ALIMERA SCIENCES INC
Form 10-Q
November 07, 2011

Table of Contents

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

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the quarterly period ended September 30, 2011**

**or**

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the transition period from _____ to _____**

**Commission File Number: 001-34703**
**Alimera Sciences, Inc.**
*(Exact name of registrant as specified in its charter)*

| | |
|---|---|
| **Delaware** | **20-0028718** |
| *(State or other jurisdiction of incorporation or organization)* | *(I.R.S. Employer Identification No.)* |
| **6120 Windward Parkway, Suite 290**<br>**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 þ No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ
As of November 3, 2011, there were 31,427,355 shares of the registrant s common stock issued and outstanding.

**ALIMERA SCIENCES, INC.**
**QUARTERLY REPORT ON FORM 10-Q**
**INDEX**

## PART I. FINANCIAL INFORMATION


| | |
|---|---|
| Item 1. Financial Statements | 2 |
| Balance Sheets as of September 30, 2011 (unaudited) and December 31, 2010 | 2 |
| Statements of Operations for the three and nine months ended September 30, 2011 and 2010 (unaudited) | 3 |
| Statements of Cash Flows for the nine months ended September 30, 2011 and 2010 (unaudited) | 4 |
| Notes to Financial Statements | 6 |
| Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations | 15 |
| Item 3. Quantitative and Qualitative Disclosures about Market Risk | 31 |
| Item 4. Controls and Procedures | 31 |


## PART II. OTHER INFORMATION


| | |
|---|---|
| Item 1A. Risk Factors | 32 |
| Item 2. Unregistered Sales of Equity Securities and Use of Proceeds | 32 |
| Item 6. Exhibits | 32 |

Exhibit 31.1
Exhibit 31.2
Exhibit 32.1
EX-101 INSTANCE DOCUMENT
EX-101 SCHEMA DOCUMENT
EX-101 CALCULATION LINKBASE DOCUMENT
EX-101 LABELS LINKBASE DOCUMENT
EX-101 PRESENTATION LINKBASE DOCUMENT

Table of Contents

## PART I. FINANCIAL INFORMATION

**ITEM 1** ***Financial Statements***

### ALIMERA SCIENCES, INC.
### BALANCE SHEETS

| | September 30, 2011 (Unaudited) | December 31, 2010 |
|---|---|---|
| | (In thousands except share and per share data) | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 38,107 | $ 28,514 |
| Investments in marketable securities | 502 | 26,330 |
| Prepaid expenses and other current assets | 1,236 | 1,078 |
| Deferred financing costs | 231 | 272 |
| Total current assets | 40,076 | 56,194 |
| PROPERTY AND EQUIPMENT at cost less accumulated depreciation | 218 | 220 |
| TOTAL ASSETS | $ 40,294 | $ 56,414 |
| CURRENT LIABILITIES: | | |
| Accounts payable | $ 1,950 | $ 1,677 |
| Accrued expenses (Note 5) | 1,459 | 2,731 |
| Outsourced services payable | 393 | 841 |
| Notes payable (Note 7) | 2,386 | 1,157 |
| Capital lease obligations | 11 | 11 |
| Total current liabilities | 6,199 | 6,417 |
| LONG-TERM LIABILITIES: | | |
| Notes payable, net of discount less current portion (Note 7) | 3,501 | 4,767 |
| Other long-term liabilities | 9 | 18 |
| STOCKHOLDERS EQUITY: | | |
| Preferred stock, $.01 par value 10,000,000 shares authorized and no shares issued and outstanding at September 30, 2011 and at December 31, 2010 | | |
| Common stock, $.01 par value 100,000,000 shares authorized and 31,407,383 shares issued and outstanding at September 30, 2011 and 100,000,000 shares authorized and 31,255,953 shares issued and outstanding at December 31, 2010 | 314 | 313 |
| Additional paid-in capital | 235,155 | 233,338 |
| Common stock warrants | 415 | 415 |
| Accumulated deficit | (205,299) | (188,854) |

| | | | | |
|---|---|---|---|---|
| TOTAL STOCKHOLDERS EQUITY | | 30,585 | | 45,212 |
| TOTAL LIABILITIES AND STOCKHOLDERS EQUITY | $ | 40,294 | $ | 56,414 |

See Notes to Financial Statements.

Table of Contents

**ALIMERA SCIENCES, INC.**
**STATEMENTS OF OPERATIONS**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| | (Unaudited) | | | |
| | (In thousands except share and per share data) | | | |
| RESEARCH AND DEVELOPMENT EXPENSES | $ 2,224 | $ 3,276 | $ 5,732 | $ 10,481 |
| GENERAL AND ADMINISTRATIVE EXPENSES | 1,421 | 1,260 | 4,827 | 3,338 |
| MARKETING EXPENSES | 2,612 | 1,583 | 5,038 | 2,209 |
| OPERATING EXPENSES | 6,257 | 6,119 | 15,597 | 16,028 |
| INTEREST INCOME | 1 | 37 | 15 | 53 |
| INTEREST EXPENSE | (284) | | (863) | (618) |
| GAIN ON EARLY EXTINGUISHMENT OF DEBT (NOTE 6) | | | | 1,343 |
| DECREASE IN FAIR VALUE OF PREFERRED STOCK CONVERSION FEATURE | | | | 3,644 |
| LOSS FROM CONTINUING OPERATIONS | (6,540) | (6,082) | (16,445) | (11,606) |
| INCOME FROM DISCONTINUED OPERATIONS (NOTE 3) | | | | 4,000 |
| NET LOSS | (6,540) | (6,082) | (16,445) | (7,606) |
| REDEEMABLE PREFERRED STOCK ACCRETION | | | | (466) |
| REDEEMABLE PREFERRED STOCK DIVIDENDS | | | | (2,638) |
| NET LOSS APPLICABLE TO COMMON SHAREHOLDERS | $ (6,540) | $ (6,082) | $ (16,445) | $ (10,710) |
| NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS Basic and diluted | $ (0.21) | $ (0.20) | $ (0.52) | $ (0.56) |
| | 31,396,517 | 31,145,856 | 31,342,752 | 19,120,860 |

WEIGHTED-AVERAGE SHARES
OUTSTANDING Basic and diluted

See Notes to Financial Statements.

Table of Contents

**ALIMERA SCIENCES, INC.**
**STATEMENTS OF CASH FLOWS**

| | Nine Months Ended September 30, 2011 | 2010 |
|---|---|---|
| | (Unaudited) (In thousands) | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $ (16,445) | $ (7,606) |
| Income from discontinued operations (Note 3) | | (4,000) |
| Change in fair value of preferred stock conversion feature | | (3,644) |
| Gain from early extinguishment of debt | | (1,343) |
| Depreciation | 106 | 145 |
| Stock compensation and other | 1,478 | 567 |
| Amortization of deferred financing costs | 318 | |
| Non-cash investment gain | | (4) |
| Changes in assets and liabilities: | | |
| Prepaid expenses and other current assets | (158) | (320) |
| Accounts payable | 273 | 231 |
| Accrued expenses and other current liabilities | (1,720) | (53) |
| Other long-term liabilities | | 2 |
| Net cash used in operating activities | (16,148) | (16,025) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of investments | | (39,962) |
| Proceeds from maturities of investments | 25,828 | |
| Purchases of property and equipment | (104) | (121) |
| Net cash provided by (used in) investing activities of continuing operations | 25,724 | (40,083) |
| Net cash provided by investing activities of discontinued operations (Note 3) | | 4,000 |
| Net cash provided by (used in) investing activities | 25,724 | (36,083) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from exercises of stock options | 210 | 28 |
| Proceeds from exercise of Series C-1 preferred warrants | | 9,997 |
| Proceeds from exercise of common stock warrants | 19 | 489 |
| Proceeds from sale of common stock | 111 | 68,395 |
| Payment of common stock offering costs | | (1,942) |
| Repayment of pSivida note payable (Note 6) | | (15,000) |
| Repayment of notes payable (Note 7) | (265) | |

| | | |
|---|---|---|
| Payment of debt modification costs | (50) | |
| Payments on capital lease obligations | (8) | (6) |
| Net cash provided by financing activities | 17 | 61,961 |
| NET INCREASE IN CASH | 9,593 | 9,853 |
| CASH Beginning of period | 28,514 | 4,858 |
| CASH End of period | $ 38,107 | $ 14,711 |

Table of Contents

**STATEMENTS OF CASH FLOWS**

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2011 | 2010 |
| | (Unaudited) (In thousands) | |
| SUPPLEMENTAL DISCLOSURES | | |
| Cash paid for interest | $ 508 | $ 525 |
| Supplemental schedule of noncash investing and financing activities: | | |
| Property and equipment acquired under capital leases | $ | $ 36 |
| Reclassification of fair value of preferred stock conversion feature to additional paid-in capital | $ | $ 36,528 |
| IPO issuance costs charged to equity | $ | $ 4,228 |

There were no income tax or dividend payments made for the nine months ended September 30, 2011 and 2010.

