Expenses	\$ 15,000
Printing and Engraving Fees	\$ 7,500
Transfer Agent and Registrar Fees	\$ 5,000
Miscellaneous Expenses	\$ 16,367
Total	\$ 75,000

**Item 14. Indemnification of Directors and Officers**

The Delaware General Corporation Law and the registrant's certificate of incorporation and bylaws provide for indemnification of the registrant's directors and officers for liabilities and expenses that they may incur in such capacities. In general, directors and officers are indemnified with respect to actions taken in good faith in a manner reasonably believed to be in, or not opposed to, the best interests of the registrant, and with respect to any criminal action or proceeding, actions that the indemnitee had no reasonable cause to believe were unlawful.

The registrant has also entered into identification agreements with its directors and executive officers. These identification agreements generally require that the registrant pay, on behalf of each director and officer party thereto, all amounts that he or she is or becomes legally obligated to pay because of any claim or claims made against him or her because of any act or omission which he or she commits or suffers while acting in his or her capacity as the registrant's director and/or officer and because of his or her being a director and/or officer. Under the Delaware General Corporation Law, absent an identification agreement or a provision in a corporation's bylaws or certificate of incorporation, indemnification of a director or officer is discretionary rather than mandatory (except in the case of a proceeding in which a director or officer is successful on the merits).

The registrant currently maintains a directors' and officers' liability insurance policy.

**Item 15. Recent Sales of Unregistered Securities**

In connection with the registrant's term loan agreement, on October 14, 2010, the registrant issued to Silicon Valley Bank, a warrant to purchase up to 31,818 shares of the registrant's common stock and to MidCap Funding III, LLC, a warrant to purchase up to 47,728 shares of the registrant's common stock pursuant to the exemption provided by Rule 506 under the Securities Act.

In connection with a modification of the registrant's term loan agreement, on May 16, 2011, the registrant issued to Midcap Funding III, LLC, a warrant to purchase up to 18,136 shares of the registrant's common stock and to Silicon Valley Bank, a warrant to purchase up to 12,090 shares of the registrant's common stock pursuant to the exemption provided by Rule 506 under the Securities Act.

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

During the year ended December 31, 2011, the registrant issued 4,705 shares of its common stock upon the exercise of warrants for an aggregate of \$19,000. The warrant the shares were issued in reliance on the exemptions provided by Section 4(2) of the Securities Act.

On October 2, 2012, the registrant issued and sold units consisting of an aggregate of 1,000,000 shares of the registrant's Series A Convertible Preferred Stock and warrants to purchase up to an aggregate of 300,000 shares of the registrant's Series A Convertible Preferred Stock. The units were sold for an aggregate of \$40.0 million to certain accredited investors without registration under the Securities Act, in reliance on the exemptions provided by Section 4(2) of the Securities Act and/or Regulation D promulgated thereunder.

No underwriters were used in the foregoing transactions.

II-1

**Table of Contents**

**Item 16. Exhibits and Financial Statement Schedules**

- 3.2 Restated Certificate of Incorporation of Registrant, as amended on various dates (filed as Exhibit 3.2 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
- 3.4.A Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.4 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
- 3.4.B Bylaw Amendment (filed as Exhibit 3.6 to the Registrant's Current Report, as filed on July 18, 2012, and incorporated herein by reference)
- 3.4.C Amended and Restated Bylaws of the Registrant, as amended (filed as Exhibit 3.4.C to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
- 3.5 Form of Certificate of Designation (filed as Exhibit 3.5 to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
- 4.3 Second Amended and Restated Investor Rights Agreement, dated March 17, 2008, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.3 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
- 4.4 Second Amended and Restated Stock Sale Agreement, dated March 17, 2008, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.4 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
- 4.5 Omnibus Amendment, dated August 25, 2009, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.5 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
- 4.6 Warrant to Purchase Stock dated October 14, 2010 issued to Silicon Valley Bank (filed as Exhibit 4.1 to Registrant's Current Report, as filed on October 18, 2010, and incorporated herein by reference)
- 4.7 Warrant to Purchase Stock dated October 14, 2010 issued to MidCap Funding III, LLC (filed as Exhibit 4.2 to Registrant's Current Report, as filed on October 18, 2010, and incorporated herein by reference)
- 4.8 Warrant to Purchase Stock dated May 16, 2011 issued to MidCap Funding III, LLC (filed as Exhibit 4.1 to Registrant's Current Report, as filed on May 17, 2011, and incorporated herein by reference)
- 4.10 Form of Warrant to Purchase Shares of Series A Preferred Stock (filed as Exhibit 4.10 to the Registrant's Current Report, as filed on July 18, 2012, and incorporated herein by reference)
- 4.10.A Warrant to Purchase Shares of Series A Preferred Stock issued to Sofinnova Venture Partners VIII, L.P. (filed as Exhibit 4.10.A to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
- 4.10.B Warrant to Purchase Shares of Series A Preferred Stock issued to Growth Equity Opportunities Fund III, LLC (filed as Exhibit 4.10.B to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
- 4.10.C Warrant to Purchase Shares of Series A Preferred Stock issued to Micro Cap Partners, L.P. (filed as Exhibit 4.10.C to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
- 4.10.D Warrant to Purchase Shares of Series A Preferred Stock issued to Palo Alto Healthcare Master Fund, L.P. (filed as Exhibit 4.10.D to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
- 4.10.E Warrant to Purchase Shares of Series A Preferred Stock issued to Palo Alto Healthcare Master Fund II, L.P. (filed as Exhibit 4.10.E to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
- 4.11 Registration Rights Agreement (filed as Exhibit 4.11 to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
- 5.1\* Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
- 10.1 Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated

