

ALIMERA SCIENCES INC  
Form 10-Q  
May 11, 2012  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 2012**

**or**

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

**For the transition period from            to**

**Commission File Number: 001-34703**

**Alimera Sciences, Inc.**

(Exact name of registrant as specified in its charter)

Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-0028718**  
(I.R.S. Employer  
Identification No.)

**6120 Windward Parkway, Suite 290**  
**Alpharetta, GA**  
(Address of principal executive offices)

**30005**  
(Zip Code)

**(678) 990-5740**

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of May 9, 2012, there were 31,432,355 shares of the registrant's common stock issued and outstanding.

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**QUARTERLY REPORT ON FORM 10-Q**

**INDEX**

**PART I. FINANCIAL INFORMATION**

<u>Item 1. Interim Condensed Financial Statements (unaudited)</u>	2
<u>Balance Sheets as of March 31, 2012 and December 31, 2011</u>	2
<u>Statements of Operations for the three months ended March 31, 2012 and 2011</u>	3
<u>Statements of Cash Flows for the three months ended March 31, 2012 and 2011</u>	4
<u>Notes to Financial Statements</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	24
<u>Item 4. Controls and Procedures</u>	24

**PART II. OTHER INFORMATION**

<u>Item 1. Legal Proceedings</u>	25
<u>Item 1A. Risk Factors</u>	25
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	25
<u>Item 3. Defaults Upon Senior Securities</u>	25
<u>Item 4. Mine Safety Disclosures</u>	25
<u>Item 5. Other Information</u>	25
<u>Item 6. Exhibits</u>	25
Exhibit 10.35	
Exhibit 31.1	
Exhibit 31.2	
Exhibit 32.1	
EX-101 INSTANCE DOCUMENT	
EX-101 SCHEMA DOCUMENT	
EX-101 CALCULATION LINKBASE DOCUMENT	
EX-101 LABELS LINKBASE DOCUMENT	
EX-101 PRESENTATION LINKBASE DOCUMENT	

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1** *Interim Condensed Financial Statements (unaudited)*  
**ALIMERA SCIENCES, INC.****BALANCE SHEETS**

	<b>March 31, 2012</b>	<b>December 31, 2011</b>
	<b>(In thousands, except share and per share data)</b>	
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 27,625	\$ 33,108
Investments in marketable securities		500
Prepaid expenses and other current assets	742	692
Deferred financing costs	172	201
Total current assets	28,539	34,501
<b>PROPERTY AND EQUIPMENT</b> at cost less accumulated depreciation	171	197
<b>TOTAL ASSETS</b>	<b>\$ 28,710</b>	<b>\$ 34,698</b>
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 1,656	\$ 1,948
Accrued expenses (Note 4)	894	1,638
Outsourced services payable	229	658
Notes payable (Note 6)	2,462	2,462
Capital lease obligations	12	12
Total current liabilities	5,253	6,718
<b>LONG-TERM LIABILITIES:</b>		
Notes payable, net of discount less current portion (Note 6)	2,332	2,868
Other long-term liabilities	156	134
<b>COMMITMENTS AND CONTIGENCIES</b>		
<b>STOCKHOLDERS EQUITY:</b>		
Preferred stock, \$.01 par value 10,000,000 shares authorized and no shares issued and outstanding at March 31, 2012 and at December 31, 2011		
Common stock, \$.01 par value 100,000,000 shares authorized and 31,427,355 shares issued and outstanding at March 31, 2012 and at December 31, 2011	314	314
Additional paid-in capital	235,971	235,619
Common stock warrants	415	415
Accumulated deficit	(215,731)	(211,370)
<b>TOTAL STOCKHOLDERS EQUITY</b>	<b>20,969</b>	<b>24,978</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS EQUITY</b>	<b>\$ 28,710</b>	<b>\$ 34,698</b>

See Notes to Financial Statements.



