ALIMERA SCIENCES INC
Form 10-Q
August 14, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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)

Delaware	**20-0028718**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

6120 Windward Parkway, Suite 290

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

(678) 990-5740

(Registrant s telephone number, including area code)

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

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

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

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

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

As of August 8, 2012, there were 31,432,355 shares of the registrant s common stock issued and outstanding.

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ALIMERA SCIENCES, INC.

QUARTERLY REPORT ON FORM 10-Q

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PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

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PART I. FINANCIAL INFORMATION

ITEM 1 *Interim Condensed Consolidated Financial Statements (unaudited)*

ALIMERA SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS

	June 30, 2012	December 31, 2011
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 22,291	$ 33,108
Investments in marketable securities		500
Prepaid expenses and other current assets	938	692
Inventory (Note 4)	206	
Deferred financing costs	145	201
Total current assets	23,580	34,501
PROPERTY AND EQUIPMENT at cost less accumulated depreciation	155	197
TOTAL ASSETS	$ 23,735	$ 34,698
CURRENT LIABILITIES:		
Accounts payable	$ 1,279	$ 1,948
Accrued expenses (Note 5)	1,147	1,638
Outsourced services payable	131	658
Notes payable (Note 7)	2,348	2,462
Capital lease obligations	12	12
Total current liabilities	4,917	6,718
LONG-TERM LIABILITIES:		
Notes payable, net of discount less current portion (Note 7)	1,793	2,868
Other long-term liabilities	174	134
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
Preferred stock, $.01 par value 10,000,000 shares authorized and no shares issued and outstanding at June 30, 2012 and at December 31, 2011 (Note 12)		
Common stock, $.01 par value 100,000,000 shares authorized and 31,432,355 shares issued and outstanding at June 30, 2012 and 100,000,000 shares authorized and 31,427,355 shares issued and outstanding at December 31, 2011	314	314
Additional paid-in capital	236,555	235,619
Common stock warrants	415	415
Accumulated deficit	(220,433)	(211,370)
TOTAL STOCKHOLDERS EQUITY	16,851	24,978
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 23,735	$ 34,698

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
	(In thousands, except share and per share data)			
RESEARCH AND DEVELOPMENT EXPENSES	$ 1,856	$ 1,751	$ 3,437	$ 3,508
GENERAL AND ADMINISTRATIVE EXPENSES	1,548	1,866	2,982	3,406
MARKETING EXPENSES	1,088	1,309	2,201	2,426
OPERATING EXPENSES	4,492	4,926	8,620	9,340
INTEREST INCOME	1	2	2	14
INTEREST EXPENSE	(211)	(284)	(445)	(579)
NET LOSS	$ (4,702)	$ (5,208)	$ (9,063)	$ (9,905)
NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS Basic and diluted	$ (0.15)	$ (0.17)	$ (0.29)	$ (0.32)
WEIGHTED-AVERAGE SHARES OUTSTANDING Basic and diluted	31,430,651	31,354,243	31,429,003	31,316,181

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended June 30,	
	2012	2011
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,063)	$ (9,905)
Depreciation and amortization	53	79
Stock compensation expense	923	1,041
Amortization of deferred financing costs and debt discount	117	216
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(246)	124
Inventory	(206)	
Accounts payable	(669)	(246)
Accrued expenses and other current liabilities	(1,018)	(1,885)
Other long-term liabilities	46	
Net cash used in operating activities	(10,063)	(10,576)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from maturities of investments	500	25,828
Purchases of property and equipment	(11)	(80)
Net cash provided by investing activities	489	25,748
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercises of stock options		190
Payment of principal on note payable	(1,250)	
Proceeds from sale of common stock	13	111
Payment of debt modification costs		(50)
Payments on capital lease obligations	(6)	(5)
Net cash (used in) provided by financing activities	(1,243)	246
NET (DECREASE) INCREASE IN CASH	(10,817)	15,418
CASH Beginning of period	33,108	28,514
CASH End of period	$ 22,291	$ 43,932
SUPPLEMENTAL DISCLOSURES		
Cash paid for interest	$ 315	$ 325

There were no income tax or dividend payments made for the six months ended June 30, 2012 and 2011.

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations

Alimera Sciences, Inc. (the Company) is a biopharmaceutical company that specializes in the research, development and commercialization of ophthalmic pharmaceuticals. The Company was formed on June 4, 2003 under the laws of the State of Delaware.

The Company is presently focused on diseases affecting the back of the eye, or retina, because the Company s management believes these diseases are not well treated with current therapies and represent a significant market opportunity. The Company s most advanced product candidate is ILUVIEN ®, which has received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain, for the treatment of vision impairment associated with diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina 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™ 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 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 had indicated that the Company would need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. During the second quarter of 2012, the Company met with the FDA to gain a better understanding of the regulatory path for ILUVIEN in the U.S. Based upon this meeting, the Company plans to submit to the FDA a response to the second CRL to include additional analysis of the benefits and risks of ILUVIEN based upon clinical data available from the FAME Study.

After meetings and discussions with the MHRA, the Company finalized and submitted its response to the PAR to the MHRA in November 2011. In February 2012, the Company received a Final Assessment Report (FAR) from the MHRA indicating that the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain had reached a consensus that ILUVIEN was approvable and that the DCP was complete. Upon receipt of the FAR, the Company entered the national phase with each of these seven countries. 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. ILUVIEN has received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies.

The Company currently plans to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and is pursuing pricing and reimbursement in those countries. In July 2012, the Company received a letter from Germany s Federal Joint Committee indicating that the automatic obligation to submit a dossier on ILUVIEN, per the Arzneimittelmarkt-Neuordnungsgesetz law, would not be necessary, and that a benefit assessment would not be required. This allows the Company to launch ILUVIEN in Germany without price restriction. In August 2012, the Company received an appraisal consultation document from the United Kingdom s National Institute for Health and Clinical Excellence (NICE) with a preliminary recommendation that ILUVIEN is not recommended given the current cost of £5500 and other variables included in

the Company s submission to NICE. This document is not NICE s final guidance and the recommendation may change prior to NICE s final appraisal determination (FAD). The Company, along with NICE s consultants and the public, has the opportunity to provide further comments on the draft appraisal by the end of August in preparation for the second appraisal meeting in September 2012. The NICE FAD is not scheduled until November 2012.

In April 2012, the Company established a wholly-owned subsidiary in the United Kingdom, Alimera Sciences Ltd., to facilitate transacting business in the EU. Since its inception there have been no employees of Alimera Sciences, Ltd.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Basis of Presentation

The Company and its wholly-owned subsidiary have prepared the accompanying unaudited interim condensed consolidated financial statements and notes thereto in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and the instructions to Form 10-Q and Article 10-01 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary to present fairly the Company s interim financial information.