See Notes to Financial Statements.

Table of Contents

**ALIMERA SCIENCES, INC.**
**NOTES TO FINANCIAL STATEMENTS**

**1. Nature of Operations**

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

On April 21, 2010, the Company s Registration Statement on Form S-1 (as amended) was declared effective by the Securities and Exchange Commission ( SEC ) for the Company s initial public offering ( IPO ), pursuant to which the Company sold 6,550,000 shares of its common stock at a public offering price of $11.00 per share. The Company received net proceeds of approximately $68,395,000 from this transaction, after deducting underwriting discounts and commissions.

During the year ended December 31, 2006, management and the board of directors of the Company approved a plan to discontinue the operations of its non-prescription business (see Note 3). As a result of the completion of the disposal of its non-prescription business in July 2007, the Company no longer has active products and will not have active products until and unless the Company receives U.S. Food and Drug Administration ( FDA ) approval and launches its initial prescription product (see Note 4).

The Company is presently focused on diseases affecting the back of the eye, or retina, because the Company s management believes these diseases are not well treated with current therapies and represent a significant market opportunity. The Company s most advanced product candidate is ILUVIEN, which is being developed for the treatment of diabetic macular edema ( DME ). DME is a disease of the retina which affects individuals with diabetes and can lead to severe vision loss and blindness. The Company has completed two Phase 3 pivotal clinical trials (collectively referred to as the FAME Study ) for ILUVIEN involving 956 patients in sites across the U.S., Canada, Europe and India to assess the efficacy and safety of ILUVIEN in the treatment of DME.

In June 2010, the Company submitted a New Drug Application ( NDA ) for ILUVIEN to the FDA that included data through month 24 of the FAME Study. In December 2010, the FDA issued a Complete Response Letter ( CRL ) in response to the Company s NDA. In the CRL, the FDA communicated its decision that the NDA could not be approved in its then present form. The FDA asked for analyses of the safety and efficacy data through month 36 of the FAME Study, including exploratory analyses in addition to those previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. The FDA also sought additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN. In a February 2011 meeting with the FDA, the FDA requested additional data related to the use of the commercial version of the ILUVIEN inserter for which approval was sought in the NDA. In May 2011, the Company submitted to the FDA a complete response to the CRL. The FDA classified the response as a Class 2 resubmission with a Prescription Drug User Fee Act ( PDUFA ) date of November 12, 2011. The PDUFA date is the date by which the Company can reasonably expect to have received the FDA s response. In July 2011, the FDA notified the Company that it will not call an advisory committee during its review of the Company s complete response to the CRL. In September 2011, the Company enrolled its first patient in a physician utilization study aimed at providing the additional data requested by the FDA with respect to the commercial version of the ILUVIEN inserter. The Company has enrolled 54 patient eyes in this study evaluating the safety and utility of the commercial version of the inserter and is targeting to enroll 100 patient eyes before commercial launch.

In July 2010, using the Decentralized Procedure, the Company submitted a Marketing Authorization Application for ILUVIEN to the Medicines and Healthcare products Regulatory Agency ( MHRA ) in the United Kingdom, which serves as the Reference Member State, and to regulatory authorities in Austria, France, Germany, Italy, Portugal and Spain. In November 2010, the Company received the Preliminary Assessment Report from the MHRA followed by additional comments from the other health authorities in December 2010. In July 2011, the Company submitted its draft responses to the clinical, non-clinical, and quality questions to the MHRA. The submission included the additional safety and efficacy data through the final readout at the end of the FAME Study. In September 2011, the MHRA provided comments to the Company s clinical responses and indicated that there were no further comments to the Company s non-clinical and quality responses. The Company is preparing, and plans to submit in November 2011,

its final response to the Preliminary Assessment Report from the MHRA and to the additional comments from the other health authorities.

**2. Basis of Presentation**

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

The accompanying unaudited interim financial statements and related notes should be read in conjunction with the Company s audited financial statements for the year ended December 31, 2010 and related notes included in the Company s Annual Report on Form 10-K, which was filed with the SEC on March 25, 2011. The financial results for any interim period are not necessarily indicative of the expected financial results for the full year.

On April 21, 2010, the Company effected a 1 for 3.4 reverse split of the Company s common and preferred stock. All share and per share amounts in the accompanying financial statements and notes have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

Table of Contents

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

**3. Discontinued Operations**

In October 2006, management and the board of directors of the Company approved a plan to discontinue the operations of its non-prescription ophthalmic pharmaceutical business ( OTC Business ). The plan included the sale of the assets of the Company s OTC Business and also the termination of its sales and marketing personnel. The Company previously determined that the discontinued OTC Business comprised operations and cash flows that could be clearly distinguished, operationally and for financial reporting purposes, from the rest of the Company. Accordingly, the results of operations for the discontinued OTC Business have been presented as discontinued operations. During the nine months ended September 30, 2010, the Company received a $4,000,000 option payment from the acquirer of the assets of the OTC Business to provide it with an additional two years to develop one of the acquired products. In July 2011, the acquirer of the assets of the OTC Business notified the Company that it will discontinue the development of the acquired products and not seek FDA approval. There were no revenues or expenses from discontinued operations during the nine month period ended September 30, 2011. The following table presents basic and diluted earnings per share from discontinued operations for the nine months ended September 30, 2010:

| | |
|---|---|
| Net income from discontinued operations (in thousands) | $ 4,000 |
| Net income from discontinued operations per share Basic and diluted | $ 0.21 |
| Weighted-average shares outstanding Basic and diluted | 19,120,860 |

**4. Factors Affecting Operations**

To date the Company has incurred recurring losses, negative cash flow from operations, and has accumulated a deficit of $205,299,000 from the Company s inception through September 30, 2011. The Company does not expect to generate revenues from its product, ILUVIEN, until early 2012, if at all, and therefore does not expect to have cash flow from operations until 2012, if at all. As of September 30, 2011, the Company had approximately $38,609,000 in cash, cash equivalents, and investments in marketable securities. In October 2010, the Company obtained a $32,500,000 senior secured credit facility ( Credit Facility ) to help fund its working capital requirements (see note 7). The Credit Facility consisted of a $20,000,000 working capital revolver and a $12,500,000 term loan. The lenders advanced $6,250,000 under the term loan and the remaining $6,250,000 was available to be advanced following FDA approval of ILUVIEN, but no later than July 31, 2011. In May 2011, the Company and its lenders amended the terms of the Credit Facility to, among other things, extend the FDA approval deadline for the second advance under the term loan to December 31, 2011, and to increase the amount available under the second advance of the term loan from $6,250,000 to $11,000,000. Management believes it has sufficient funds available to fund its operations through the projected launch of ILUVIEN and the expected generation of revenue in early 2012. The commercialization of ILUVIEN is dependent upon approval by the FDA, however, and management cannot be sure that ILUVIEN will be approved by the FDA or that, if approved, future sales of ILUVIEN will generate enough revenue to fund the Company s operations beyond its launch. Due to the uncertainty around FDA approval, management also cannot be certain that the Company will not need additional funds for the launch of ILUVIEN. If ILUVIEN is not approved, or if approved, does not generate sufficient revenue, the Company may adjust its commercial plans so that it can continue to operate with its existing cash resources or seek to raise additional financing.