herein by reference)

II-2

**Table of Contents**

10.2	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and C. Daniel Myers (filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.3	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and Richard Eiswirth (filed as Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.4	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and David Holland (filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.5	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and Susan Caballa (filed as Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.6	Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and Kenneth Green (filed as Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.7	Alimera Sciences, Inc. 2004 Incentive Stock Plan, as amended (filed as Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.7.A	Form of Option Certificate under the Alimera Sciences, Inc. 2004 Incentive Stock Plan (filed as Exhibit 10.7.A to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.8	Alimera Sciences, Inc. 2005 Incentive Stock Plan (filed as Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.8.A	Form of Option Certificate under the Alimera Sciences, Inc. 2005 Incentive Stock Plan (filed as Exhibit 10.8.A to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.9	2010 Equity Incentive Plan (filed as Exhibit 10.9 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
10.10	2010 Employee Stock Purchase Plan (filed as Exhibit 10.10 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
10.11	Management Cash Incentive Plan (filed as Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.12	Compensation Program for Non-Employee Directors (filed as Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.13	Amended and Restated Collaboration Agreement by and between pSivida, Inc. (f/k/a/Control Delivery Systems, Inc.) and Alimera Sciences, Inc., dated as of March 14, 2008 (filed as Exhibit 10.13 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)
10.14	Asset Purchase Agreement between Bausch & Lomb Incorporated and Alimera Sciences, Inc., dated as of December 20, 2006 (filed as Exhibit 10.14 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)
10.15	Asset Purchase Agreement between Bausch & Lomb Incorporated and Alimera Sciences, Inc., dated as of February 16, 2007 (filed as Exhibit 10.15 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)
10.16	License and Option Agreement by and between Emory University and Alimera Sciences, Inc., dated as of July 16, 2009 (filed as Exhibit 10.16 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)
10.17	License and Option Agreement by and between Emory University and Alimera Sciences, Inc., dated as of August 31, 2009 (filed as Exhibit 10.17 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)