**Table of Contents****ALIMERA SCIENCES, INC.****STATEMENTS OF OPERATIONS**

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(In thousands, except share and</b>	
	<b>per share data)</b>	
RESEARCH AND DEVELOPMENT EXPENSES	\$ 1,581	\$ 1,757
GENERAL AND ADMINISTRATIVE EXPENSES	1,434	1,540
MARKETING EXPENSES	1,113	1,117
 TOTAL OPERATING EXPENSES	 4,128	 4,414
INTEREST INCOME	1	12
INTEREST EXPENSE	(234)	(295)
 NET LOSS	 \$ (4,361)	 \$ (4,697)
 NET LOSS PER SHARE Basic and diluted	 \$ (0.14)	 \$ (0.15)
 WEIGHTED-AVERAGE SHARES OUTSTANDING Basic and diluted	 31,427,355	 31,277,697

See Notes to Financial Statements.

**Table of Contents****ALIMERA SCIENCES, INC.****STATEMENTS OF CASH FLOWS**

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(In thousands)</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,361)	\$ (4,697)
Depreciation and amortization	26	44
Stock compensation expense	352	438
Amortization of deferred financing costs and debt discount	61	114
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(50)	232
Accounts payable	(292)	336
Accrued expenses and other current liabilities	(1,173)	(1,457)
Other long-term liabilities	25	
<b>Net cash used in operating activities</b>	<b>(5,412)</b>	<b>(4,990)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Proceeds from maturities of investments	500	25,827
Purchases of property and equipment		(4)
<b>Net cash provided by investing activities</b>	<b>500</b>	<b>25,823</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercises of stock options		113
Payment of principal on note payable	(568)	
Payments on capital lease obligations	(3)	(3)
<b>Net cash (used in) provided by financing activities</b>	<b>(571)</b>	<b>110</b>
<b>NET (DECREASE) INCREASE IN CASH</b>	<b>(5,483)</b>	<b>20,943</b>
CASH Beginning of period	33,108	28,514
CASH End of period	\$ 27,625	\$ 49,457
<b>SUPPLEMENTAL DISCLOSURES</b>		
Cash paid for interest	\$ 154	\$ 143

There were no income tax or dividend payments made for the three months ended March 31, 2012 and 2011.

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 has received marketing authorization in the United Kingdom and Austria, and has been recommended for marketing authorization in France, Germany, Italy, Portugal 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 which 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>®</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 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 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 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 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. 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. In the second quarter of 2012, ILUVIEN received marketing authorization in Austria and the United Kingdom for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies.

**2. Basis of Presentation**

The Company has prepared the accompanying unaudited interim 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 financial statements reflect all adjustments, which include normal recurring adjustments, necessary to present fairly the Company's interim financial information.

The accompanying unaudited interim 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



## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

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.

---

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

*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 will have 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 \$215,731,000 from the Company's inception through March 31, 2012. As of March 31, 2012, the Company had approximately \$27,625,000 in cash and cash equivalents. In October 2010, the Company obtained a \$32,500,000 senior secured credit facility (Credit Facility) to help fund its working capital requirements (Note 6). 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.

Management believes it has sufficient funds available to fund its operations through the projected commercialization of ILUVIEN in the EU countries in which ILUVIEN has received, or has been recommended for, marketing authorization 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 these EU countries, 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 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 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 FINANCIAL STATEMENTS (Continued)****4. Accrued Expenses**

Accrued expenses consisted of the following:

	March 31, 2012	December 31, 2011
	(In thousands)	
Accrued clinical investigator expenses	\$ 635	\$ 788
Accrued severance expenses (1)		206
Accrued other compensation expenses	221	621
Other accrued expenses	38	23
<b>Total accrued expenses</b>	<b>\$ 894</b>	<b>\$ 1,638</b>

- (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 three months ended March 31, 2012.

**5. 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 (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.

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**NOTES TO 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 March 31, 2012 and December 31, 2011, pSivida owed the Company \$4,364,000 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 financial statements.

**6. 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 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 3.0% of the total amount of principal then outstanding if the prepayment occurs between one year and two years after the funding date of Term Loan A (Term Loan A Funding Date), 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.