**5. Accrued Expenses**

Accrued expenses consisted of the following:

| | September 30, 2011 | December 31, 2010 |
|---|---|---|
| | (In thousands) | |
| Accrued clinical investigator expenses | $ 518 | $ 1,911 |
| Accrued compensation expenses | 873 | 730 |

| | | | | |
|---|---|---|---|---|
| Other accrued expenses | | 68 | | 90 |
| Total accrued expenses | $ | 1,459 | $ | 2,731 |

Table of Contents

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

**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;
- forgive all outstanding development payments, penalties and interest as of the effective date of the March 2008 agreement, which totaled $6.8 million;
- continue responsibility for regulatory, clinical, preclinical, manufacturing, marketing and sales for the remaining development and commercialization of the products;
- assume all financial responsibility for the development of the products and assume 80% of the commercialization costs of the products (instead of 50% as provided under the February 2005 agreement); and
- make an additional milestone payment of $25.0 million after the first product under the March 2008 agreement has been approved by the FDA.

The $15,000,000 promissory note accrued interest at 8% payable quarterly and was payable in full to pSivida upon the earlier of a liquidity event as defined in the note (including an initial public offering of the Company s common stock greater than $75,000,000), the occurrence of an event of default under the Company s agreement with pSivida or September 30, 2012. If the note was not paid in full by March 31, 2010, the interest rate was to increase to 20% effective as of April 1, 2010, and the Company would be required to begin making principal payments of $500,000 per month. On April 27, 2010, the Company paid pSivida $15,225,000 in principal and interest to satisfy the note payable. As a result, the Company recognized a gain of $1,343,000 on the extinguishment of this debt in the accompanying financial statements for the nine month period ended September 30, 2010.

The Company s license rights to pSivida s proprietary delivery device could revert to pSivida if the Company were to (i) fail twice to cure its breach of an obligation to make certain payments to pSivida following receipt of written notice thereof; (ii) fail to cure other breaches of material terms of its agreement with pSivida within 30 days after notice of such breaches or such longer period (up to 90 days) as may be reasonably necessary if the breach cannot be cured within such 30-day period; (iii) file for protection under the bankruptcy laws, make an assignment for the benefit of creditors, appoint or suffer appointment of a receiver or trustee over its property, file a petition under any bankruptcy or insolvency act or have any such petition filed against it and such proceeding remains undismissed or unstayed for a period of more than 60 days; or (iv) notify pSivida in writing of its decision to abandon its license with respect to a certain product using pSivida s proprietary delivery device. The Company was not in breach of its agreement with pSivida as of September 30, 2011.

Upon commercialization of ILUVIEN, the Company must share 20% of net profits of ILUVIEN, as defined by the agreement, with pSivida. In connection with this arrangement the Company is entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida s share of net profits. As of September 30, 2011 and December 31, 2010 the Company was owed $3,556,000 and $2,224,000, respectively, in commercialization costs. Due to the uncertainty of FDA approval of the NDA for ILUVIEN, the Company has fully reserved these amounts in the accompanying financial statements.

Table of Contents

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

**7. Term Loan and Working Capital Revolver**

*Term Loan*

On October 14, 2010 ( Effective Date ), the Company entered into a Loan and Security Agreement ( Term Loan Agreement ) with Silicon Valley Bank and MidCap Financial LLP ( Lenders ). Pursuant to the original terms of the Term Loan Agreement, the Company was entitled to borrow up to $12.5 million, of which $6.25 million ( Term Loan A ) was advanced to the Company on the Effective Date. The Company was entitled to draw down the remaining $6.25 million under the Term Loan ( Term Loan B and together with Term Loan A, the Term Loan ) if the FDA approved the Company s NDA for ILUVIEN prior to or on July 31, 2011. On May 16, 2011, the Company and the Lenders amended the Term Loan Agreement ( Term Loan Modification ) to, among other things, extend until December 31, 2011 the date by which the FDA must approve the NDA in order for the Company to draw down Term Loan B and increase the amount of Term Loan B by $4.75 million to $11.0 million. In addition, the maturity date of the Term Loan was extended from October 31, 2013 to April 30, 2014 ( Term Loan Maturity Date ).

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 then beginning August 2011, the Company is required to repay the principal in 33 equal monthly installments plus interest at a rate of 11.5%. The Company is required to pay interest at a rate of 12.5% on the amount borrowed, if any, under Term Loan B through April 30, 2012, and thereafter will be required to repay the principal in equal monthly installments through the Term Loan Maturity Date, plus interest at a rate of 12.5%.

If the Company repays Term Loan A prior to maturity, the Company must pay to the Lenders a prepayment fee equal to 5.0% of the total amount of principal then outstanding if the prepayment had occurred within one year after the funding date of Term Loan A ( Term Loan A Funding Date ), 3.0% of such amount if the prepayment occurs between one year and two years after the Term Loan A Funding Date and 1.0% of such amount if the prepayment occurs thereafter (subject to a 50% reduction in the event that the prepayment occurs in connection with an acquisition of the Company). If Term Loan B is advanced to the Company, then the amount of the prepayment fee on both Term Loan A and Term Loan B will be reset to 5.0% and the time-based reduction of the prepayment fee will be measured from the funding date of Term Loan B (subject to the same 50% reduction in the event of an acquisition of the Company), rather than from the Term Loan A Funding Date.

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.

Table of Contents

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

On the Effective Date, the Company issued to the Lenders warrants to purchase an aggregate of up to 39,773 shares of the Company s common stock. Each of the warrants is exercisable immediately, has a per-share exercise price of $11.00 and has a term of 10 years. The Company estimated the fair value of warrants granted using the Black-Scholes option pricing model. The aggregate fair value of the warrants was estimated to be $389,000. The Company allocated a portion of the proceeds from the Term Loan Agreement to the warrants in accordance with Accounting Standards Codification ( 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 also hold warrants to purchase an aggregate of up to 69,999 shares of the Company s common stock, which are exercisable only if Term Loan B is 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 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 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.

*Working Capital Revolver*

Also on the Effective Date, the Company and Silicon Valley Bank entered into a Loan and Security Agreement, pursuant to which the Company obtained a secured revolving line of credit ( Working Capital Revolver ) from Silicon Valley Bank with borrowing availability up to $20,000,000 ( Revolving Loan Agreement ). On May 16, 2011, the Company and Silicon Valley Bank amended the Revolving Loan Agreement to extend the maturity date of the Working Capital Revolver from October 31, 2013 to April 30, 2014.

The Working Capital Revolver is a working capital-based revolving line of credit in an aggregate amount of up to the lesser of (i) $20,000,000, or (ii) 85% of eligible domestic accounts receivable. As of September 30, 2011, no amounts under the Working Capital Revolver were outstanding or 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 would have paid to Silicon Valley Bank a fee of $400,000 if the termination occured within one year after the Effective Date and a fee of $200,000 if the termination occurs more than one year after the Effective Date (each a Termination Fee ), provided in each case that such Termination Fee will be reduced by 50% in the event of an acquisition of the Company.

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

Table of Contents

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

**8. Earnings (Loss) Per Share (EPS)**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| | (Unaudited) | | (Unaudited) | |
| Series A preferred stock and convertible accrued dividends | | | | 3,002,205 |
| Series B preferred stock | | | | 3,063,383 |
| Series C preferred stock | | | | 2,488,762 |
| Series C-1 preferred stock | | | | 1,187,651 |
| Series C-1 Preferred stock warrants | | | | 56,723 |
| Common stock warrants | 28,086 | 77,114 | 29,366 | 112,644 |
| Stock options | 1,502,469 | 1,633,441 | 1,573,106 | 1,669,748 |
| | 1,530,555 | 1,710,555 | 1,602,472 | 11,581,116 |

**9. Preferred Stock**

Prior to the Company s IPO, the Company had four series of preferred stock. On April 27, 2010 and in connection with the IPO, all outstanding shares of the Company s preferred stock were converted into 22,863,696 shares of common stock and all preferred stock dividends were eliminated. Significant terms of all series of the preferred stock were as follows:

Dividends were cumulative and accrued on a daily basis at the rate of 8% per annum beginning on the date of issuance and based on the original issue price, as adjusted for any stock dividend, stock split, combination, or other event involving the preferred stock. Dividends accrued, whether or not declared, annually and were due and payable when and if declared by the Board of Directors, upon a liquidating event upon redemption of the preferred stock or on the date that the preferred stock was otherwise acquired by the Company.