**Table of Contents**

10.18	Office Lease by and between Rubicon, L.C. and Alimera Sciences, Inc., dated as of May 27, 2003, as amended (filed as Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.25	License Agreement between Alimera Sciences, Inc. and Dainippon Sumitomo Pharma Co., Ltd., dated November 4, 2007 (filed as Exhibit 10.25 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
10.26	Commercial Contract Manufacturing Agreement, between Alimera Sciences, Inc. and Alliance Medical Products, Inc., dated February 5, 2010 (filed as Exhibit 10.26 to Amendment No. 6 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 20, 2010, and incorporated herein by reference)
10.27	Loan and Security Agreement dated October 14, 2010 between Registrant, Silicon Valley Bank and MidCap Funding III, LLC (filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, as filed on October 18, 2010, and incorporated herein by reference)
10.28	Loan and Security Agreement dated October 14, 2010 between Registrant and Silicon Valley Bank (filed as Exhibit 10.2 to Registrant's Current Report on Form 8-K, as filed on October 18, 2010, and incorporated herein by reference)
10.29	Contract Sales Agreement dated October 4, 2010 between the Registrant and OnCall LLC (filed as Exhibit 10.29 to Registrant's Annual Report on Form 10-K, as filed on March 25, 2011, and incorporated herein by reference)
10.30	Form of Notice of Stock Option Grant and Stock Option Agreement under 2010 Equity Incentive Plan (filed as Exhibit 10.30 to Registrant's Annual Report on Form 10-K, as filed on March 25, 2011, and incorporated herein by reference)
10.31	First Loan Modification Agreement dated May 16, 2011 between Registrant, Silicon Valley Bank and MidCap Funder III, LLC (filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, as filed on May 17, 2011, and incorporated herein by reference)
10.32	First Loan Modification Agreement dated May 16, 2011 between Registrant and Silicon Valley Bank (filed as Exhibit 10.2 to Registrant's Current Report on Form 8-K, as filed on May 17, 2011, and incorporated herein by reference)
10.33	Amendment to Manufacturing Agreement between Registrant and Alliance Medical Products, Inc. (filed as Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q, as filed on August 5, 2011, and incorporated herein by reference)
10.34	Form of Notice of Stock Unit Award and Stock Unit Agreement under 2010 Equity Incentive Plan (filed as Exhibit 10.34 to Registrant's Quarterly Report on Form 10-Q, as filed on March 30, 2012, and incorporated herein by reference)
10.35	Manufacturing Agreement by and Between the Registrant and Flextronics Medical Sales and Marketing, Ltd. (filed as Exhibit 10.35 to Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2012, and incorporated herein by reference)
10.36	Securities Purchase Agreement dated July 17, 2012 (filed as Exhibit 10.36 to the Registrant's Current Report, as filed on July 18, 2012, and incorporated herein by reference)
10.37	Amendment No. 1 to Securities Purchase Agreement dated September 21, 2012 (filed as Exhibit 10.37 to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
10.38	UK Sub-Plan of the 2010 Equity Incentive Plan of Alimera Sciences, Inc. (filed as Exhibit 10.38 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference)
10.39	Form of UK Sub-Plan Notice of Stock Option Grant and Stock Option Agreement (filed as Exhibit 10.39 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference)
10.40 **	Contract of Employment, dated November 3, 2012, by and between the Registrant and Phillip Ashman
21.1	List of subsidiaries of the Registrant (including jurisdiction of organization and names under which subsidiaries do business) (filed as Exhibit 21.1 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference)
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (contained in Exhibit 5.1)
24.1	Power of Attorney (included in the signature pages to the registration statement)
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

Compensation Arrangement.

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

\* Filed herewith.

\*\* To be filed.

+ Users of this data are advised pursuant to Rule 406T of Regulation S-T that this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

II-4

---

**Table of Contents**

**Item 17. Undertakings**

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;





**Table of Contents**

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than a payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing this Form S-1 and that it has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Alpharetta, Georgia on November 16, 2012.

**ALIMERA SCIENCES, INC.**

By: /s/ C. Daniel Myers  
C. Daniel Myers

President and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints C. Daniel Myers and Richard S. Eiswirth, Jr., and each of them, his true and lawful attorneys-in-fact and agents, with full power to act separately and full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or his or their substitute or substitutes may lawfully do or cause to be done by virtue hereof.

This Power of Attorney shall not revoke any powers of attorney previously executed by the undersigned. This Power of Attorney shall not be revoked by any subsequent power of attorney that the undersigned may execute, unless such subsequent power of attorney specifically provides that it revokes this Power of Attorney by referring to the date of the undersigned's execution of this Power of Attorney. For the avoidance of doubt, whenever two or more powers of attorney granting the powers specified herein are valid, the agents appointed on each shall act separately unless otherwise specified.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ C. Daniel Myers C. Daniel Myers	President, Chief Executive Officer and Director (Principal Executive Officer)	November 16, 2012
/s/ Richard S. Eiswirth, Jr. Richard S. Eiswirth, Jr.	Chief Operating Officer and Chief Financial Officer  (Principal Financial Officer and Principal Accounting Officer)	November 16, 2012
/s/ Philip R. Tracy Philip R. Tracy	Director and Chairman of the Board	November 16, 2012
/s/ Glen Bradley, Ph.D. Glen Bradley, Ph.D.	Director	November 16, 2012
/s/ Mark J. Brooks Mark J. Brooks	Director	November 16, 2012
/s/ Brian K. Halak, Ph.D. Brian K. Halak, Ph.D.	Director	November 16, 2012
/s/ Garheng Kong, M.D., Ph.D. Garheng Kong, M.D., Ph.D.	Director	November 16, 2012