The accompanying unaudited interim condensed consolidated financial statements and related notes should be read in conjunction with the Company s audited financial statements for the year ended December 31, 2011 and related notes included in the Company s Annual Report on Form 10-K, which was filed with the SEC on March 30, 2012. The financial results for any interim period are not necessarily indicative of the expected financial results for the full year.

Recent Accounting Pronouncements In May 2011, the FASB amended the FASB Accounting Standards Codification to converge the fair value measurement guidance in U.S. GAAP and International Financial Reporting Standards. Some of the amendments clarify the application of existing fair value measurement requirements, while other amendments change particular principles in fair value measurement guidance. In addition, the amendments require additional fair value disclosures. The amendments are effective for fiscal years beginning after December 15, 2011 and should be applied prospectively. The Company does not believe the adoption of these amendments 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 $220,433,000 from the Company s inception through June 30, 2012. As of June 30, 2012, the Company had approximately $22,291,000 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 7). The Credit Facility consisted of a $20,000,000 working capital revolver and a $12,500,000 term loan. The lenders have advanced $6,250,000 under the term loan. In May 2011, the Credit Facility was amended to increase the term loan to $17,250,000, the remaining $11,000,000 of which would have been advanced following FDA approval of ILUVIEN, but no later than December 31, 2011. As a result of the issuance of the second CRL by the FDA in November 2011 regarding the NDA for ILUVIEN, the remaining $11,000,000 is no longer available to the Company. Additionally, the Company may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which the Company would not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to the Company. On February 6, 2012, the Company received a letter from the lenders stating that they reserve the right to assert that the occurrence of certain events, including the issuance of the second CRL and a decrease in the market value of the Company s public equity securities, may represent a material impairment of the value of the collateral under the loan agreements. To date, the lenders have not made such an assertion, and in the opinion of management a material impairment of the value of the collateral has not occurred.

On July 17, 2012, the Company entered into a securities purchase agreement (Purchase Agreement) with certain investors for a $40,000,000 Series A Convertible Preferred Stock (Series A Preferred) financing (Note 12). The Purchase Agreement provides for the sale of 1,000,000 shares of the Company s Series A Preferred and warrants to purchase an additional 300,000 shares of Series A Preferred. For each unit consisting of one share of Series A Preferred and a Warrant to purchase .30 of a Share of Series A Preferred, the Investors agreed to pay $40.00, resulting in gross proceeds to the Company of approximately $40,000,000, before deducting related expenses payable by the Company. The transaction is subject to the approval of a majority of the Company s common shareholders. In connection with the Purchase Agreement the Company obtained voting agreements from parties holding approximately 56% of the stock outstanding indicating that they would vote in favor of the transaction. The transaction is expected to close in September 2012.

The Company plans to proceed with the direct commercialization of ILUVIEN in Germany, the United Kingdom and France in 2013. The Company believes that, assuming the closing of the Series A Preferred financing, it will have sufficient funds available to fund its operations beyond the projected commercialization of ILUVIEN in these EU countries. The Company does not expect the generation of revenue until 2013,

and therefore does not expect to have cash flow from operations until 2014, if at all. If the Series A Preferred financing is not completed, or 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.

4. Inventory

Inventory is stated at the lower of cost or market (net realizable value). Inventory consisted of the following:

	June 30, 2012	December 31, 2011
	(In thousands)	
Finished goods	$	$
Component parts (1)	206	
Total inventory	$ 206	$

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(1) Component parts at June 30, 2012 consisted of manufactured components of the ILUVIEN inserter.

5. Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2012	December 31, 2011
	(In thousands)	
Accrued clinical investigator expenses	$ 565	$ 788
Accrued severance expenses (1)	33	206
Accrued other compensation expenses	531	621
Other accrued expenses	18	23
Total accrued expenses	$ 1,147	$ 1,638

(1) In connection with the FDA s CRL issued to the Company in November 2011 (Note 1), management and the board of directors of the Company approved a reduction in force pursuant to which the Company terminated the employment of 11 employees. The affected employees were notified in December 2011. The Company incurred $401,000 of severance expense in December 2011 in connection with the reduction in force of which $206,000 was payable at December 31, 2011. All amounts due at December 31, 2011 were paid to affected employees during the six months ended June 30, 2012. At June 30, 2012 there was $33,000 of accrued severance expenses attributable to the termination of the employment of one employee during the second quarter of 2012 and was unrelated to the reduction in force of December 2011.

6. pSivida Agreement

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

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 June 30, 2012 and December 31, 2011, pSivida owed the Company $4,634,000 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.

7. Term Loan and Working Capital Revolver

Term Loan

On October 14, 2010 (Effective Date), the Company entered into a Loan and Security Agreement (Term Loan Agreement) with Silicon Valley Bank and MidCap Financial LLP (Lenders). Pursuant to the original terms of the Term Loan Agreement, the Company was entitled to borrow up to $12.5 million, of which $6.25 million (Term Loan A) was advanced to the Company on the Effective Date. The Company was entitled to draw down the remaining $6.25 million under the Term Loan (Term Loan B and together with Term Loan A, the Term Loan) if the

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

FDA approved the Company s NDA for ILUVIEN prior to or on July 31, 2011. On May 16, 2011, the Company and the Lenders amended the Term Loan Agreement (Term Loan Modification) to, among other things, extend until December 31, 2011 the date by which the FDA must approve the NDA in order for the Company to draw down Term Loan B and increase the amount of Term Loan B by $4.75 million to $11.0 million. In addition, the maturity date of the Term Loan was extended from October 31, 2013 to April 30, 2014 (Term Loan Maturity Date). As a result of the issuance of the second CRL by the FDA in November 2011 (Note 1), the Company did not drawn down Term Loan B by December 31, 2011 and the availability to draw down Term Loan B expired.

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

If the Company repays Term Loan A prior to maturity, the Company must pay to the Lenders a prepayment fee equal to 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 and 1.0% of such amount if the prepayment occurs thereafter (subject to a 50% reduction in the event that the prepayment occurs in connection with an acquisition of the Company).

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

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

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

On February 6, 2012, the Company received a letter from the Lenders stating that they reserve the right to assert that 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 June 30, 2012 and December 31, 2011, respectively, no amounts under the Working Capital Revolver were outstanding or available to the Company. The Company may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which it does not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to the Company.

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

To secure the repayment of any amounts borrowed under the Revolving Loan Agreement, the Company granted to Silicon Valley Bank a first priority security interest in all of its assets, including its intellectual property, however, the lien on the Company s intellectual property will be released if the Company meets certain financial conditions. The occurrence of an event of default could result in the acceleration of the

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company s obligations under the Revolving Loan Agreement and an increase to the applicable interest rate, and would permit Silicon Valley Bank to exercise remedies with respect to the collateral under the Revolving Loan Agreement. The Company also agreed not to pledge or otherwise encumber its intellectual property assets. Additionally, the Company must seek Silicon Valley Bank s approval prior to the payment of any cash dividends to its stockholders.