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

On the Effective Date, the Company issued to the Lenders warrants to purchase an aggregate of up to 39,773 shares of the Company's common stock. Each of the warrants is exercisable immediately, has a per-share exercise price of \$11.00 and has a term of 10 years. The Company estimated the fair value of warrants granted using the Black-Scholes option pricing model. The aggregate fair value of the warrants was estimated to be \$389,000. The Company allocated a portion of the proceeds from the Term Loan Agreement to the warrants in accordance with ASC 470-20-25-2, Debt Instruments with Detachable Warrants. As a result, the Company recorded a discount of \$366,000 which is being amortized to interest expense using the effective interest method. The Lenders will have certain registration rights with respect to the shares of common stock issuable upon exercise of all of their warrants. The Company paid to the Lenders an upfront fee of \$62,500 on the Effective Date and an additional fee of \$50,000 in connection with the Term Loan Modification. In accordance with ASC 470-50-40-17, Debt Modifications and Extinguishments, the Company is amortizing the unamortized discount on Term Loan A and the \$50,000 modification fee over the remaining term of Term Loan A, as modified. The Lenders also hold warrants to purchase an aggregate of up to 69,999 shares of the Company's common stock, which were exercisable only if Term Loan B had been advanced to the Company. Each of these warrants has a per share exercise price of \$11.00 and a term of 10 years. In addition, the Lenders would have had certain registration rights with respect to the shares of common stock issuable upon exercise of all of their warrants.

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

On February 6, 2012, the Company received a letter from the Lenders stating that they reserve the right to assert that 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 March 31, 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.



**Table of Contents****ALIMERA SCIENCES, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****7. 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:

	Three Months Ended March 31,	
	2012	2011
Common stock warrants	2,782	30,615
Stock options	619,000	1,632,683
	621,782	1,663,298

**8. Stock Options**

During the three months ended March 31, 2012 and 2011, the Company recorded compensation expense related to stock options of approximately \$341,000 and \$415,000, respectively. As of March 31, 2012, the total unrecognized compensation cost related to non-vested stock options granted was \$3,320,000 and is expected to be recognized over a weighted average period of 2.6 years. The following table presents a summary of stock option transactions for the three months ended March 31, 2012 and 2011:

	Three Months Ended March 31,			
	2012	Weighted Average Exercise Price	2011	Weighted Average Exercise Price
Options at beginning of period	Options 2,607,446	\$ 3.88	Options 2,741,985	\$ 3.81
Grants	1,075,000	1.66		
Forfeitures	(36,927)	8.67		
Exercises			(77,530)	1.45
Options at end of period	3,645,519	3.17	2,664,455	3.87

The following table provides additional information as of March 31, 2012:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value (In thousands)
Outstanding	3,645,519	\$ 3.17	7.04 years	\$ 4,686



Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

Exercisable	2,127,492	2.75	5.36 years	2,840
Expected to vest	1,139,317	4.23	9.29 years	1,252

**Table of Contents****ALIMERA SCIENCES, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

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	\$
Exercisable	2,058,585	2.74	5.54 years	
Expected to vest	532,303	8.28	8.42 years	

*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 will vest upon the receipt of marketing authorization of ILUVIEN in four of the seven EU countries in which ILUVIEN was recommended for marketing authorization (Note 1). At March 31, 2012, there was \$145,000 of unrecorded compensation expense in connection with the Company's RSUs.

**9. Income Taxes**

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 March 31, 2012 and December 31, 2011, the Company had federal net operating loss (NOL) carry-forwards of approximately \$124,727,000 and \$120,353,000 and state NOL carry-forwards of approximately \$108,189,000 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. The Company periodically evaluates its NOL carry-forwards and whether certain changes in ownership, including its initial public offering (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

Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

(or comparable provisions of state law). The Company has not performed a formal analysis of its NOLs in connection with IRC Section 382.

**Table of Contents****ALIMERA SCIENCES, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****10. Fair Value**

The Company adopted 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 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	March 31, 2012		Total
		Level 2	Level 3	
(In thousands)				
Cash equivalents(1)	\$ 26,941	\$	\$	\$ 26,941
Assets measured at fair value	\$ 26,941	\$	\$	\$ 26,941
	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. Pricing sources include industry standard data providers, security master files from large financial institutions, and other third party

## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

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**

**PART I. FINANCIAL INFORMATION**

**ITEM 2 *Management's Discussion and Analysis of Financial Condition and Results of Operations***  
**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND PROJECTIONS**

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

delay in or failure to obtain regulatory approval of the Company's product candidates;

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

the extent of government regulations;

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

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

dependence on third-party manufacturers to manufacture the Company's product candidates in sufficient quantities and quality;

uncertainty of clinical trial results;

limited sales and marketing infrastructure;

inability of the Company to successfully market and sell ILUVIEN following regulatory approval; and

the Company's ability to operate its business in compliance with the covenants and restrictions that it is subject to under its credit facility.