Upon any liquidation, dissolution, or winding up of the Company, the preferred stockholders were entitled to a liquidation preference payment equal to (i) the sum of the liquidation value plus all accumulated, accrued, and unpaid dividends and (ii) the pro rata share of any remaining amounts such holder would have been entitled to receive had such holder s shares been converted into common stock immediately prior to the liquidation, dissolution, or winding up.

At any time subsequent to March 17, 2013, the holders of a majority of the preferred stock could have required the Company to redeem all or any portion of the preferred stock. If the preferred stock was redeemed, the redemption would have occurred in equal installments over a three-year period. The price paid

by the Company to redeem the shares would have been the greater of (i) the original issue price, plus all accumulated, accrued, and unpaid dividends, and (ii) the fair market value of the preferred stock being redeemed at the time of the redemption.

Because the preferred stock provided the holders the right to require the Company to redeem such shares for cash after March 17, 2013 at the greater of (i) the original issue price plus any accrued but unpaid dividends and (ii) the fair market value of the preferred stock being redeemed, the embedded conversion feature required separate accounting. Consequently, the conversion feature had to be bifurcated from the preferred stock and accounted for separately at each issuance date. The carrying value of the embedded derivative was adjusted to fair value at the end of each reporting period and the change in fair value was recognized in the statement of operations.

Table of Contents

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

On January 8, 2010 warrants to purchase shares of the Company s Series C-1 preferred stock were exercised resulting in $10,000,000 in cash proceeds and the issuance of 1,935,700 additional shares of Series C-1 preferred stock. The Company recorded a derivative liability of $3,471,000 upon the exercise of the warrants and the issuance of 1,935,700 shares of Series C-1 preferred stock in January 2010.

At each reporting date, the Company adjusted the carrying value of the embedded derivatives to estimated fair value and recognized the change in such estimated value in its statement of operations. The estimated fair value of the derivatives at April 27, 2010 was $36,528,000. The Company recognized a gain of $3,644,000 associated with the change in fair value for the nine months ended September 30, 2010. In connection with the IPO, the embedded derivatives were eliminated.

In connection with the Company s IPO in April 2010, the Company authorized 10,000,000 shares of $0.01 par value preferred stock. No shares of preferred stock were issued or outstanding at September 30, 2011 and December 31, 2010, respectively.

**10. Stock Options**

During the three months ended September 30, 2011 and 2010, the Company recorded compensation expense related to stock options of approximately $417,000 and $189,000, respectively. During the nine months ended September 30, 2011 and 2010, the Company recorded stock compensation expense of approximately $1,416,000 and $447,000, respectively. As of September 30, 2011, the total unrecognized compensation cost related to non-vested stock options granted was $4,220,000 and is expected to be recognized over a weighted average period of 2.9 years. The following table presents a summary of stock option transactions for the three and nine months ended September 30, 2011 and 2010:

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2011 | | 2010 | |
| | 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 | 2,677,474 | $ 3.98 | 2,281,311 | $ 2.39 | 2,741,985 | $ 3.81 | 2,225,778 | $ 2.14 |
| Grants | 90,000 | 7.95 | 108,500 | 6.74 | 155,000 | 7.83 | 173,500 | 8.34 |
| Forfeitures | | | (13,708) | 5.20 | (7,500) | 11.00 | (14,444) | 5.11 |
| Exercises | (10,000) | 2.04 | (5,879) | 1.40 | (132,011) | 1.59 | (14,610) | 1.94 |
| Options at end of period | 2,757,474 | | 2,370,224 | | 2,757,474 | | 2,370,224 | |
| Weighted average per share fair value of options granted during the period | $ 5.81 | | $ 5.35 | | $ 5.67 | | $ 6.74 | |

The following table provides additional information as of September 30, 2011:

| | Weighted | Weighted |
|---|---|---|

| | Shares | Average Exercise Price | Average Contractual Term | Aggregate Intrinsic Value (In thousands) |
|---|---|---|---|---|
| Outstanding | 2,757,474 | $ 4.12 | 6.53 years | $ 12,089 |
| Exercisable | 1,972,951 | 2.61 | 5.70 years | 10,921 |
| Expected to vest | 721,005 | 7.92 | 8.64 years | 1,053 |

Table of Contents

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

The following table provides additional information as of December 31, 2010:

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

**11. 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 FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes an interpretation of ASC 740-10. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position; therefore, no ASC 740-10 liabilities have been recorded.

Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of deferred tax assets due to the history of operating losses, a valuation allowance has been established against the entire net deferred tax asset balance. The valuation allowance is based on management s estimates of taxable income in the jurisdictions in which the Company operates and the period over which deferred tax assets will be recoverable. In the event that actual results differ from these estimates or the Company adjusts these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact the Company s financial position and results of operations.

At September 30, 2011 and December 31, 2010, the Company had federal net operating loss ( NOL ) carry-forwards of approximately $112,141,000 and $97,813,000 and state NOL carry-forwards of approximately $95,604,000 and $80,995,000, respectively, that are available to reduce future income unless otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2023 and 2030, and the state NOL carry-forwards will expire at various dates between 2020 and 2030.

NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of the Company were to occur. The Company has not yet completed a formal evaluation of the impact of its IPO (Note 1) on the Company s NOL carry-forwards and whether certain changes in ownership have occurred that would limit the Company s ability to utilize a portion of its NOL carry-forwards.

Table of Contents

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

**12. Fair Value**

The Company adopted Statement of Financial Accounting Standards No. 157, Fair Value Measurements (ASC 820), effective January 1, 2008. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the exit price ) in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. The hierarchy of those valuation approaches is broken down into three levels based on the reliability of inputs as follows:

Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. An active market for the asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. The valuation under this approach does not entail a significant degree of judgment.

Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include: quoted prices for similar assets or liabilities in active markets, inputs other than quoted prices that are observable for the asset or liability, (e.g., interest rates and yield curves observable at commonly quoted intervals or current market) and contractual prices for the underlying financial instrument, as well as other relevant economic measures.

Level 3 inputs are unobservable inputs for the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

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

| | September 30, 2011 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| | (Unaudited) (In thousands) | | | |
| Cash equivalents(1) | $ 37,437 | $ | $ | $ 37,437 |
| Investments in marketable debt securities(2) | | 502 | | 502 |
| Assets measured at fair value | $ 37,437 | $ 502 | $ | $ 37,939 |

| | December 31, 2010 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| | (In thousands) | | | |
| Cash equivalents(1) | $ 27,393 | $ | $ | $ 27,393 |
| Investments in marketable debt securities(2) | | 26,330 | | 26,330 |
| Assets measured at fair value | $ 27,393 | $ 26,330 | $ | $ 53,723 |

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

(2) Valuations are based on quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly. These prices include broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Pricing sources include industry standard data providers, security master files from large financial institutions, and other third party sources which are input into a distribution-curve-based algorithm to determine a daily market value. This creates a consensus price or a weighted average price for each security.

Table of Contents

## PART I. FINANCIAL INFORMATION

**ITEM 2** ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

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

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

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to 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 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, 2010, which contain 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 Part II of this report and Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the SEC from time to time, including Forms 10-Q, 8-K and 10-K, which may supplement, modify, supersede or update those risk factors. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if

substantially realized, that they will have the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

Table of Contents

**Overview**

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

Our most advanced product candidate is ILUVIEN, which we are developing for the treatment of diabetic macular edema ( DME ). DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. In September 2010, we completed two Phase 3 pivotal clinical trials (collectively, our FAME Study ) for ILUVIEN involving 956 patients in sites across the U.S., Canada, Europe and India to assess the efficacy and safety of ILUVIEN in the treatment of DME.

In June 2010, we submitted a New Drug Application ( NDA ) for ILUVIEN to the FDA that included data through month 24 of the FAME Study. In December 2010, the FDA issued a Complete Response Letter ( CRL ) in response to our NDA. In the CRL, the FDA communicated its decision that the NDA could not be approved in its then present form. The FDA asked for analyses of the safety and efficacy data through month 36 of the FAME Study, including exploratory analyses in addition to those previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. The FDA also sought additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN. In a February 2011 meeting with the FDA, the FDA requested additional data related to the use of the commercial version of the ILUVIEN inserter for which approval was sought in the NDA. In May 2011, we submitted to the FDA a complete response to the CRL. The FDA classified the response as a Class 2 resubmission with a Prescription Drug User Fee Act ( PDUFA ) date of November 12, 2011. The PDUFA date is the date by which we can reasonably expect to have received the FDA s response. In July 2011, the FDA notified us that it will not call an advisory committee during its review of our complete response to the CRL. In September 2011, we enrolled our first patient in a physician utilization study aimed at providing the additional data requested by the FDA with respect to the commercial version of the ILUVIEN inserter. We have enrolled 54 patient eyes in this study evaluating the safety and utility of the commercial version of the inserter and are targeting to enroll 100 patient eyes before commercial launch.