8. Loss Per Share (EPS)

Basic EPS is calculated in accordance with ASC 260, *Earnings per Share,* by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated in accordance with ASC 260 by adjusting weighted average common shares outstanding for the dilutive effect of common stock options, warrants, convertible preferred stock and accrued but unpaid convertible preferred stock dividends. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive. Weighted average common stock equivalents that could potentially dilute basic EPS in the future were not included in the computation of diluted EPS because to do so would have been anti-dilutive were as follows:

	Three Months Ended June 30,		Six Months ended June 30,	
	2012	2011	2012	2011
Common stock warrants	4,236	29,393	3,598	30,009
Stock options	1,134,081	1,539,230	873,866	1,599,046
Total potentially dilutive securities	1,138,317	1,568,623	877,464	1,629,055

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Stock Options

During the three months ended June 30, 2012 and 2011, the Company recorded compensation expense related to stock options of approximately $453,000 and $584,000, respectively. During the six months ended June 30, 2012 and 2011, the Company recorded compensation expense related to stock options of approximately $794,000 and $999,000, respectively. As of June 30, 2012, the total unrecognized compensation cost related to non-vested stock options granted was $2,975,000 and is expected to be recognized over a weighted average period of 2.34 years. The following table presents a summary of stock option transactions for the three and six months ended June 30, 2012 and 2011:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2012		2011		2012		2011	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options at beginning of period	3,645,519	$ 3.17	2,664,455	$ 3.87	2,607,446	$ 3.88	2,741,985	$ 3.81
Grants	52,500	2.77	65,000	7.67	1,127,500	1.71	65,000	7.67
Forfeitures			(7,500)	11.00	(36,927)	8.67	(7,500)	11.00
Exercises			(44,481)	1.73			(122,011)	1.55
Options at end of period	3,698,019	3.17	2,677,474	3.98	3,698,019	3.17	2,677,474	3.98
Weighted average per share fair value of options granted during the period	$ 2.07		$ 5.47		$ 1.33		$ 5.47	

The following table provides additional information as of June 30, 2012:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value (In thousands)
Outstanding	3,698,019	$ 3.17	6.83 years	$ 3,560
Exercisable	2,285,662	2.85	5.39 years	2,216
Expected to vest	1,043,371	4.17	9.07 years	896

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

Per the terms of the Company s 2004 and 2005 Option Plans (Plans), the Company s Series A Preferred Stock financing (Note 12) would constitute a change of control for the purposes of Plan vesting and as a result all unvested options under the Plans would become vested. As of June 30, 2012 there were 96,639 unvested options and $251,000 of unrecognized compensation expense in connection with the 2004 and 2005 Plans.

Restricted Stock Units

In February 2012, the Company awarded 85,437 Restricted Stock Units (RSUs), to executive officers and employees at a grant date fair value of $1.70 per RSU. A RSU is a stock award that entitles the holder to receive shares of the Company s common stock as the award vests. The fair value of the RSUs was determined on the date of grant based on the closing price of the Company s common stock on the date of grant, which equals the RSU s intrinsic value. The RSUs were to vest upon the receipt of marketing authorization of ILUVIEN in four of the seven EU countries in which ILUVIEN is recommended for marketing authorization (Note 1). During the three and six months ended June 30, 2012, the

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company recognized $109,000 in compensation expense in connection with the RSUs. At June 30, 2012, there was $36,000 of unrecorded compensation expense in connection with the Company s RSUs. On July 18, 2012, France granted marketing authorization to ILUVIEN and, as a result, the RSUs became fully vested and the Company recorded $36,000 of compensation expense (Note 12).

10. 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 June 30, 2012 and December 31, 2011, the Company had federal net operating loss (NOL) carry-forwards of approximately $129,234,000 and $120,353,000 and state NOL carry-forwards of approximately $112,697,000 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 (or comparable provisions of state law). The Company has not performed a formal analysis of its NOLs in connection with IRC Section 382.

11. 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.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	June 30, 2012			
	Level 1	Level 2	Level 3	Total
		(In thousands)		
Cash equivalents (1)	$ 21,941	$	$	$ 21,941
Assets measured at fair value	$ 21,941	$	$	$ 21,941

	December 31, 2011			
	Level 1	Level 2	Level 3	Total
		(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 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.

12. Subsequent Events

Series A Convertible Preferred Stock Financing

On July 17, 2012, the Company entered into a securities purchase agreement (Purchase Agreement) with certain investors for a $40,000,000 Series A Convertible Preferred Stock (Series A Preferred Stock) financing (Financing). The Purchase Agreement provides for the sale of 1,000,000 shares of the Company s Series A Preferred Stock and warrants (each, a Warrant) to purchase an additional 300,000 shares of Series A Preferred Stock. For each unit consisting of one share of Series A Preferred Stock and a Warrant to purchase .30 shares of Series A Preferred Stock, the investors agreed to pay $40.00 (Original Purchase Price), which is expected to result in gross proceeds to the Company of $40,000,000, before deducting expenses payable by the Company. The Financing is subject to the approval of the holders of a majority of the Company s outstanding common stock, as well as other customary closing conditions. In connection with the Purchase Agreement, stockholders holding approximately 56% of the Company s common stock outstanding as of July 17, 2012 entered into separate agreements with the Company pursuant to which they agreed to vote in favor of the Financing. As a result, the Company and the investors expect the Financing will be approved by the Company s stockholders and will close during the third quarter of 2012.

Each share of Series A Preferred Stock will be initially convertible into approximately 13.75 shares of the Company s common stock based on an initial conversion price of $2.91 per share (Conversion Price). The Conversion Price will be subject to standard broad-based weighted average anti-dilution adjustments prior to the date on which the Company has received and publicly announces the approval by the FDA of the NDA for ILUVIEN (FDA Approval Date), provided that in no event shall the Conversion Price be adjusted below $1.00 (as adjusted for stock dividends, splits, combinations and similar events). The Original Purchase Price and the Conversion Price will be subject to adjustments for stock dividends, splits, combinations and similar events. The Warrants will be exercisable upon issuance at an exercise price of $44.00 per share of

Series A Preferred Stock, provided, however, that the Warrants may be exercised, at the option of the holders, directly for the common stock that would otherwise then be issuable upon conversion of the Series A Preferred Stock covered by such Warrants.