Edgar Filing: ALIMERA SCIENCES INC - Form S-1

/s/ James Largent  
James Largent

Director

November 16, 2012

/s/ Peter J. Pizzo, III  
Peter J. Pizzo, III

Director

November 16, 2012

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

Director

November 16, 2012

II-7

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit</b>	<b>Exhibit</b>
<b>Number</b>	<b>Title</b>
3.2	Restated Certificate of Incorporation of Registrant, as amended on various dates (filed as Exhibit 3.2 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
3.4.A	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.4 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
3.4.B	Bylaw Amendment (filed as Exhibit 3.6 to the Registrant's Current Report, as filed on July 18, 2012, and incorporated herein by reference)
3.4.C	Amended and Restated Bylaws of the Registrant, as amended (filed as Exhibit 3.4.C to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
3.5	Form of Certificate of Designation (filed as Exhibit 3.5 to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
4.3	Second Amended and Restated Investor Rights Agreement, dated March 17, 2008, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.3 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.4	Second Amended and Restated Stock Sale Agreement, dated March 17, 2008, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.4 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.5	Omnibus Amendment, dated August 25, 2009, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.5 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.6	Warrant to Purchase Stock dated October 14, 2010 issued to Silicon Valley Bank (filed as Exhibit 4.1 to Registrant's Current Report, as filed on October 18, 2010, and incorporated herein by reference)
4.7	Warrant to Purchase Stock dated October 14, 2010 issued to MidCap Funding III, LLC (filed as Exhibit 4.2 to Registrant's Current Report, as filed on October 18, 2010, and incorporated herein by reference)
4.8	Warrant to Purchase Stock dated May 16, 2011 issued to MidCap Funding III, LLC (filed as Exhibit 4.1 to Registrant's Current Report, as filed on May 17, 2011, and incorporated herein by reference)
4.10	Form of Warrant to Purchase Shares of Series A Preferred Stock (filed as Exhibit 4.10 to the Registrant's Current Report, as filed on July 18, 2012, and incorporated herein by reference)
4.10.A	Warrant to Purchase Shares of Series A Preferred Stock issued to Sofinnova Venture Partners VIII, L.P. (filed as Exhibit 4.10.A to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
4.10.B	Warrant to Purchase Shares of Series A Preferred Stock issued to Growth Equity Opportunities Fund III, LLC (filed as Exhibit 4.10.B to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
4.10.C	Warrant to Purchase Shares of Series A Preferred Stock issued to Micro Cap Partners, L.P. (filed as Exhibit 4.10.C to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
4.10.D	Warrant to Purchase Shares of Series A Preferred Stock issued to Palo Alto Healthcare Master Fund, L.P. (filed as Exhibit 4.10.D to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
4.10.E	Warrant to Purchase Shares of Series A Preferred Stock issued to Palo Alto Healthcare Master Fund II, L.P. (filed as Exhibit 4.10.E to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
4.11	Registration Rights Agreement (filed as Exhibit 4.11 to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)

## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

- 5.1\* Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
- 10.1 Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)

II-8

**Table of Contents**

- 10.2 Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and C. Daniel Myers (filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.3 Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and Richard Eiswirth (filed as Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.4 Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and David Holland (filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.5 Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and Susan Caballa (filed as Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.6 Amended and Restated Employment Agreement, dated August 18, 2008, by and between the Registrant and Kenneth Green (filed as Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.7 Alimera Sciences, Inc. 2004 Incentive Stock Plan, as amended (filed as Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.7.A Form of Option Certificate under the Alimera Sciences, Inc. 2004 Incentive Stock Plan (filed as Exhibit 10.7.A to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.8 Alimera Sciences, Inc. 2005 Incentive Stock Plan (filed as Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.8.A Form of Option Certificate under the Alimera Sciences, Inc. 2005 Incentive Stock Plan (filed as Exhibit 10.8.A to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.9 2010 Equity Incentive Plan (filed as Exhibit 10.9 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
- 10.10 2010 Employee Stock Purchase Plan (filed as Exhibit 10.10 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
- 10.11 Management Cash Incentive Plan (filed as Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.12 Compensation Program for Non-Employee Directors (filed as Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
- 10.13 Amended and Restated Collaboration Agreement by and between pSivida, Inc. (f/k/a/Control Delivery Systems, Inc.) and Alimera Sciences, Inc., dated as of March 14, 2008 (filed as Exhibit 10.13 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)
- 10.14 Asset Purchase Agreement between Bausch & Lomb Incorporated and Alimera Sciences, Inc., dated as of December 20, 2006 (filed as Exhibit 10.14 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)
- 10.15 Asset Purchase Agreement between Bausch & Lomb Incorporated and Alimera Sciences, Inc., dated as of February 16, 2007 (filed as Exhibit 10.15 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)
- 10.16 License and Option Agreement by and between Emory University and Alimera Sciences, Inc., dated as of July 16, 2009 (filed as Exhibit 10.16 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)
- 10.17 License and Option Agreement by and between Emory University and Alimera Sciences, Inc., dated as of August 31, 2009 (filed as Exhibit 10.17 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 16, 2010, and incorporated herein by reference)