In July 2010, using the Decentralized Procedure, we submitted a Marketing Authorization Application for ILUVIEN to the Medicines and Healthcare products Regulatory Agency ( MHRA ) in the United Kingdom, which serves as the Reference Member State, and to regulatory authorities in Austria, France, Germany, Italy, Portugal and Spain. In November 2010, we received the Preliminary Assessment Report from the MHRA followed by additional comments from the other health authorities in December 2010. In July 2011, we submitted our draft responses to the clinical, non-clinical, and quality questions to the MHRA. The submission included the additional safety and efficacy data through the final readout at the end of the FAME Study. In September 2011, the MHRA provided comments to our clinical responses and indicated that there were no further comments to our non-clinical and quality responses. We are preparing, and plan to submit in November 2011, our final response to the Preliminary Assessment Report from the MHRA and to the additional comments from the other health authorities.

If our NDA for ILUVIEN is approved by the FDA, we plan to commercialize ILUVIEN in the U.S. by marketing and selling it to retinal specialists as early as early 2012. In addition to treating DME, ILUVIEN is being studied in three Phase 2 clinical trials for the treatment of the dry form of age-related macular degeneration ( AMD ), the wet form of AMD and retinal vein occlusion ( RVO ).

We intend to seek a collaboration partner for sales and marketing activities outside North America. We currently contract with development partners or outside firms for various operational aspects of our development activities, including the preparation of clinical supplies and have no plans to establish in-house manufacturing capabilities.

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of September 30, 2011, we have accumulated a deficit of $205.3 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

- complete the clinical development and registration of ILUVIEN;

- build our sales and marketing capabilities for the anticipated commercial launch of ILUVIEN in early 2012;
- add the necessary infrastructure to support our growth;
- evaluate the use of ILUVIEN for the treatment of other diseases; and
- advance the clinical development of other new product candidates that we may license or acquire in the future.

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

As of September 30, 2011, we had approximately $38.6 million in cash, cash equivalents, and investments in marketable securities. In addition to our net IPO proceeds, our cash and cash equivalents include the January 2010 receipt of $10.0 million in proceeds from the exercise of outstanding Series C-1 warrants, and a $4.0 million option payment from Bausch & Lomb Incorporated ( Bausch & Lomb ) upon the exercise by Bausch & Lomb of its option to extend by two years the period during which it may continue to develop an allergy product acquired from us in 2006.

In October 2010, we obtained a $32.5 million senior secured credit facility ( Credit Facility ) to help fund our working capital requirements. The Credit Facility consisted of a $20.0 million working capital revolver and a $12.5 million term loan. The lenders advanced $6.25 million under the term loan and the remaining $6.25 million was available for funding following FDA approval of ILUVIEN, but no later than July 31, 2011. In May 2011, the lenders and we amended the terms of the Credit Facility to, among other things, extend the FDA approval deadline for the second advance under the term loan to December 31, 2011, and to increase the amount available under the second advance of the term loan from $6.25 million to $11.0 million. In addition, the maturity date of the Credit Facility was extended from October 31, 2013 to April 30, 2014. We may draw on the working capital revolver against eligible, domestic accounts receivable. As of September 30, 2011, no amounts under the working capital revolver were outstanding or available.

We do not expect to generate revenues from our product, ILUVIEN, until early 2012, if at all, and therefore we do not expect to have positive cash flow from operations before that time. We believe our cash, cash equivalents, investments in marketable securities and Credit Facility are sufficient to fund our operations through the projected launch of ILUVIEN and the expected generation of revenue in early 2012. The commercialization of ILUVIEN is dependent upon approval by the FDA, however, and we cannot be sure that ILUVIEN will be approved by the FDA or that, if approved, future sales of ILUVIEN will generate enough revenue to fund our operations beyond its launch. Due to the uncertainty around FDA approval, our management cannot be certain that we will not need additional funds for the launch of ILUVIEN. If ILUVIEN is not approved, or if approved, does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

During the third quarter of 2011, we terminated our two agreements with Emory University pursuant to which we had licensed certain nicotinamide adenine dinucleotide phosphate (NADPH) oxidase inhibitors, however we continue our evaluation of other NADPH oxidase inhibitors for use in the treatment of diseases of the eye, including dry AMD, wet AMD and diabetic retinopathy.

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

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

Under the February 2005 agreement, we and pSivida agreed to collaborate on the development of ILUVIEN for DME, and share financial responsibility for the development expenses equally. 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 derived by us from the sale of ILUVIEN. Total consideration to pSivida in connection with the execution of the March 2008 agreement was $33.8 million, which consisted of a cash payment of $12.0 million, the issuance of a $15.0 million note payable, and the forgiveness of $6.8 million in outstanding receivables. The $15.0 million promissory note accrued interest at 8% per annum, payable quarterly and was payable

in full to pSivida upon the earliest of a liquidity event as defined in the agreement, the occurrence of an event of default under our agreement with pSivida, or September 30, 2012. If the note was not paid in full by March 31, 2010, the interest rate was to increase to 20% effective as of April 1, 2010, and we were required to begin making principal payments of $500,000 per month.

On April 27, 2010, we paid pSivida approximately $15.2 million in principal and interest to satisfy the note payable with the proceeds from our IPO.

We will owe pSivida an additional milestone payment of $25.0 million upon FDA approval of ILUVIEN.

Table of Contents

***Our Credit Facility***

***Term Loan***

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 approve 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 (the Term Loan Maturity Date ).

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 then beginning August 2011, we are required to repay the principal in 33 equal monthly installments plus interest at a rate of 11.5%. We are required to pay interest at a rate of 12.5% on the amount borrowed, if any, under Term Loan B through April 30, 2012, and thereafter we will be required to repay the principal in equal monthly installments through the Term Loan Maturity Date, plus interest at a rate of 12.5%.

If we repay Term Loan A prior to maturity, we must pay to the Lenders a prepayment fee equal to 5.0% of the total amount of principal then outstanding if the prepayment had occurred within one year after the funding date of Term Loan A ( Term Loan A Funding Date ), 3.0% of such amount if the prepayment occurs between one year and two years after the Term Loan A Funding Date and 1.0% of such amount if the prepayment occurs thereafter (subject to a 50% reduction in the event that the prepayment occurs in connection with an acquisition of us). If Term Loan B is advanced to us, then the amount of the prepayment fee on both Term Loan A and Term Loan B will be reset to 5.0% and the time-based reduction of the prepayment fee will be measured from the funding date of Term Loan B (subject to the same 50% reduction in the event of an acquisition of us), rather than from the Term Loan A Funding Date.

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.

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 also hold warrants to purchase an aggregate of up to 69,999 shares of our common stock, which are exercisable only if Term Loan B is advanced to us. Each of these warrants has a per share exercise price of $11.00 and a term of 10 years. 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.

Table of Contents

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

***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 $20,000,000 ( Revolving Loan Agreement ). On May 16, 2011, Silicon Valley Bank and we amended the Revolving Loan Agreement to extend the maturity date of the Working Capital Revolver from October 31, 2013 to April 30, 2014.

The Working Capital Revolver is a working capital-based revolving line of credit in an aggregate amount of up to the lesser of (i) $20,000,000, or (ii) 85% of eligible domestic accounts receivable. As of September 30, 2011, no amounts under the Working Capital Revolver were outstanding or 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 would have paid to Silicon Valley Bank a fee of $400,000 if the termination occured within one year after the Effective Date and a fee of $200,000 if the termination occurs more than one year after the Effective Date (each a Termination Fee ), provided in each case that such Termination Fee will be reduced by 50% in the event we are acquired.