The Series A Preferred Stock will be entitled to receive dividends and other distributions pro rata with the common stock. Each share of Series A Preferred Stock will automatically convert into common stock at the then applicable Conversion Rate, equal to the Original Purchase Price divided by the then applicable Conversion Price, upon the occurrence of both (i) the FDA Approval Date and (ii) the date on which the Company consummates an equity financing transaction pursuant to which it sells to one or more third party investors either (A) common stock or (B) other equity securities that are convertible into common stock and that have rights, preferences or privileges senior to or on parity with the Series A Preferred Stock, in each case having an as-converted to common stock price of not less than $10.00 per share (as adjusted for stock dividends, splits, combinations and similar events) and that results in gross proceeds to the Company of at least $30,000,000. The Series A Preferred Stock will not be redeemable and will not be convertible at the option of the Company.

Marketing Authorization

In July 2012, France and Germany granted ILUVIEN marketing authorization for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies.

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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, contemplates project, target, likely, potential, continue, will, would, should, could, or the negative of these terms and similar expressions or w forward-looking statements. The events and circumstances reflected in the Company s forward-looking statements may not occur and actual results could differ materially from those projected in the Company s forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to:

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

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

We encourage you to read the discussion and analysis of our financial condition and our 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.

Overview

We are a biopharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. We are presently focused on diseases affecting the back of the eye, or retina, because we believe these diseases are not well treated with current therapies and represent a significant market opportunity.

Our most advanced product candidate is ILUVIEN®, which has received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain, for the treatment of vision impairment associated with diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness.

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

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analysis of the data from our two Phase 3 pivotal clinical trials (collectively, the FAME TM Study) through its final readout at month 36, we determined that a pre-planned subgroup of chronic DME patients demonstrated a greater benefit to risk profile than the full population dataset in our original filings.

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

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

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. ILUVIEN has received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies.

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

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 June 30, 2012, we have accumulated a deficit of $220.4 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

- complete the clinical development and registration of ILUVIEN;
- prepare for the anticipated commercial launch of ILUVIEN in the EU in early 2013, at the earliest;
- continue to seek regulatory approval of ILUVIEN in the U.S. and other jurisdictions;
- evaluate the use of ILUVIEN for the treatment of other diseases; and

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

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

As of June 30, 2012, we had approximately $22.3 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 the they reserve the right to assert that recent events, including the issuance of the second CRL and a decrease in the market value of our public equity securities, may represent a material impairment of the value of the collateral under the loan agreements. To date, the lenders have not made such an assertion, and in our opinion a material impairment of the value of the collateral has not occurred.

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On July 17, 2012, we entered into a securities purchase agreement (Purchase Agreement) with certain investors, for a $40.0 million Series A Convertible Preferred Stock (Series A Preferred Stock) financing (Financing). The Purchase Agreement provides for the sale of 1,000,000 shares of our Series A Preferred Stock and warrants (each, a Warrant) to purchase an additional 300,000 shares of Series A Preferred Stock. For each unit consisting of one share of Series A Preferred Stock and a Warrant to purchase .30 shares of Series A Preferred Stock, the investors agreed to pay $40.00 (Original Purchase Price), which is expected to result in gross proceeds to us of $40.0 million, before deducting expenses payable by us. The Financing is subject to the approval of the holders of a majority of our outstanding common stock, as well as other customary closing conditions. In connection with the Purchase Agreement, stockholders holding approximately 56% of our common stock outstanding as of July 17, 2012 entered into separate agreements with us pursuant to which they agreed to vote in favor of the Financing. As a result, the investors and we expect the Financing will be approved by our stockholders and will close during the third quarter of 2012.

Each share of Series A Preferred Stock will be initially convertible into approximately 13.75 shares of our common stock, based on an initial conversion price of $2.91 per share (Conversion Price). The Conversion Price will be subject to standard broad-based weighted average anti-dilution adjustments prior to the date on which we have received and publicly announce the approval by the FDA of the NDA for ILUVIEN (FDA Approval Date), provided, that in no event shall the Conversion Price be adjusted below $1.00 (as adjusted for stock dividends, splits, combinations and similar events). The Original Purchase Price and the Conversion Price will be subject to adjustments for stock dividends, splits, combinations and similar events. The Warrants will be exercisable upon issuance at an exercise price of $44.00 per share of Series A Preferred Stock, provided, however, that the Warrants may be exercised, at the option of the holders, directly for the common stock that would otherwise then be issuable upon conversion of the Series A Preferred Stock covered by such Warrants.

The Series A Preferred Stock will be entitled to receive dividends and other distributions pro rata with the common stock. Each share of Series A Preferred Stock will automatically convert into common stock at the then applicable Conversion Rate, equal to the Original Purchase Price divided by the then applicable Conversion Price, upon the occurrence of both (i) the FDA Approval Date and (ii) the date on which we consummate an equity financing transaction pursuant to which we sell to one or more third party investors either (A) common stock or (B) other equity securities that are convertible into common stock and that have rights, preferences or privileges senior to or on parity with the Series A Preferred Stock, in each case having an as-converted to common stock price of not less than $10.00 per share (as adjusted for stock dividends, splits, combinations and similar events) and that results in gross proceeds to us of at least $30.0 million. The Series A Preferred Stock will not be redeemable and will not be convertible at our option.

We plan to proceed with the direct commercialization of ILUVIEN in the United Kingdom, France and Germany in 2013. We believe that, assuming the closing of the Financing, we will have sufficient funds available to fund our operations beyond the projected commercialization of ILUVIEN in these EU countries. We do not expect the generation of revenue until 2013, and therefore does not expect to have cash flow from operations until 2014, if at all. 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 April 2012, we established a wholly-owned subsidiary in the United Kingdom, Alimera Sciences Ltd., to facilitate transacting business in the EU. Since its inception there have been no employees of Alimera Sciences, Ltd.

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.

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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.

Our Credit Facility

Term Loan Agreement

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

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

If we repay Term Loan A prior to maturity, we must pay to the Lenders a prepayment fee equal to 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 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.

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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 June 30, 2012 and December 31, 2011, respectively, no amounts under the Working Capital Revolver were outstanding or available to us. We may only draw on the revolving line of credit against eligible U.S. domestic accounts receivable, which we do not expect to have prior to the launch of ILUVIEN in the U.S. Therefore, the revolving line of credit, which expires in April 2014, is not currently, and may never be, available to us.

