

ALIMERA SCIENCES INC  
Form 10-Q  
November 13, 2013

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

FORM 10-Q  
(Mark One)

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

For the quarterly period ended September 30, 2013

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 001-34703

Alimera Sciences, Inc.  
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	20-0028718 (I.R.S. Employer Identification No.)
6120 Windward Parkway, Suite 290 Alpharetta, GA	30005 (Zip Code)
(Address of principal executive offices)	
(678) 990-5740 (Registrant's telephone number, including area code)	

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No   
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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

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

As of November 8, 2013, there were 31,610,991 shares of the registrant's common stock issued and outstanding.

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## PART I. FINANCIAL INFORMATION

## ITEM 1. Interim Condensed Consolidated Financial Statements (unaudited)

## ALIMERA SCIENCES, INC.

## CONSOLIDATED BALANCE SHEETS

	September 30, 2013	December 31, 2012
	(In thousands, except share and per share data)	
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 23,104	\$ 49,564
Accounts receivable	464	—
Prepaid expenses and other current assets	3,220	2,029
Inventory (Note 5)	3,030	719
Deferred financing costs	286	95
Total current assets	30,104	52,407
PROPERTY AND EQUIPMENT — at cost less accumulated depreciation	432	114
<b>TOTAL ASSETS</b>	<b>\$ 30,536</b>	<b>\$ 52,521</b>
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 2,746	\$ 1,973
Accrued expenses (Note 6)	1,667	1,179
Outsourced services payable	1,364	2,616
Notes payable (Note 8)	1,528	2,273
Capital lease obligations	9	6
Total current liabilities	7,314	8,047
<b>NON-CURRENT LIABILITIES:</b>		
Derivative warrant liability	10,525	4,418
Notes payable — less current portion (Note 8)	3,472	703
Other non-current liabilities	27	209
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$.01 par value — 10,000,000 shares authorized at September 30, 2013 and December 31, 2012:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 1,000,000 issued and outstanding at September 30, 2013 and at December 31, 2012; liquidation preference of \$40,000 at September 30, 2013 and at December 31, 2012	32,045	32,045
Common stock, \$.01 par value — 100,000,000 shares authorized, 31,591,289 shares issued and outstanding at September 30, 2013 and 31,541,286 shares issued and outstanding at December 31, 2012	316	315
Additional paid-in capital	239,218	237,485
Common stock warrants	417	415
Accumulated deficit	(262,573)	(231,116)
Accumulated other comprehensive loss	(225)	—
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>9,198</b>	<b>39,144</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 30,536</b>	<b>\$ 52,521</b>
See Notes to Consolidated Financial Statements.		

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(In thousands, except share and per share data)			
REVENUE	\$758	\$—	\$937	\$—
COST OF GOODS SOLD	(57	) —	(68	) —
GROSS MARGIN	701	—	869	—
RESEARCH AND DEVELOPMENT EXPENSES	1,780	2,199	5,983	5,636
GENERAL AND ADMINISTRATIVE EXPENSES	2,113	1,506	7,252	4,488
SALES AND MARKETING EXPENSES	4,524	1,503	12,985	3,704
OPERATING EXPENSES	8,417	5,208	26,220	13,828
INTEREST EXPENSE AND OTHER	(134	) (186	) (397	) (629
UNREALIZED FOREIGN CURRENCY GAIN, NET	508	—	552	—
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	6,229	—	(6,107	) —
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	—	(153	) —
NET LOSS	\$(1,113	) \$(5,394	) \$(31,456	) \$(14,457
ACCRETION OF PREFERRED STOCK BENEFICIAL CONVERSION FEATURE	—	—	(4,950	) —
NET LOSS APPLICABLE TO COMMON SHAREHOLDERS	\$(1,113	) \$(5,394	) \$(36,406	) \$(14,457
NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDERS — Basic and diluted	\$(0.04	) \$(0.17	) \$(1.15	) \$(0.46
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	31,591,289	31,465,752	31,570,739	31,443,568