To secure the repayment of any amounts borrowed under the Revolving Loan Agreement, we granted to Silicon Valley Bank a first priority security interest in all of our assets, 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.

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

At the inception of our company, we were focused primarily on the development and commercialization of non-prescription over-the-counter ophthalmic products. In October 2006, due to the progress and resource requirements related to the development of ILUVIEN, we decided to discontinue our non-prescription business. As a result, we received proceeds of $10.0 million from the sale of our allergy products in December 2006 and $6.7 million from the sale of our dry eye product in July 2007, both to Bausch & Lomb. If one of the allergy products had received FDA approval, we were entitled to an additional $8.0 million payment from Bausch & Lomb under the sales agreement. In January 2010, we received a $4.0 million option payment from Bausch & Lomb upon the exercise by Bausch & Lomb of its option to extend the period during which it may continue to develop this allergy product by two years. However, in July 2011, Bausch & Lomb notified us that it will discontinue the development of this allergy product and not seek FDA approval. As a result of the discontinuation of our non-prescription business, all revenues and expenses associated with our over-the-counter portfolio are included in the loss from discontinued operations in the accompanying statements of operations.

Table of Contents

## Financial Operations Overview

***Revenue***

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

***Research and Development Expenses***

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

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

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

We expect that a large percentage of our research and development expenses in the future will be incurred in support of our current and future technical, preclinical and clinical development programs. These expenditures are subject to numerous uncertainties in terms of both their timing and total cost to completion. We expect to continue to develop stable formulations of 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.

Table of Contents

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

None of our product candidates has received FDA or foreign regulatory marketing approval. In order to grant marketing approval, a health authority such as the FDA or foreign regulatory agencies must conclude that clinical and preclinical data establish the safety and efficacy of our product candidates with an appropriate benefit to risk profile relevant to a particular indication, and that the product can be manufactured under current Good Manufacturing Practice ( cGMP ) in a reproducible manner to deliver the product s intended performance in terms of its stability, quality, purity and potency. Until our submissions are reviewed by health authorities, there is no way to predict the outcome of their review. Even if the clinical studies meet their predetermined primary endpoints, and a registration dossier is accepted for filing, a health authority could still determine that an appropriate benefit to risk relationship does not exist for the indication that we are seeking. We cannot forecast with any degree of certainty which of our product candidates will be subject to future collaborations or how such arrangements would affect our development plan or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will receive cash inflows from the commercialization and sale of an approved product candidate.

***General and Administrative Expenses***

General and administrative expenses consist primarily of compensation for employees in executive and administrative functions, including finance, accounting and human resources. Other significant costs include facilities costs and professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents. We anticipate incurring a significant increase in general and administrative expenses, as we add additional employees and continue to operate as a public company. These increases will include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants, lawyers and accountants. We also expect to continue to incur significant costs to comply with the corporate governance, internal control and similar requirements applicable to public companies.

***Marketing Expenses***

Marketing expenses consist of compensation for employees responsible for assessing the commercial opportunity of and developing market awareness and launch plans for our product candidates, professional fees associated with developing brands for our product candidates and maintaining public relations efforts. 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. We intend to capitalize on our management s past experience and expertise with eye-care products by marketing and selling ILUVIEN to the approximately 1,600 retinal specialists practicing in the approximately 900 retina centers across the U.S.

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

***Interest and Other Income***

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

Table of Contents

***Interest Expense***

Beginning in March 2008, we began recognizing interest on our $15.0 million note payable to pSivida at an effective interest rate of 12.64% per annum (this note accrued interest at the rate of 8% per annum from inception through March 31, 2010 and at the rate of 20% per annum effective as of April 1, 2010). On April 27, 2010, we paid pSivida approximately $15.2 million in principal and interest to satisfy the note payable. In October 2010, we received the initial advance of $6.25 million under our Term Loan from Silicon Valley Bank and MidCap Financial LLP and began recognizing interest at an effective interest rate of 13.0% per annum (interest on this term loan is payable monthly at the rate of 11.5% per annum and included a termination payment of 3.0% of the amount advanced). On May 16, 2011, the Lenders and we amended the Term Loan Agreement to, among other things, extend until December 31, 2011 the date by which the FDA must approve the NDA in order for us to receive the second advance under the Term Loan and to increase the amount of the second advance by $4.75 million to $11.0 million. In addition, the maturity date of the Term Loan was extended from October 31, 2013 until April 30, 2014. In connection with the modification of our Term Loan, the termination payment was increased from 3.0% to 4.0% of the amount advanced and the effective interest rate on the initial advance increased to 13.4%.

***Change in Fair Value of Preferred Stock Conversion Feature***

Prior to being converted into common stock in connection with our IPO, our preferred stock contained certain conversion features which were considered embedded derivatives. We accounted for such embedded derivative financial instruments in accordance with ASC 815. We recorded derivative financial instruments as assets or liabilities in our balance sheet measured at their fair value. We recorded the changes in fair value of such instruments as non-cash gains or losses in the statement of operations. The preferred stock conversion feature was eliminated upon the conversion of our preferred stock to common stock in connection with our IPO in April 2010.

***Preferred Stock Accretion***

Prior to our IPO, our preferred stock was recorded at issuance at the proceeds received net of any issuance discounts, issuance costs and the fair value of the conversion features at issuance. The difference between the amount recorded at issuance and the original issue price was accreted on a straight-line basis over a period extending from the date of issuance to the date at which the preferred stock would have become redeemable at the option of the holder. Accretion of the difference ceased upon the conversion of our preferred stock to common stock in connection with our IPO in April 2010.

***Preferred Stock Dividends***

Prior to our IPO, our preferred stock accrued dividends at 8% per annum which were recorded as an increase in the carrying amount of the respective preferred stock. At the time our preferred stock was converted into common stock in connection with our IPO, $1.5 million of dividends accrued on our Series A preferred stock prior to November 17, 2005 were converted into 380,301 shares of our common stock. All other preferred stock dividends were eliminated upon conversion of the underlying preferred stock in April 2010.

***Basic and Diluted Net (Loss) Income Applicable to Common Stockholders per Common Share***

We calculated net loss per share in accordance with ASC 260. We have determined that our previously outstanding Series A, Series B, Series C and Series C-1 preferred stock represent participating securities in accordance with ASC 260. However, since we operate at a loss, and losses are not allocated to the preferred stock, the two class method does not affect our calculation of earnings per share. We had a net loss from continuing operations for all periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive. Dilutive common stock equivalents would include the dilutive effect of convertible securities, common stock options, warrants for convertible securities and warrants for common stock equivalents. Potentially dilutive weighted average common stock equivalents totaled approximately 1,573,933 and 11,581,116 for the nine months ended September 30, 2011 and 2010, respectively, and 1,530,555 and 1,710,555 for the three months ended September 30, 2011 and 2010, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods of net loss from continuing operations because of their anti-dilutive effect. Therefore, for the three and nine months ended September 30, 2011 and 2010, respectively, the weighted average shares used to calculate both basic and diluted loss per share are the same.

***Critical Accounting Policies and Estimates***

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

Table of Contents

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

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

***Research and Development Costs***

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

***Stock-Based Compensation***

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

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

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

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

Total stock-based compensation expense related to all our stock option awards for the three and nine months ended September 30, 2011 and 2010, respectively, was comprised of the following:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| | (Unaudited) (In thousands) | | | |
| Marketing | $ 94 | $ 121 | $ 262 | $ 278 |
| Research and development | 98 | 21 | 285 | 43 |
| General and administrative | 225 | 47 | 869 | 126 |
| Total employee stock-based compensation expense | $ 417 | $ 189 | $ 1,416 | $ 447 |

Table of Contents

***Income Taxes***

We recognize deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of its assets and liabilities in accordance with ASC 740. 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 September 30, 2011 we had federal NOL carry-forwards of approximately $112.1 million and state NOL carry-forwards of approximately $95.6 million, respectively, that are available to reduce future income otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2023 and 2030 and the state NOL carry-forwards will expire at various dates between 2020 and 2030. If it is determined that significant ownership changes have occurred since these NOLs were generated, we may be subject to annual limitations on the use of these NOLs under Internal Revenue Code Section 382 (or comparable provisions of state law). We have not yet completed a formal evaluation of whether our IPO resulted in certain changes in ownership that would limit our ability to utilize a portion of our NOL carry-forwards.