**Table of Contents**

10.18	Office Lease by and between Rubicon, L.C. and Alimera Sciences, Inc., dated as of May 27, 2003, as amended (filed as Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on October 30, 2009, and incorporated herein by reference)
10.25	License Agreement between Alimera Sciences, Inc. and Dainippon Sumitomo Pharma Co., Ltd., dated November 4, 2007 (filed as Exhibit 10.25 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
10.26	Commercial Contract Manufacturing Agreement, between Alimera Sciences, Inc. and Alliance Medical Products, Inc., dated February 5, 2010 (filed as Exhibit 10.26 to Amendment No. 6 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 20, 2010, and incorporated herein by reference)
10.27	Loan and Security Agreement dated October 14, 2010 between Registrant, Silicon Valley Bank and MidCap Funding III, LLC (filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, as filed on October 18, 2010, and incorporated herein by reference)
10.28	Loan and Security Agreement dated October 14, 2010 between Registrant and Silicon Valley Bank (filed as Exhibit 10.2 to Registrant's Current Report on Form 8-K, as filed on October 18, 2010, and incorporated herein by reference)
10.29	Contract Sales Agreement dated October 4, 2010 between the Registrant and OnCall LLC (filed as Exhibit 10.29 to Registrant's Annual Report on Form 10-K, as filed on March 25, 2011, and incorporated herein by reference)
10.30	Form of Notice of Stock Option Grant and Stock Option Agreement under 2010 Equity Incentive Plan (filed as Exhibit 10.30 to Registrant's Annual Report on Form 10-K, as filed on March 25, 2011, and incorporated herein by reference)
10.31	First Loan Modification Agreement dated May 16, 2011 between Registrant, Silicon Valley Bank and MidCap Funder III, LLC (filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, as filed on May 17, 2011, and incorporated herein by reference)
10.32	First Loan Modification Agreement dated May 16, 2011 between Registrant and Silicon Valley Bank (filed as Exhibit 10.2 to Registrant's Current Report on Form 8-K, as filed on May 17, 2011, and incorporated herein by reference)
10.33	Amendment to Manufacturing Agreement between Registrant and Alliance Medical Products, Inc. (filed as Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q, as filed on August 5, 2011, and incorporated herein by reference)
10.34	Form of Notice of Stock Unit Award and Stock Unit Agreement under 2010 Equity Incentive Plan (filed as Exhibit 10.34 to Registrant's Quarterly Report on Form 10-Q, as filed on March 30, 2012, and incorporated herein by reference)
10.35	Manufacturing Agreement by and Between the Registrant and Flextronics Medical Sales and Marketing, Ltd. (filed as Exhibit 10.35 to Registrant's Quarterly Report on Form 10-Q, as filed on August 14, 2012, and incorporated herein by reference)
10.36	Securities Purchase Agreement dated July 17, 2012 (filed as Exhibit 10.36 to the Registrant's Current Report, as filed on July 18, 2012, and incorporated herein by reference)
10.37	Amendment No. 1 to Securities Purchase Agreement dated September 21, 2012 (filed as Exhibit 10.37 to the Registrant's Current Report, as filed on October 2, 2012, and incorporated herein by reference)
10.38	UK Sub-Plan of the 2010 Equity Incentive Plan of Alimera Sciences, Inc. (filed as Exhibit 10.38 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference)
10.39	Form of UK Sub-Plan Notice of Stock Option Grant and Stock Option Agreement (filed as Exhibit 10.39 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference)
10.40 **	Contract of Employment, dated November 3, 2012, by and between the Registrant and Phillip Ashman
21.1	List of subsidiaries of the Registrant (including jurisdiction of organization and names under which subsidiaries do business) (filed as Exhibit 21.1 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 7, 2012, and incorporated herein by reference)
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (contained in Exhibit 5.1)
24.1	Power of Attorney (included in the signature pages to the registration statement)
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document



## Edgar Filing: ALIMERA SCIENCES INC - Form S-1

101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

Compensation Arrangement.

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

\* Filed herewith.

\*\* To be filed.

+ Users of this data are advised pursuant to Rule 406T of Regulation S-T that this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

II-10