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

We encourage you to read the discussion and analysis of our financial condition and our unaudited consolidated financial statements contained in this report. We also encourage you to read Item 1A of Part II of this report entitled "Risk Factors" and Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of this report, other unknown or unpredictable factors also could affect our results. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

---

## **Table of Contents**

### **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<sup>®</sup>, which has received marketing authorization in the United Kingdom and Austria, and has been recommended for marketing authorization in France, Germany, Italy, Portugal 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.

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>™</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 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. The FDA has indicated that we will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. We expect to meet with the FDA in the second quarter of 2012 to discuss the CRL and the regulatory status of ILUVIEN.

After meetings and discussions with the MHRA, we finalized and submitted our response to the PAR to the MHRA in November 2011. In February 2012, we received a Final Assessment Report (FAR) from the 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 patients with chronic DME. In the second quarter of 2012, ILUVIEN received marketing authorization in Austria and the United Kingdom for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies.

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 March 31, 2012, we have accumulated a deficit of \$215.7 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

complete the clinical development and registration of ILUVIEN;

prepare for the anticipated commercial launch of ILUVIEN in the EU in late 2012, at the earliest;



## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

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.

---

## **Table of Contents**

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 March 31, 2012, we had approximately \$27.6 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.

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

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.

## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

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.

---

## **Table of Contents**

### **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 3.0% of the total amount of principal then outstanding if the prepayment occurs between one year and two years after the funding date of Term Loan A (Term Loan A Funding Date) and 1.0% of such amount if the prepayment occurs thereafter (subject to a 50% reduction in the event that the prepayment occurs in connection with an acquisition of us).

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

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

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

On February 6, 2012, we received a letter from the Lenders stating that they reserve the right to assert that 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 March 31, 2012 and December 31, 2011, respectively, no amounts under the Working

## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

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 fee will be reduced by 50% in the event such termination is in connection with an acquisition of us.

## **Table of Contents**

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.

## **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, the anticipated EU commercial launch of ILUVIEN in late 2012, at the earliest, 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.

## **Table of Contents**

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

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

the number of sites included in the trials;

the length of time required to enroll eligible patients;

the number of patients that participate in the trials;

the number of doses that patients receive;

the drop-out or discontinuation rates of patients;

the duration of patient follow-up;

the phase of development the product candidate is in; and

the efficacy and safety profile of the product candidate.

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

Our most advanced product candidate is ILUVIEN, which has received marketing authorization in the United Kingdom and Austria, and has been recommended for marketing authorization in France, Germany, Italy, Portugal and Spain, for the treatment of vision impairment associated with 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 regulatory 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



## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

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

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

## **Table of Contents**

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

In preparation for a potential U.S. commercial launch of ILUVIEN, we began recruiting sales and marketing infrastructure personnel with extensive ophthalmic-based sales experience in the fourth quarter of 2010. We hired our marketing and managed markets directors, three sales directors and our four field-based managed markets managers but did not add the personnel and incur the costs of hiring and training an internal sales force. We entered into a relationship with OnCall LLC, a contract sales force company, and would have utilized their employees to act as our sales representatives if we had received approval of the ILUVIEN NDA from the FDA. Due to the receipt of the second CRL, we have eliminated our sales management team and field-based managed markets managers at this time. We incurred \$401,000 of personnel and severance costs related to this 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 three months ended March 31, 2012.

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

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

### ***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 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 621,782 and 1,663,298 for the three months ended March 31, 2012 and 2011, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods of net loss because of their anti-dilutive effect. Therefore, for the three months ended March 31, 2012 and 2011, respectively, the weighted average shares used to calculate both basic and diluted loss per share are the same.

### ***Critical Accounting Policies and Estimates***

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

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

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

costs that will be subject to estimation.