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

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

Table of Contents

**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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| | (In thousands) | | | |
| RESEARCH AND DEVELOPMENT EXPENSES | $ 2,224 | $ 3,276 | $ 5,732 | $ 10,481 |
| GENERAL AND ADMINISTRATIVE EXPENSES | 1,421 | 1,260 | 4,827 | 3,338 |
| MARKETING EXPENSES | 2,612 | 1,583 | 5,038 | 2,209 |
| TOTAL OPERATING EXPENSES | 6,257 | 6,119 | 15,597 | 16,028 |
| INTEREST INCOME | 1 | 37 | 15 | 53 |
| INTEREST EXPENSE | (284) | | (863) | (618) |
| GAIN ON EARLY EXTINGUISHMENT OF DEBT | | | | 1,343 |
| DECREASE (INCREASE) IN FAIR VALUE OF DERIVATIVE | | | | 3,644 |
| LOSS FROM CONTINUING OPERATIONS | (6,540) | (6,082) | (16,445) | (11,606) |

***Three months ended September 30, 2011 compared to the three months ended September 30, 2010***

*Research and development expenses.* Research and development expenses decreased by approximately $1.1 million, or 33.3%, to approximately $2.2 million for the three months ended September 30, 2011 compared to approximately $3.3 million for the three months ended September 30, 2010. The decrease was primarily attributable to decreases of $1.2 million in costs associated with our FAME Study, $380,000 in costs incurred to file marketing applications for ILUVIEN in Austria, France, Germany, Italy, Portugal, Spain and the U.K. in the third quarter of 2010 and $130,000 in costs for technical development as we reach the final stages of the development of the inserter for ILUVIEN, offset by an increase of $510,000 in costs related to the physician utilization study which is being conducted to assess the safety and utility of the commercial version of the inserter for ILUVIEN. The decrease in costs for our FAME Study was primarily attributable to decreases of $910,000 for our CROs and $260,000 for clinical trial site costs as the FAME Study was completed in 2010.

*General and administrative expenses.* General and administrative expenses increased by approximately $160,000, or 12.3%, to approximately $1.4 million for the three months ended September 30, 2011 compared to approximately $1.3 million for the three months ended September 30, 2010.

*Marketing expenses.* Marketing expenses increased by approximately $1.0 million, or 62.5%, to approximately $2.6 million for the three months ended September 30, 2011 compared to approximately $1.6 million for the three months ended September 30, 2010. This increase was primarily attributable to increases of $490,000 in costs related to our advertising agency s development of a detailed advertising and promotional plan for the commercial launch of ILUVIEN, $400,000 in compensation costs related to the hiring of additional personnel in advance of the launch of ILUVIEN and $190,000 in additional pharmaeconomic work to evaluate the pricing of ILUVIEN in the U.S. and Europe.

*Interest expense.* Interest expense was approximately $280,000 for the three months ended September 30, 2011. Interest expense for the three months ended September 30, 2010 was immaterial. Interest expense for the three months ended September 30, 2011 was incurred in connection with our Credit Facility with Silicon Valley Bank and MidCap Financial LLP, secured in the fourth quarter of 2010.

***Income from discontinued operations***

We did not have any income or loss from discontinued operations for either the three months ended September 30, 2011 or the three months ended September 30, 2010.

Table of Contents

***Nine months ended September 30, 2011 compared to the nine months ended September 30, 2010***

*Research and development expenses.* Research and development expenses decreased by approximately $4.7 million, or 44.8%, to approximately $5.7 million for the nine months ended September 30, 2011 compared to approximately $10.5 million for the nine months ended September 30, 2010. The decrease was primarily attributable to decreases of $3.9 million in costs associated with our FAME Study, $1.9 million in costs to file our NDA in the U.S. and marketing applications for ILUVIEN in Austria, France, Germany, Italy, Portugal, Spain, and the U.K. in 2010, offset by increases of $620,000 in costs related to the physician utilization study which is being conducted to assess the safety and utility of the commercial version of the inserter for ILUVIEN. The decrease in costs for our FAME Study was primarily attributable to decreases of $910,000 for our CROs and $260,000 for clinical trial site costs as the FAME Study was completed in 2010 and $500,000 in costs associated with contracting medical science liaisons to engage with retina specialists in the study of ILUVIEN. The decrease in costs for our FAME Study was primarily attributable to decreases of $2.3 million for our CROs, $1.1 million for clinical trial site costs and $370,000 for our third party reading center for the analysis of retinal images as the FAME Study was completed in 2010.

*General and administrative expenses.* General and administrative expenses increased by approximately $1.5 million, or 45.5%, to approximately $4.8 million for the nine months ended September 30, 2011 compared to approximately $3.3 million for the nine months ended September 30, 2010. The increase was primarily attributable to increases of $610,000 in stock compensation expense, $400,000 in personnel costs and $260,000 in costs incurred after our IPO in April 2010 associated with operating as a public company including additional audit, tax and legal fees, increased directors and officers insurance costs, and board of directors compensation.

*Marketing expenses.* Marketing expenses increased by approximately $2.8 million, or 127.3%, to approximately $5.0 million for the nine months ended September 30, 2011 compared to approximately $2.2 for the nine months ended September 30, 2010. The increase was primarily attributable to increases of $1.3 million in compensation costs related to the hiring of additional key personnel in advance of the launch of ILUVIEN, $1.0 million in costs related to our advertising agency s development of a detailed advertising and promotional plan for the commercial launch of ILUVIEN, $200,000 in costs associated with the establishment of our managed care programs, $180,000 in costs relating to pharmaeconomic studies to evaluate the pricing of ILUVIEN in the U.S. and Europe, and $170,000 in additional medical marketing activity as we expand our presence at key industry events and prepare for entry into the European market.

*Interest expense.* Interest expense increased by approximately $240,000, or 38.7%, to approximately $860,000 for the nine months ended September 30, 2011 compared to approximately $620,000 for the nine months ended September 30, 2010. Interest expense for the nine months ended September 30, 2011 was incurred in connection with our Credit Facility with Silicon Valley Bank and MidCap Financial LLP, secured in the fourth quarter of 2010. Interest expense for the nine months ended September 30, 2010 was incurred in connection with our $15.0 million promissory note payable to pSivida, which was repaid in April 2010.

*Decrease in fair value of preferred stock conversion feature.* For the nine months ended September 30, 2010, we recognized a gain of approximately $3.6 million related to the decrease of the fair value of the conversion feature of our preferred stock. The conversion feature of our preferred stock was eliminated in connection with our IPO in April 2010.

***Income from discontinued operations***

We recognized income from discontinued operations during the nine months ended September 30, 2010 of $4.0 million for a payment we received from Bausch & Lomb. This payment was related to the exercise by Bausch & Lomb of its option to extend by two years the period during which it may continue to develop an allergy product acquired from us in 2006. We did not have any income or loss from discontinued operations for the nine months ended September 30, 2011.

***Liquidity and Capital Resources***

We have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of $205.3 million from our inception through September 30, 2011. 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.

Table of Contents

On April 21, 2010, our Registration Statement on Form S-1 (as amended) was declared effective by the SEC for our IPO, pursuant to which we sold 6,550,000 shares of our common stock at a public offering price of $11.00 per share. We received net proceeds of approximately $68.4 million from this transaction, after deducting underwriting discounts and commissions. In October 2010, we obtained a $32.5 million senior secured credit facility to help fund our working capital requirements. The Credit Facility consisted of a $20.0 million Working Capital Revolver and a $12.5 million Term Loan. The Lenders advanced $6.25 million under the Term Loan and the remaining $6.25 million was available for funding following FDA approval of ILUVIEN, but no later than July 31, 2011. On May 16, 2011, we and the Lenders amended the terms of the Credit Facility to among other things, extend the FDA approval deadline for the second advance under the Term Loan to December 31, 2011, and to increase the amount available under the second advance 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. We may draw on the Working Capital Revolver against eligible, domestic accounts receivable, but as of September 30, 2011, no amounts under the Working Capital Revolver were outstanding or available to us.