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(In thousands)			
NET LOSS	\$ (1,113 )	\$ (5,394 )	\$ (31,456 )	\$ (14,457 )
OTHER COMPREHENSIVE LOSS				
Foreign currency translation adjustments	(270 )	—	(225 )	—
TOTAL OTHER COMPREHENSIVE LOSS	(270 )	—	(225 )	—
COMPREHENSIVE LOSS	\$ (1,383 )	\$ (5,394 )	\$ (31,681 )	\$ (14,457 )

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

	Nine Months Ended September 30,	
	2013	2012
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(31,456	) \$(14,457
Unrealized foreign currency gain, net	(552	) —
Loss from early extinguishment of debt	153	—
Depreciation and amortization	101	80
Stock-based compensation expense and other	1,597	1,259
Amortization of deferred financing costs and debt discount	118	169
Loss on change in fair value of derivative warrant liability	6,107	—
Changes in assets and liabilities:		
Accounts receivable	(451	) —
Prepaid expenses and other current assets	(1,130	) (204
Inventory	(2,227	) (671
Accounts payable	717	(854
Accrued expenses and other current liabilities	(866	) 117
Other non-current liabilities	(204	) 65
Net cash used in operating activities	(28,093	) (14,496
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Proceeds from maturities of investments	—	500
Purchases of property and equipment	(386	) (15
Net cash (used in) provided by investing activities	(386	) 485
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	59	—
Payment of principal on notes payable	(3,030	) (1,705
Proceeds from issuance of notes payable	5,000	—
Payment of debt costs	(292	) (42
Proceeds from sale of common stock	33	14
Payments on capital lease obligations	(9	) (9
Net cash provided by (used in) financing activities	1,761	(1,742
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS	258	—
NET DECREASE IN CASH AND CASH EQUIVALENTS	(26,460	) (15,753
CASH AND CASH EQUIVALENTS — Beginning of Period	49,564	33,108
CASH AND CASH EQUIVALENTS — End of Period	\$23,104	\$17,355
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for interest	\$511	\$413
Supplemental schedule of non-cash investing and financing activities:		
Property and equipment acquired under capital leases	\$33	\$—
There were no income tax or dividend payments made for the nine months ended September 30, 2013 and 2012.		

See Notes to Consolidated Financial Statements.



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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS

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

The Company is presently focused on diseases affecting the back of the eye, or retina, because the Company's management believes these diseases are not well treated with current therapies and represent a significant market opportunity. The Company's only commercial product is ILUVIEN<sup>®</sup>, which has received marketing authorization in the United Kingdom, Austria, Portugal, France, Germany and Spain, and has been recommended for marketing authorization in Italy, for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. As part of the approval process in these countries, the Company has committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in patients treated per the labeled indication.

The Company launched ILUVIEN in the United Kingdom and Germany in April and May of 2013, respectively, and currently plans to launch ILUVIEN in France in 2014. To date, the majority of the Company's sales have been in Germany. The Company was able to launch in Germany without price restrictions, but continues to work with the statutory health insurance funds in Germany to streamline reimbursement for ILUVIEN.

In January 2013, the United Kingdom's National Institute for Health and Care Excellence (NICE) published final guidance for England and Wales indicating that ILUVIEN does not satisfy NICE's definition of cost effectiveness for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies given the cost of £5,500. The Company submitted a simple patient access scheme (PAS) for ILUVIEN to NICE for consideration under its rapid review facility. In October 2013, the NICE Appraisal Committee issued a positive Final Appraisal Determination recommending ILUVIEN funding for the treatment of pseudophakic eyes in chronic DME patients that are insufficiently responsive to available therapies. The final draft guidance reverses the published guidance issued by NICE on January 23, 2013, and takes into consideration the PAS. The final technology appraisal guidance is expected to be published in November 2013.