***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.

**Table of Contents*****Stock-Based Compensation***

Effective January 1, 2005, we adopted the fair value recognition provisions of ASC 718, *Compensation - Stock Compensation*, using the modified prospective application method. We recognize the grant date fair value as compensation cost of employee stock-based awards using the straight-line method over the actual vesting period, adjusted for our estimates of forfeiture. Typically, we grant stock options with a requisite service period of four years from the grant date. We have elected to use the Black-Scholes option pricing model to determine the fair value of stock-based awards.

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

Our determination of the fair market value of share-based payment awards on the grant date using option valuation models requires the input of highly subjective assumptions, including the expected price volatility and option life. For the calculation of expected volatility, because we lack significant company-specific historical and implied volatility information, we estimate our volatility by utilizing an average of volatilities of publicly traded companies, including our own, deemed similar to us in terms of product composition, stage of lifecycle, capitalization and scope of operations. We intend to continue to consistently apply this process using this same index until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

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

Total stock-based compensation expense related to all our stock option awards for the three months ended March 31, 2012 and 2011, respectively, was comprised of the following:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(Unaudited)</b>	
	<b>(In thousands)</b>	
Marketing	\$ 58	\$ 97
Research and development	95	101
General and administrative	188	217
Total employee stock-based compensation expense related to stock option awards	\$ 341	\$ 415

***Restricted Stock Units***

In February 2012, we awarded 85,447 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 will vest upon the receipt of marketing approval of ILUVIEN in four of the seven EU countries in which ILUVIEN was recommended for marketing authorization. At March 31, 2012, there was \$145,000 of unrecorded compensation expense in connection with our 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 its assets and liabilities in accordance with ASC 740, *Income Taxes*. We evaluate the positive and negative evidence bearing upon the realizability of our deferred tax assets on an annual basis. Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of our deferred tax assets due to our history of operating losses, a valuation allowance has been established against our deferred tax asset balances to reduce the net carrying value to an amount that is more likely than not to be realized. As a result we have fully reserved against the deferred tax asset balances. The valuation allowances are based on our estimates of taxable income in the jurisdictions in which we operate and the period over which deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact our financial position and results of operations. Our deferred tax assets primarily consist of net operating loss (NOL) carry-forwards. At March 31, 2012 we had federal NOL carry-forwards of approximately \$124.7 million and state NOL carry-forwards of approximately \$108.2 million, respectively, that are available to reduce future income otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2023 and 2031 and the state NOL carry-forwards will expire at various dates between 2020 and 2031. We periodically evaluate our NOL carry-forwards and whether certain changes in ownership, including our IPO, have occurred that would limit our ability to utilize a portion of our NOL carry-forwards. If it is determined that significant ownership changes have occurred since these NOLs were generated, we may be subject to annual limitations on the use of these NOLs under Internal Revenue Code (IRC) Section 382 (or comparable provisions of state law). We have not performed a formal analysis of our NOLs in connection with IRC Section 382.

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

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

**Results of Operations**

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(Unaudited)</b>	
	<b>(In thousands)</b>	
RESEARCH AND DEVELOPMENT EXPENSES	\$ 1,581	\$ 1,757
GENERAL AND ADMINISTRATIVE EXPENSES	1,434	1,540
MARKETING EXPENSES	1,113	1,117
TOTAL OPERATING EXPENSES	4,128	4,414
INTEREST AND OTHER INCOME	1	12
INTEREST EXPENSE	(234)	(295)
NET LOSS	\$ (4,361)	\$ (4,697)

**Three months ended March 31, 2012 compared to the three months ended March 31, 2011**

*Research and development expenses.* Research and development expenses decreased by approximately \$200,000, or 11.1%, to approximately \$1.6 million for the three months ended March 31, 2012 compared to approximately \$1.8 million for the three months ended March 31, 2011.

## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

The decrease was primarily attributable to decreases of \$380,000 in costs associated with our FAME Study completed in 2011, \$220,000 in costs associated with contracting medical science liaisons to engage with retina specialists in the study of ILUVIEN which was terminated in the fourth quarter of 2011 and \$140,000 in costs for technical development as we approached the final stages of the development of the inserter for ILUVIEN, offset by increases of \$380,000 in costs related to a consultant engaged to assist with the continued pursuit of approval of ILUVIEN in the U.S. and \$210,000 in costs related to the physician utilization study which is being conducted to assess the safety and utility of the commercial version of the inserter for ILUVIEN.