As of September 30, 2011, we had approximately $38.6 million in cash, cash equivalents and investments in marketable securities. We believe that we have sufficient funds available to fund our operations through the projected launch of ILUVIEN and the expected generation of revenue in early 2012. The commercialization of ILUVIEN is dependent upon approval by the FDA, however, we cannot be sure that ILUVIEN will be approved by the FDA or that, if approved, future sales of ILUVIEN will generate enough revenue to fund the Company s operations beyond its launch. Due to the uncertainty around FDA approval, management cannot be certain that we will not need additional funds for the launch of ILUVIEN. If ILUVIEN is not approved, or if approved, does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

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

As of September 30, 2011, we had $38.6 million in cash, cash equivalents and investments in marketable securities. We have invested a substantial portion of our available cash in money market funds placed with a reputable financial institution for which credit loss is not anticipated. We have established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

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

Table of Contents

For the nine months ended September 30, 2010, cash used in our continuing operations of $16.0 million was primarily due to our net loss from continuing operations of $11.6 million increased by non-cash gains of $3.6 million related to the change in fair value of our preferred stock conversion feature and $1.3 million associated with the repayment of our $15.0 million promissory note to pSivda in April 2010, offset by non-cash charges of $560,000 for stock compensation expense and $150,000 for depreciation and amortization expense. Further increasing our net cash used in continuing operations was an increase in prepaid and other current assets of $320,000 offset by an increase in accounts payable and accrued expenses and other current liabilities of $180,000. The increase in prepaid and other current assets was primarily due to an increase of $180,000 of advances made to the third party manufacturer of ILUVIEN to scale up commercialization and an increase of $150,000 of prepaid annual directors and officers insurance premiums, offset by a reduction of $100,000 of prepaid costs related to our FAME Study and other ancillary clinical studies as work on these studies continued. The increase in accounts payable and accrued expenses and other current liabilities was primarily due to an increase of $250,000 of amounts payable to providers of corporate communications and medical marketing services as pre-launch activities continued.

For the nine months ended September 30, 2011, net cash provided by our investing activities was $25.7 million, which was primarily due to the maturities of investments of marketable securities. For the nine months ended September 30, 2010, net cash used in our investing activities was $36.1 million, which was primarily due to the purchase of $40.0 million of investments of marketable securities and the purchase of $120,000 of computer equipment and software to facilitate the filing of our NDA and for use by new employees, offset by the receipt of $4.0 million from Bausch & Lomb upon the exercise by Bausch & Lomb of its option to extend by two years the period during which it may continue to develop an allergy product acquired from us in 2006.

For the nine months ended September 30, 2011, cash provided by financing activities was $17,000. This was primarily due to proceeds of $340,000 from the exercise of stock options and from the purchase of our stock in connection with our employee stock purchase plan, offset by $270,000 in principal payments to Silicon Valley Bank and MidCap Financial. For the nine months ended September 30, 2010 net cash provided by our financing activities was $62.0 million, which was due primarily to the receipt of net proceeds of $68.4 million, after underwriting discounts and commissions, from our IPO, net proceeds of $10.0 million from the exercise of warrants to purchase shares of our Series C-1 preferred stock, and $520,000 from the exercise of options and warrants to purchase shares of our stock offset by the payment of $1.9 million of costs related to our IPO and by the repayment of our $15.0 million promissory note to pSivida.

***Contractual Obligations and Commitments***

Other than the amendments to our Credit Facility described below, 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, 2010, filed with the SEC on March 25, 2011.

***Our Credit Facility***

***Term Loan***

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 approve 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 (the Term Loan Maturity Date ).

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 then beginning August 2011 we are required to repay the principal in 33 equal monthly installments plus interest at a rate of 11.5%. We are required to pay interest at a rate of 12.5% on the amount borrowed, if any, under Term Loan B through April 30, 2012, and thereafter we will be required to repay the principal in equal monthly installments through

the Term Loan Maturity Date, plus interest at a rate of 12.5%.

Table of Contents

If we repay Term Loan A prior to maturity, we must pay to the Lenders a prepayment fee equal to 5.0% of the total amount of principal then outstanding if the prepayment had occurred within one year after the funding date of Term Loan A ( Term Loan A Funding Date ), 3.0% of such amount if the prepayment occurs between one year and two years after the Term Loan A Funding Date and 1.0% of such amount if the prepayment occurs thereafter (subject to a 50% reduction in the event that the prepayment occurs in connection with an acquisition of us). If Term Loan B is advanced to us, then the amount of the prepayment fee on both Term Loan A and Term Loan B will be reset to 5.0% and the time-based reduction of the prepayment fee will be measured from the funding date of Term Loan B (subject to the same 50% reduction in the event of an acquisition of us), rather than from the Term Loan A Funding Date.

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.

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 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 also hold warrants to purchase an aggregate of up to 69,999 shares of our common stock. Each of these warrants is exercisable only if Term Loan B is advanced to us, has a per share exercise price of $11.00 and has a term of 10 years. In addition, the Lenders will have certain registration rights with respect to the shares of common stock issuable upon exercise of 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 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 our accounts at all financial institutions.

***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 $20,000,000 (the Revolving Loan Agreement ). On May 16, 2011, the Lenders and we amended the Revolving Loan Agreement to extend the maturity date of the Working Capital Revolver from October 31, 2013 to April 30, 2014.

The Working Capital Revolver is a working capital-based revolving line of credit in an aggregate amount of up to the lesser of (i) $20,000,000, or (ii) 85% of eligible domestic accounts receivable. As of September 30, 2011, no amounts under the Working Capital Revolver were 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 pay to Silicon Valley Bank a fee of $400,000 if the termination had occurred within one year after the Effective Date and a fee of $200,000 if the termination occurs more than one year after the Effective Date (each a Termination Fee ), provided in each case that such Termination Fee will be reduced by 50% in the event we are acquired.

Table of Contents

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

***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.

***New Accounting Pronouncements***

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

Table of Contents

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

We are exposed to market risk related to changes in interest rates. As of September 30, 2011, we had approximately $38.6 million in cash, cash equivalents and investments in marketable securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio. We contract for the conduct of some of our clinical trials and other research and development activities with contract research organizations and investigational sites in the U.S., Europe and India. We may be exposed 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**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic reports filed with the SEC is recorded, processed and summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and no evaluation of controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Our management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Under the supervision and with the participation of the our management, including the Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2011. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2011, the end of the period covered by this Quarterly Report on Form 10-Q, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

**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 September 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

## PART II. OTHER INFORMATION

**ITEM 1A** ***Risk Factors***

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the SEC on March 25, 2011, we identify under Item 1A of Part I important factors which could affect our business, financial condition, results of operations and future operations and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Form 10-Q. There have been no material changes in our risk factors subsequent to the filing of our Form 10-K for the fiscal year ended December 31, 2010. However, the risks described in our Form 10-K are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

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

***Recent Sales of Unregistered Securites***

In September 2011, we issued 4,411 shares of our common stock upon the exercise of warrants for an aggregate of $19,000. No underwriters were involved in the sale of such securities. The issuance of the securities was deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) thereof. The recipient of the securities represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the warrant agreements and securities issued in such transactions.

***Use of Proceeds***

On April 21, 2010, our Registration Statement on Form S-1 (File No. 333-162782) was declared effective by the SEC for our IPO, pursuant to which we sold 6,550,000 shares of our common stock at a public offering price of $11.00 per share. We received net proceeds of approximately $66.1 million from this transaction, after deducting underwriting discounts, commissions and other offering costs. On April 27, 2010 we paid $15.2 million to pSivida to satisfy our $15.0 million note payable and accrued but unpaid interest thereon. There have been no material changes in our use or planned use of proceeds from the IPO from that described in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, filed with the SEC on June 7, 2010.

**ITEM 6** ***Exhibits***

| Exhibit Number | Description |
|---|---|
| 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. |

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

Table of Contents

**SIGNATURES**

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

Alimera Sciences, Inc.

/s/ C. Daniel Myers

**C. Daniel Myers**
**Chief Executive Officer and President**
**(Principal executive officer)**

November 7, 2011

/s/ Richard S. Eiswirth, Jr.

**Richard S. Eiswirth, Jr.**
**Chief Operating Officer and Chief Financial Officer**
**(Principal financial and accounting officer)**

November 7, 2011

Table of Contents

**ALIMERA SCIENCES, INC.**
**EXHIBIT INDEX**

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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. |

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.