On July 24, 2013, the Transparency Commission (Commission de la Transparence or CT) of the French National Health Authority (Haute Autorite de Sante) issued a favorable opinion for the reimbursement and hospital listing of ILUVIEN by the French National Health Insurance for the treatment of chronic DME considered insufficiently responsive to available therapies. In the opinion, ILUVIEN was deemed as providing a "moderate medical benefit" as defined by the Service Medical Rendu. As a result, patients will be reimbursed for 100% of the cost of ILUVIEN under the Affection de Longue Duree, a specific program for severe chronic diseases such as diabetes. When comparing the clinical benefit of ILUVIEN to existing therapies (Amelioration du Service Medical Rendu or ASMR), the CT rated the product at "level IV" which will be used in considering the price and any reimbursement conditions for ILUVIEN in France.

In September 2013, the Company submitted an application to the Medicines and Healthcare Products Regulatory Agency in the United Kingdom, as the Reference Member State, for 10 additional European Union (EU) country approvals through the Mutual Recognition Procedure.

The Company submitted a New Drug Application (NDA) in June 2010 for ILUVIEN in the U.S. with the U.S. Food and Drug Administration (FDA). The Company resubmitted its NDA with revisions in May 2011 and April 2013 to address matters raised in the FDA's Complete Response Letters (CRLs) relating to the NDA. In October 2013, the Company received a third CRL from the FDA stating that the NDA could not be approved in its current form. In the third CRL, the FDA identified clinical and statistical deficiencies and indicated that the benefits of ILUVIEN did not outweigh its risks. Further, the FDA indicated that results from a new clinical trial would need to be submitted, together with at least 12 months of follow-up data for all enrolled patients, to support certain indications previously discussed with the FDA. The FDA suggested that a meeting with the Dermatologic and Ophthalmic Drugs Advisory



Committee may be of assistance in addressing the deficiencies identified above and providing advice whether a patient population can be identified in which the benefits of the drug product might outweigh the risks.

The Company was notified of a January 2014 meeting of the Advisory Committee, shortly after the issuance of the CRL. In a subsequent communication with the FDA, the Company believes it clarified that the purpose of the Advisory Committee meeting is to consider the benefits and risks of ILUVIEN based on existing data available from its FAME Study. The Company believes that if this were a positive meeting, it could lead to further discussions with the FDA regarding the potential approvability of the NDA.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In the third CRL, the FDA also referenced deficiencies in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured. The Company does not believe that these deficiencies will affect its European commercial supply. The Company and its third-party manufacturer are in the process of resolving these deficiencies.

**2. BASIS OF PRESENTATION**

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

The accompanying unaudited interim financial statements and related notes should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2012 and related notes included in the Company's Annual Report on Form 10-K, which was filed with the SEC on March 28, 2013. The financial results for any interim period are not necessarily indicative of the expected financial results for the full year.

**3. ACCOUNTING POLICIES**

The accounting policies followed for quarterly financial reporting are the same as those disclosed in the Notes to Financial Statements included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2012. Certain of the Company's more significant accounting policies adopted in the current year are as follows:

**Segment Reporting**

The Company's chief decision maker is the Chief Executive Officer (CEO). While the CEO is apprised of a variety of financial metrics and information, the business is principally managed on an aggregate basis. All of the Company's revenues are currently, and for the foreseeable future, generated in the European Union (EU). Additionally, the majority of the Company's expenditures and personnel either directly support its efforts in the EU, or cannot be specifically attributed to a geography outside of the EU. Therefore, the Company has only one reportable operating segment. If the Company commercializes ILUVIEN in additional jurisdictions in the future, management expects to report multiple operating segments based on geographic segmentation.

**Translation Policy**

The U.S. dollar is the functional currency for Alimera Sciences, Inc. The Euro is the functional currency for the majority of the Company's operating subsidiaries outside of the U.S.

For Alimera Sciences, Inc., foreign currency assets and liabilities are remeasured into U.S. dollars at end-of-period exchange rates, except for non-monetary balance sheet accounts, which are remeasured at historical exchange rates.