---

## **Table of Contents**

*General and administrative expenses.* General and administrative expenses decreased by approximately \$100,000 or 6.7%, to approximately \$1.4 million for the three months ended March 31, 2012 compared to approximately \$1.5 million for the three months ended March 31, 2011.

*Marketing expenses.* Marketing expenses were approximately \$1.1 million for the three months ended March 31, 2012 and 2011, respectively. We reduced our spending in the United States by approximately \$630,000 in comparison to the prior year due to the cancellation of the previously expected commercial launch of ILUVIEN in the U.S. during this first quarter, including approximately \$200,000 associated with our sales managers that were terminated in the fourth quarter of 2011. However, our marketing expenses remained relatively flat year over year as we increased our pre-launch activities in Europe.

*Interest expense.* Interest expense decreased by approximately \$70,000, or 23.3%, to approximately \$230,000 for the three months ended March 31, 2012 compared to approximately \$300,000 for the three months ended March 31, 2011. Interest expense for the three months ended March 31, 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.

### ***Liquidity and Capital Resources***

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of \$215.7 million from our inception through March 31, 2012. Prior to our IPO in April 2010, we funded our operations through the private placement of common stock, preferred 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 March 31, 2012, we had approximately \$27.6 million in cash and cash equivalents. We believe that we have sufficient funds available to fund our operations through the projected commercialization of ILUVIEN in the seven EU countries in which ILUVIEN has received, or has been recommended for, marketing authorization and the expected generation of revenue in late 2012, at the earliest, if at all, and therefore do not expect to have cash flow from operations until 2013, if at all. In these EU countries, we plan to commercialize ILUVIEN directly or with a partner. If we choose to commercialize ILUVIEN directly, we will need to raise additional capital in the future to continue to fund our operations beyond commercialization. Even if we raise additional capital, the commercialization of ILUVIEN, directly or with a partner, is dependent upon numerous factors and we cannot be sure that future sales of ILUVIEN will generate enough revenue to fund the Company's operations beyond the initial commercialization. Due to the uncertainty around the commercial launch of ILUVIEN, management cannot be certain that we will not need additional funds for its commercialization. If ILUVIEN is not approved 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 three months ended March 31, 2012, cash used in our operations of \$5.4 million was primarily due to our net loss of \$4.4 million offset by non-cash stock-based compensation and other expense of \$350,000. Further increasing our cash used in operations was a net 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 \$50,000. Accounts payable, accrued expenses and other current liabilities decreased primarily due to decreases of \$540,000 for a termination payment to the administrator of our U.S. reimbursement and patient assistance programs, \$430,000 in amounts payable to our CROs, \$330,000 of 2011 employee bonus payments made in the first quarter of 2012, \$210,000 in severance payments associated with our fourth quarter reduction in force and \$150,000 in amounts payable to the investigators of our clinical studies, offset by an increase of \$170,000 in amounts payable to vendors performing pharmacoeconomic studies to evaluate the pricing of ILUVIEN in the EU.

For the three months ended March 31, 2011, cash used in our operations of \$5.0 million was primarily due to our net loss of \$4.7 million offset by non-cash stock-based compensation and other expense of \$440,000. Further increasing our cash used in operations was a net decrease in accounts payable, accrued expenses and other current liabilities of \$1.1 million, offset by a decrease in prepaid expenses and other current assets of \$230,000. Accounts payable, accrued expenses and other current liabilities decreased primarily due to net decreases of \$620,000 of amounts paid to providers of advertising, corporate communications, and medical marketing services for pre-launch activities due to the postponement of

## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

the launch of ILUVIEN previously anticipated to occur in the first half of 2011, \$410,000 of amounts paid to investigators in our FAME Study, and \$280,000 of accrued compensation that was paid in the first quarter of 2011. Prepaid and other current assets decreased primarily due to the collection of interest receivable on a portion of our investment portfolio that matured during the three months ended March 31, 2011.



## **Table of Contents**

For the three months ended March 31, 2012, net cash provided by our investing activities was \$500,000, which was due to the maturities of investments. For the three months ended March 31, 2011, net cash provided by our investing activities was \$25.8 million, which was due to the maturities of investments.