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

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

Series A Preferred Financing

On July 17, 2012, we entered into a securities purchase agreement (Purchase Agreement) with certain investors, for a $40.0 million Series A Convertible Preferred Stock (Series A Preferred Stock) financing (Financing). The Purchase Agreement provides for the sale of 1,000,000 shares of our Series A Preferred Stock and warrants (each, a Warrant) to purchase an additional 300,000 shares of Series A Preferred Stock. For each unit consisting of one share of Series A Preferred Stock and a Warrant to purchase .30 shares of Series A Preferred Stock, the investors agreed to pay $40.00 (Original Purchase Price), which is expected to result in gross proceeds to us of $40.0 million, before deducting expenses payable by us. The Financing is subject to the approval of the holders of a majority of our outstanding common stock, as well as other customary closing conditions. In connection with the Purchase Agreement, stockholders holding approximately 56% of our common stock outstanding as of July 17, 2012 entered into separate agreements with us pursuant to which they agreed to vote in favor of the Financing. As a result, the investors and we expect the Financing will be approved by our stockholders and will close during the third quarter of 2012.

Each share of Series A Preferred Stock will be initially convertible into approximately 13.75 shares of our common stock, based on an initial conversion price of $2.91 per share (Conversion Price). The Conversion Price will be subject to standard broad-based weighted average anti-dilution adjustments prior to the date on which we have received and publicly announce the approval by the FDA of the NDA for ILUVIEN (FDA Approval Date), provided, that in no event shall the Conversion Price be adjusted below $1.00 (as adjusted for stock dividends, splits, combinations and similar events). The Original Purchase Price and the Conversion Price will be subject to adjustments for stock dividends, splits, combinations and similar events. The Warrants will be exercisable upon issuance at an exercise price of $44.00 per share of Series A Preferred Stock, provided, however, that the Warrants may be exercised, at the option of the holders, directly for the common stock that would otherwise then be issuable upon conversion of the Series A Preferred Stock covered by such Warrants.

The Series A Preferred Stock will be entitled to receive dividends and other distributions pro rata with the common stock. Each share of Series A Preferred Stock will automatically convert into common stock at the then applicable Conversion Rate, equal to the Original Purchase Price divided by the then applicable Conversion Price, upon the occurrence of both (i) the FDA Approval Date and (ii) the date on which we consummate an equity financing transaction pursuant to which we sell to one or more third party investors either (A) common stock or (B) other equity securities that are convertible into common stock and that have rights, preferences or privileges senior to or on parity with the Series A Preferred Stock, in each case having an as-converted to common stock price of not less than $10.00 per share (as adjusted for stock dividends, splits, combinations and similar events) and that results in gross proceeds to us of at least $30.0 million. The Series A Preferred Stock will not be redeemable and will not be convertible at our option.

Financial Operations Overview

Revenue

To date we have only generated revenue from our dry eye non-prescription product. From the launch of that product in September 2004 to its sale in July 2007, we generated $4.4 million in net revenues. We do not expect to generate any significant additional revenue until after the anticipated EU commercial launch of ILUVIEN in 2013, or unless or until we obtain regulatory approval in additional jurisdictions of, and

commercialize, our product candidates or in-license additional products that generate revenue. In addition to generating revenue from product sales, we intend to seek to generate revenue from other sources such as upfront fees, milestone payments in connection with collaborative or strategic relationships, and royalties resulting from the licensing of our product candidates and other intellectual property. We expect any revenue we generate will fluctuate from quarter to quarter as a result of the nature, timing and amount of any milestone payments we may receive from potential collaborative and strategic relationships, as well as revenue we may receive upon the sale of our products to the extent any are successfully commercialized.

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Research and Development Expenses

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

- salaries and related expenses for personnel;
- fees paid to consultants and contract research organizations (CRO) in conjunction with independently monitoring clinical trials and acquiring and evaluating data in conjunction with clinical trials, including all related fees such as investigator grants, patient screening, lab work and data compilation and statistical analysis;
- costs incurred with third parties related to the establishment of a commercially viable manufacturing process for our product candidates;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- costs related to upfront and milestone payments under in-licensing agreements;
- costs related to compliance with FDA, EU or other regulatory requirements;
- consulting fees paid to third-parties involved in research and development activities; and
- costs related to stock options or other stock-based compensation granted to personnel in development functions.

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

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

- the number of sites included in the trials;

the length of time required to enroll eligible patients;

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, Austria, Portugal, France and Germany, and has been recommended for marketing authorization in Italy 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

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of their review. Even if the clinical studies meet their predetermined primary endpoints, and a registration dossier is accepted for filing, a health authority could still determine that an appropriate benefit to risk relationship does not exist for the indication that we are seeking. We cannot forecast with any degree of certainty which of our product candidates will be subject to future collaborations or how such arrangements would affect our development plan or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will receive cash inflows from the commercialization and sale of an approved product candidate.

General and Administrative Expenses

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

Marketing Expenses

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

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

We expect significant increases in our marketing and selling expenses as we hire additional personnel and establish our sales and marketing capabilities in anticipation of the commercialization of ILUVIEN in Germany, the United Kingdom and France.

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 six months ended June 30, 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 1,138,317 and 1,568,623 for the three months ended June 30, 2012 and 2011, respectively, and 877,464 and 1,629,055 for the six months ended June 30, 2012 and 2011, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods of net loss because of their anti-dilutive effect. Therefore, for the three and six months ended June 30, 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 interim condensed consolidated financial statements which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from

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other sources. Actual results and experiences may differ materially from these estimates. We believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Clinical Trial Prepaid and Accrued Expenses

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

Research and Development Costs

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

Stock-Based Compensation

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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
	(Dollars in thousands)			
Marketing	$ 57	$ 71	$ 115	$ 168
Research and development	90	85	185	187
General and administrative	306	428	494	644
Total employee option-based compensation expense	$ 453	$ 584	$ 794	$ 999

Per the terms of our 2004 and 2005 Option Plans (Plans), our Series A Preferred Stock financing would constitute a change of control for the purposes of Plan vesting and as a result all unvested options under the Plans would become vested. As of June 30, 2012 there were 96,639 unvested options and $251,000 of unrecognized compensation expense in connection with the 2004 and 2005 Plans.

Restricted Stock Units

In February 2012, we awarded 85,437 Restricted Stock Units (RSUs), to our executive officers and employees at a grant date fair value of $1.70 per RSU. A RSU is a stock award that entitles the holder to receive shares of our common stock as the award vests. The fair value of the RSUs was determined on the date of grant based on the closing price of our common stock on the date of grant, which equals the RSU s intrinsic value. The RSUs were to vest upon the receipt of marketing approval of ILUVIEN in four of the seven EU countries in which ILUVIEN was recommended for marketing authorization. During the three and six months ended June 30, 2012, the Company recognized $109,000 in compensation expense in connection with the RSUs. At June 30, 2012, there was $36,000 of unrecorded compensation expense in connection with our RSUs. On July 18, 2012, France granted marketing authorization to ILUVIEN and, as a result, the RSUs became fully vested and we recorded $36,000 of compensation expense.

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 June 30, 2012 we had federal NOL carry-forwards of approximately $129.2 million and state NOL carry-forwards of approximately $112.7 million, respectively, that are available to reduce future income otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2023 and 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.

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Results of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
	(in thousands)			
RESEARCH AND DEVELOPMENT EXPENSES	$ 1,856	$ 1,751	$ 3,437	$ 3,508
GENERAL AND ADMINISTRATIVE EXPENSES	1,548	1,866	2,982	3,406
MARKETING EXPENSES	1,088	1,309	2,201	2,426
TOTAL OPERATING EXPENSES	4,492	4,926	8,620	9,340
INTEREST INCOME	1	2	2	14
INTEREST EXPENSE	(211)	(284)	(445)	(579)
NET LOSS	(4,702)	(5,208)	(9,063)	(9,905)

Three months ended June 30, 2012 compared to the three months ended June 30, 2011

Research and development expenses. Research and development expenses increased by approximately $100,000, or 5.6%, to approximately $1.9 million for the three months ended June 30, 2012 compared to approximately $1.8 million for the three months ended June 30, 2011. The increase was primarily attributable to increases of approximately $750,000 in costs related to a consultant engaged to assist with the continued pursuit of approval of ILUVIEN in the U.S. and $160,000 in costs related to the physician utilization study which is being conducted to assess the safety and utility of the commercial version of the ILUVIEN inserter, offset by decreases of $340,000 in costs for consultants engaged to assist with preparing for a previously anticipated FDA Advisory Board meeting, $220,000 in costs associated with contracting with medical science liaisons to engage with retina specialists in the U.S. in the study of ILUVIEN in connection with the previously expected commercial launch of ILUVIEN in the U.S., $150,000 in costs for technical development as we approached the final stages of the development of the inserter for ILUVIEN and $120,000 in costs associated with our ancillary studies.

General and administrative expenses. General and administrative expenses decreased by approximately $400,000, or 21.1%, to approximately $1.5 million for the three months ended June 30, 2012 compared to approximately $1.9 million for the three months ended June 30, 2011. The decrease was primarily attributable to decreases of approximately $110,000 in legal and professional accounting fees and $100,000 in personnel costs relating to employees terminated in connection with our reduction in force in December 2011.

Marketing expenses. Marketing expenses decreased by approximately $200,000, or 15.4%, to approximately $1.1 million for the three months ended June 30, 2012 compared to approximately $1.3 million for the three months ended June 30, 2011. The decrease was primarily attributable to a decrease of approximately $690,000 in costs associated with the previously expected commercial launch of ILUVIEN in the U.S., offset by an increase of $400,000 in costs attributable to our pre-launch activities in Europe.

Interest expense. Interest expense decreased by approximately $70,000, or 25.0%, to approximately $210,000 for the three months ended June 30, 2012 compared to approximately $280,000 for the three months ended June 30, 2011. Interest expense for the three months ended June 30, 2012 and 2011, respectively, was incurred in connection with our Credit Facility with Silicon Valley Bank and MidCap Financial LLP. The decrease was primarily attributable to lower principal balances with both Silicon Valley Bank and MidCap Financial LLP as a result of amortization payments beginning August 2011.

Six months ended June 30, 2012 compared to the six months ended June 30, 2011

Research and development expenses. Research and development expenses decreased by approximately $100,000, or 2.9%, to approximately $3.4 million for the six months ended June 30, 2012 compared to approximately $3.5 million for the six months ended June 30, 2011. The decrease was primarily attributable to decreases of approximately $440,000 in costs associated with contracting with medical science liaisons to engage with retina specialists in the study of ILUVIEN, $350,000 in costs for consultants engaged to assist with preparing for a previously anticipated FDA Advisory Board meeting, $330,000 in costs associated with the CROs of our FAME Study, $290,000 in costs for technical development as we approached the final stages of the development of the inserter for ILUVIEN and $120,000 in costs associated with our ancillary studies, offset by increases of approximately $1.1 million in costs related to a consultant engaged to assist with the continued pursuit of approval of ILUVIEN in the U.S. and $370,000 in costs related to the physician utilization study which is being conducted to assess the safety

and utility of the commercial version of the ILUVIEN inserter.

General and administrative expenses. General and administrative expenses decreased by approximately $400,000, or 11.8%, to approximately $3.0 million for the six months ended June 30, 2012 compared to approximately $3.4 million for the six months ended June 30, 2011. The decrease was primarily attributable to decreases of approximately $190,000 in personnel costs relating to employees terminated in connection with our reduction in force in December 2011 and $140,000 in legal and professional accounting fees.

Marketing expenses. Marketing expenses decreased by approximately $200,000, or 8.3%, to approximately $2.2 million for the six months ended June 30, 2012 compared to approximately $2.4 million for the six months ended June 30, 2011. The decrease was primarily attributable to a decrease of approximately $1.2 million in costs associated with the previously expected commercial launch of ILUVIEN in the U.S., offset by an increase of $930,000 in costs attributable to our pre-launch activities in the EU.

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Interest expense. Interest expense decreased by approximately $130,000, or 22.4%, to approximately $450,000 for the six months ended June 30, 2012 compared to approximately $580,000 for the six months ended June 30, 2011. Interest expense for the six months ended June 30, 2012 and 2011, respectively, was incurred in connection with our Credit Facility with Silicon Valley Bank and MidCap Financial LLP. The decrease was primarily attributable to lower principal balances with both Silicon Valley Bank and MidCap Financial LLP due to amortization payments beginning August 2011.

Liquidity and Capital Resources

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of $220.4 million from our inception through June 30, 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 June 30, 2012, we had $22.3 million in cash and cash equivalents. On July 17, 2012, we entered into a securities purchase agreement with certain investors for a $40,000,000 Series A Convertible Preferred Stock financing. The Purchase Agreement provides for the sale of 1,000,000 shares of our Series A Preferred and warrants to purchase an additional 300,000 shares of Series A Preferred. For each unit consisting of one share of Series A Preferred and a Warrant to purchase .30 of a Share of Series A Preferred, the Investors agreed to pay $40.00, resulting in gross proceeds to us of approximately $40,000,000, before deducting related expenses payable by us. The transaction is subject to the approval of a majority of our common shareholders. In connection with the Purchase Agreement we obtained voting agreements from parties holding approximately 55% of the stock outstanding indicating that they would vote in favor of the transaction. The transaction is expected to close in September 2012.

We plan to proceed with the direct commercialization of ILUVIEN in the United Kingdom, France and Germany in 2013. We believe that, assuming the closing of the Series A Convertible Preferred Stock financing, we will have sufficient funds available to fund our operations beyond the projected commercialization of ILUVIEN in these EU countries. We do not expect the generation of revenue until 2013, and therefore do not expect to have cash flow from operations until 2014, if at all. 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.