For the three months ended March 31, 2012, net cash used in our financing activities was \$570,000, which was primarily due to payments of principal on our notes payable to Silicon Valley Bank and MidCap Financial LLP. For the three months ended March 31, 2011, net cash provided by our financing activities was \$110,000, which was primarily due to proceeds from the exercise of stock options.

### ***Contractual Obligations and Commitments***

In connection with our efforts to obtain the approval of ILUVIEN from the FDA, in February 2012, we engaged a consultant for services related to the continued pursuit of approval of ILUVIEN in the U.S. During the three months ended March 31, 2012, we recorded charges of \$375,000 pertaining to consulting fees related to our agreement with this consultant. We expect to record an additional \$875,000 in charges in connection with this agreement during the six months ended September 30, 2011.

In March 2012, we entered into a Manufacturing Services Agreement with Flextronics Medical Sales and Marketing, Ltd. (Flextronics). Under the agreement, Flextronics will manufacture, at its location in Tijuana, Mexico, our proprietary inserter system for use with ILUVIEN. Under the agreement, we will pay certain per product unit prices based on regularly scheduled shipments of a minimum number of product units. The initial term of the agreement expires on February 24, 2015. After the expiration of the initial term, the agreement will automatically renew for separate but successive one-year terms unless either party provides written notice to the other party that it does not intend to renew the agreement at least eighteen (18) months prior to the end of the term. The agreement may be terminated by either party under certain circumstances.

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 30, 2012.

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

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

### ***New Accounting Pronouncements***

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

## **Table of Contents**

### **ITEM 3 *Qualitative and Quantitative Disclosures about Market Risk***

We are exposed to market risk related to changes in interest rates. As of March 31, 2012, we had approximately \$27.6 million in cash and cash equivalents. Our interest income is exposed to market risk primarily due to changes in the general level of U.S. interest rates. Due to the highly liquid nature of our cash equivalents and their low risk profile, an immediate 10% change in interest rates would not have a material effect on the fair market value of our cash equivalents. 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 cash equivalents.

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 March 31, 2012, we have not borrowed any funds available under the revolving loan agreement.

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

### **ITEM 4 *Controls and Procedures***

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2012. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2012, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### **Changes in Internal Control over Financial Reporting**

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the three months ended March 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1 *Legal Proceedings***

We are not party to any material pending legal proceedings and management is not aware of any contemplated proceedings by and governmental authority against us.

**ITEM 1A *Risk Factors***

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, filed with the SEC on March 30, 2012, we identify under Item 1A of Part I important factors which could affect our business, financial condition, results of operations and future operations and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Form 10-Q. There have been no material changes in our risk factors subsequent to the filing of our Form 10-K for the fiscal year ended December 31, 2011. However, the risks described in our Form 10-K are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

**ITEM 2 *Unregistered Sales of Equity Securities and Use of Proceeds***

None.

**ITEM 3 *Defaults Upon Senior Securities***

None.

**ITEM 4 *Mine Safety Disclosures***

Not applicable.

**ITEM 5 *Other Information***

None.

**ITEM 6 *Exhibits***

<b>Exhibit Number</b>	<b>Description</b>
10.35*	Manufacturing Services Agreement by and between the Registrant and Flextronics Medical Sales and Marketing, Ltd.
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.

## Edgar Filing: ALIMERA SCIENCES INC - Form 10-Q

\* Confidential treatment has been requested with respect to certain portions of this document.

The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Alimera Sciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Alimera Sciences, Inc.

/s/ C. Daniel Myers

**C. Daniel Myers**  
**Chief Executive Officer and President**

**(Principal executive officer)**

May 11, 2012

/s/ Richard S. Eiswirth, Jr.

**Richard S. Eiswirth, Jr.**  
**Chief Operating Officer and Chief Financial Officer**

**(Principal financial and accounting officer)**

May 11, 2012

**Table of Contents**

**ALIMERA SCIENCES, INC.**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
10.35*	Manufacturing Services Agreement by and between the Registrant and Flextronics Medical Sales and Marketing, Ltd.
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Acting Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.

\* Confidential treatment has been requested with respect to certain portions of this document.

The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Alimera Sciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.