For the six months ended June 30, 2012, cash used in our operations of $10.1 million was primarily due to our net loss of $9.1 million offset by non-cash stock-based compensation and other expense of $920,000. Further increasing our cash used was a decrease in accounts payable, accrued expenses and other current liabilities of $1.7 million, and increases in prepaid expenses and other current assets and inventory of $450,000. The change in accounts payable, accrued expenses and other current liabilities was primarily due to decreases of approximately $540,000 paid to the administrator of our U.S. reimbursement and patient assistance programs for a termination payment and final billing due to the suspension of our commercialization of ILUVIEN in the U.S., $530,000 in amounts payable to our CROs, $220,000 in amounts payable to the investigators of our clinical studies, $210,000 in severance payments associated with our fourth quarter reduction in force and $110,000 in amounts payable to vendors performing pharmaeconomic studies to evaluate the pricing of ILUVIEN in the EU. The increases in prepaid expenses and other current assets and inventory were primarily due to increases of approximately $210,000 for inventory comprised of components for the ILUVIEN inserter and $200,000 for prepaid insurance.

For the six months ended June 30, 2011, cash used in our operations of $10.6 million was primarily due to our net loss of $9.9 million offset by non-cash stock-based compensation and other expense of $1.3 million. Further increasing our cash used was a decrease in accounts payable, accrued expenses and other current liabilities of $2.1 million, offset by a net decrease in prepaid expenses and other current assets of $130,000. The change in accounts payable, accrued expenses and other current liabilities was primarily due to decreases of approximately $1.4 million in amounts due to our clinical sites for the FAME trial and $500,000 in amounts due to our CROs.

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

For the six months ended June 30, 2012, cash used by financing activities was $1.2 million, which was primarily due to payments of principal on our notes payable to Silicon Valley Bank and MidCap Financial LLP. For the six months ended June 30, 2011, cash provided by financing activities was $250,000, which was primarily due to proceeds from the exercises of stock options and stock purchases made by employees through our employee stock purchase plan.

Contractual Obligations and Commitments

In February 2012 we engaged a consultant in connection with our efforts to obtain the approval of ILUVIEN from the FDA. During the three and six months ended June 30, 2012, respectively, we recorded charges of $750,000 and $1.1 million pertaining to consulting fees related to our agreement with this consultant. We expect to record an additional $625,000 in charges in connection with this agreement during the three months ended September 30, 2012.

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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

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

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

We are exposed to market risk related to changes in interest rates. As of June 30, 2012, we had approximately $22.3 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 June 30, 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 June 30, 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 June 30, 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 June 30, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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. Except as set forth below, 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 and set

forth below 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.

Risks Related to Our Dependence on ILUVIEN®

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

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

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

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

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

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

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

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

In February 2012, ILUVIEN was recommended for marketing authorization in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the treatment of vision impairment associated with chronic DME considered

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

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

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

- our inability to recruit and retain adequate numbers of effective personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating a commercial organization in the EU.

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

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

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

Risks Related to Our Business and Industry

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

We are not currently generating revenues and we cannot estimate with precision the extent of our future losses. Although ILUVIEN recently received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain, we do not currently have any products that are available for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of ILUVIEN. We currently do not expect to generate revenue from the sale of ILUVIEN in the EU until 2013. ILUVIEN has not been approved for marketing in the U.S. and may never receive such approval. As a result of these factors, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. As of June 30, 2012, we have accumulated a net deficit of $220.4 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and successfully marketed. We cannot assure you that

we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

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As of June 30, 2012, we had approximately $22.3 million in cash and cash equivalents. We believe that, assuming the closing of our Series A Convertible Preferred Stock financing, we have sufficient funds available to fund our operations beyond the projected commercialization of ILUVIEN in Germany, the United Kingdom and France and the expected generation of revenue in 2013. The commercialization of ILUVIEN is dependent upon numerous factors and we cannot be sure that future sales of ILUVIEN will generate enough revenue to fund our operations beyond its commercialization. If ILUVIEN does not generate sufficient revenue in the EU, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

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

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

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

- a drug candidate may not be safe or effective;
- regulatory agencies may interpret data from preclinical and clinical testing in different ways from those which we do;
- they may not approve of our manufacturing processes;
- they may conclude that the drug candidate does not meet quality standards for stability, quality, purity and potency; and
- they may change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the U.S. For example, the FDA may not approve of certain of our methods for analyzing our trial data, including how we evaluate the relationship between risk and benefit. Further, we may pursue approval of and market other product candidates, outside the U.S. and specifically in Canada and additional countries in the EU. Regulatory agencies within these countries will require that we obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedures within these countries can involve additional testing,

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and the time required to obtain approval may differ from that required to obtain FDA approval. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain additional foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

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

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

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

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

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

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

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Risks Relating to Our Financial Results and Need for Financing

If we fail to complete our previously announced proposed Series A Convertible Preferred Stock financing and do not otherwise obtain the capital necessary to fund our operations when needed, we could be forced to revise our business plans or discontinue our operations.

As of June 30, 2012, we had available cash and cash equivalents of approximately $22.3 million. On July 17, 2012, we entered into a securities purchase agreement (Purchase Agreement) with certain institutional investors under which we agreed to sell and issue an aggregate of 1,000,000 shares of Series A Convertible Preferred Stock, each share of which is initially convertible into approximately 13.75 shares of our common stock (Series A Preferred Stock), and related warrants to purchase up to an aggregate of 300,000 shares of Series A Preferred Stock (Warrants), which is expected to result in gross proceeds of $40.0 million, not including any proceeds from the exercise of the Warrants (Financing). Completion of this Financing is subject to the satisfaction of certain conditions, some of which are outside of our control, including but not limited to:

- stockholder approval of the Financing;
- the continued accuracy of the representations and warranties made by us in the Purchase Agreement;
- our performance of all obligations, covenants and agreements required to be performed by us prior to closing;
- the registration of the common stock underlying the Series A Preferred Stock;
- the authorization of the common stock underlying the Series A Preferred Stock to be traded on the NASDAQ Global Market;
- no material adverse change in our business, operations, financial condition or results of operations, subject to certain exceptions set forth in the Purchase Agreement;
- no action shall taken and no statute, rule, regulation, executive order, decree, ruling or injunction enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction that prohibits the consummation of the Financing;
- no revocation of the approval of ILUVIEN in any jurisdiction in which it, as of the date of the Purchase Agreement, had been approved and authorized by the proper governmental authority for sale and distribution;
- the appointment of a designee of one of the investors to our board of directors; and
- no breaches of covenants that place restrictions on the operation of our business without the approval of the investors.

Based on our current business plans and budget, we believe our current cash resources and the proceeds from the Financing will be sufficient to fund our operations beyond the initial commercial launch of ILUVIEN in the United Kingdom, France and Germany.

If we do not complete the Financing for any reason, we would be forced to preserve our cash position through a combination of cost reduction measures, licenses of ILUVIEN, sales of assets likely at values significantly below their potential worth, or the pursuit of alternative financing transactions that would likely be on terms substantially more disadvantageous to us and dilutive to our stockholders. We would need to augment our cash through additional and possibly repetitive dilutive financings. If we are unable to raise additional funds, we could be forced to revise our business plans or discontinue our operations.

Even if we complete the Financing, we may need additional capital to support our growth, which may be difficult to obtain and restrict our operations and will result in additional dilution to our stockholders.

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

- the amount of our future operating losses;

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- third party expenses relating to the commercialization of ILUVIEN;
- the level of success of the initial commercial launch of ILUVIEN in the United Kingdom, France and Germany;
- the status of our new drug application or ILUVIEN in the U.S.;
- the timing of approvals, if any, of ILUVIEN in additional jurisdictions;
- the need and cost of conducting additional clinical trials for ILUVIEN;
- the amount of our research and development, marketing and general and administrative expenses;
- the extent to which we enter into, maintain, and derive revenues from licensing agreements, including agreements to out-license ILUVIEN, research and other collaborations, joint ventures and other business arrangements;
- the extent to which we acquire, and our success in integrating, technologies or companies; and
- regulatory changes and technological developments in our markets.

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

Risks Related to Our Common Stock

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

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

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failure to complete the Financing;

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

failure of ILUVIEN to be approved in any additional jurisdiction;

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

results from our clinical trial programs;

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

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

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

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

third-party coverage and reimbursement policies;

additions or departures of key personnel;

commencement of, or our involvement in, litigation;

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

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

changes in earnings estimates or recommendations by securities analysts;

any major change in our board or management;

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

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

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

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

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

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As of July 18, 2012, our executive officers, key employees, directors and their affiliates and investors participating in the Financing beneficially owned, in the aggregate, approximately 60.6% of our outstanding common stock. Assuming the closing of the Financing and the appointment to our board of directors of a representative of one of the investors in the Financing, as required under the Purchase Agreement, our executive officers, key employees, directors and their affiliates and investors participating in the Financing will beneficially own, in the aggregate, approximately 74.3% of our outstanding common stock, assuming the conversion of all shares of Series A Preferred Stock and the exercise and subsequent conversion of the Warrants. As a result, these stockholders, if acting together, may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions, and this concentration of voting power may have the effect of delaying or impeding actions that could be beneficial to you, including actions that may be supported by our board of directors.

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

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

In addition to our outstanding common stock, as of June 30, 2012, there were a total of 3,698,019 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options and restricted stock units granted under our equity incentive plans. Upon the exercise of these options and the settlement of these restricted stock units, in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under the SEC s Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

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

If completed, our Financing will result in substantial dilution of the percentage ownership of our stockholders.

Our current stockholders, other than the one participating in the Financing, will incur immediate and substantial dilution of their percentage ownership of our common stock if the Financing is completed. The aggregate ownership of all holders of our outstanding common stock immediately prior to closing of the Financing (excluding the stockholder participating in the Financing) will be reduced to approximately 61.5% of the outstanding shares of our common stock after the closing, or 56.4% assuming exercise in full of the Warrants.

If the Financing is completed, the investors in the Financing will acquire shares of capital stock and warrants representing a substantial portion of our common stock on an as-converted basis.

If the Financing is completed, the investors in the Financing would acquire shares of Series A Preferred Stock and Warrants, which, when combined with shares of common stock currently owned by the lead investor, represent approximately 43.6% of our then outstanding common stock, assuming the conversion of all shares of Series A Preferred Stock and the exercise in full and subsequent conversion of the Warrants. Immediately following completion of the Financing, those investors would hold a sufficient portion of our outstanding shares so as to permit them, if they chose to act in concert, to substantially influence all actions requiring stockholder approval, including the election of directors, a merger, business combination or other strategic or financing transaction that would require stockholder approval.

The Series A Preferred Stock will contain covenants that may limit our business flexibility.

For so long as at least 37.5% of the shares of Series A Preferred Stock originally issued to the investors at the closing of the Financing are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Preferred Stock: (i) increase or decrease the authorized number of shares of Series A Preferred Stock; (ii) authorize, create, issue or obligate the company to issue (by reclassification, merger or otherwise) any security (or any class or series thereof) or any indebtedness, in each case that has any rights, preferences or privileges senior to, or on a parity with, the Series A Preferred Stock, or any security convertible into or exercisable for any such security or

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indebtedness, subject to limited exceptions for certain debt transactions; (iii) amend our certificate of incorporation or the certificate of designation, in each case in a manner that adversely affects the rights, preference or privileges of the Series A Preferred Stock; (iv) redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of common stock or preferred stock; provided, however, that this restriction shall not apply to (A) the redemption of rights issued pursuant to any poison pill rights plan or similar plan adopted by us after the closing of the proposed financing or (B) the repurchases of stock from former employees, officers, directors or consultants who performed services for us in connection with the cessation of such employment or service pursuant to the terms of existing agreements with such individuals; (v) declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (A) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Preferred Stock is made pursuant to the certificate of designation or (B) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with the implementation of a poison pill rights plan or similar plan by us; (vi) authorize or approve any increase to the number of aggregate shares of capital stock reserved for issuance pursuant to stock option, stock purchase plans or other equity incentive plans such that the total aggregate number of shares issued under such plans and reserved for issuance under such plans (on an as-converted basis) exceeds the number of shares issued and reserved for issuance under such plans (on an as-converted basis) on the date of the closing of the proposed financing by more than 20% (adjusted for stock splits, combinations, stock dividends, recapitalizations and the like), provided that any increases resulting solely from the annual increases resulting from the evergreen provisions of equity incentive plans in effect on the date of the closing of the proposed financing shall not be subject to this restriction and shall not be included for purposes of determining whether such 20% increase has occurred; (vii) issue stock or other equity securities of any subsidiary (other than to us or another of our wholly-owned subsidiary or declare or pay any dividend or other distribution of cash, shares or other assets or redemption or repurchase of shares of any subsidiary; or (viii) incur any secured indebtedness other than certain limited debt transactions. There is no guarantee that the investors would approve any such transaction, even where such a transaction would be in the best interests of our stockholders. Any failure to obtain such approval could harm our business and result in a decrease in the value of our common stock.

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***

Exhibit Number	Description
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.

* 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.

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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)

August 14, 2012

/s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
Chief Operating Officer and Chief Financial Officer

(Principal financial and accounting officer)

August 14, 2012

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ALIMERA SCIENCES, INC.

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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.