Revenue and expenses are remeasured at average exchange rates in effect during each period, except for those expenses related to the non-monetary balance sheet amounts, which are remeasured at historical exchange rates. Gains or losses from foreign currency remeasurement are included in income.

For the operating subsidiaries outside of the U.S. that are denominated in the Euro, assets and liabilities are translated at end-of-period rates while revenues and expenses are translated at average rates in effect during the period. Equity is translated at historical rates and the resulting cumulative translation adjustments are included as a component of accumulated other comprehensive income.

**Revenue Recognition**

The Company recognizes revenue from its product sales when title passes and the risks and reward of ownership have passed to the customer based on the terms of sale. Title passes generally upon shipment or upon receipt by the customer depending on the agreement with the customer. Precise information regarding the receipt of product by the customer is not always readily available. In these cases, the Company estimates the date of receipt based upon its

shipping policies by geographic location. In the Company's current commercial markets of Germany and the United Kingdom, its shipping policies require delivery within 24 hours of shipment in most instances.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are generated through sales primarily to pharmacies, hospitals and wholesalers. The carrying amount of accounts receivable is reduced by an allowance for doubtful accounts that reflects management's best estimate of the amounts that will not be collected. In addition to reviewing delinquent accounts receivable, management considers many factors in estimating its general allowance, including historical data, experience, customer types, credit worthiness, and economic trends. From time to time, management may adjust its assumptions for anticipated changes in any of those or other factors expected to affect collectability. Provisions for doubtful accounts are charged to operations at the time management determines these accounts may become uncollectable. The Company writes off accounts receivable when management determines they are uncollectable and credits payments subsequently received on such receivables to bad debt expense in the period received. There were no write-offs for the three or nine months periods ended September 30, 2013, and no allowance for doubtful accounts as of September 30, 2013.

Inventory Policy

Inventories are stated at the lower of cost or market with cost determined under the first in, first out (FIFO) method. Included in inventory costs are component parts, work-in-progress and finished goods. The Company relies on third party manufacturers for the production of all inventory and does not capitalize any internal costs. The Company periodically reviews inventories for excess or obsolete inventory and writes down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than that estimated, or if there are any further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-downs will be required.

Recent Accounting Pronouncements

In March 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) No. 2013-05: Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity (ASU 2013-05), which applies to the release of the cumulative translation adjustment resulting from certain events occurring in foreign subsidiaries. ASU 2013-05 is effective for fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2012. The adoption of ASU 2013-05 did not have a material impact on the Company's interim financial statements.

In February 2013, the FASB issued ASU No. 2013-02: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02), which adds new disclosure requirements for items reclassified out of accumulated other comprehensive income. ASU 2013-02 is effective for fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2012. The adoption of ASU 2013-02 did not have a material impact on the Company's interim financial statements.

Foreign Currency Transactions

The Company applies the guidelines as set out in Section 830-20-35 of the FASB Accounting Standards Codification (ASC) 830-20-35, foreign currency transactions (ASC 830-20-35). Pursuant to ASC 830-20-35 foreign currency transactions are transactions denominated in currencies other than U.S. Dollar, the Company's reporting currency or Euro, the functional currency of Alimera Sciences Limited and Alimera Sciences BV. Foreign currency transactions may produce receivables or payables that are fixed in terms of the amount of foreign currency that will be received or paid. A change in exchange rates between the functional currency and the currency in which a transaction is denominated increases or decreases the expected amount of functional currency cash flows upon settlement of the transaction. That increase or decrease in expected functional currency cash flows is a foreign currency transaction gain or loss that generally shall be included in determining net income for the period in which the exchange rate changes. Likewise, a transaction gain or loss (measured from the transaction date or the most recent intervening balance sheet date, whichever is later) realized upon settlement of a foreign currency transaction generally shall be included in determining net income for the period in which the transaction is settled. Pursuant to ASC 830-20-25 the following

shall apply to all foreign currency transactions of an enterprise and its investees: (a) at the date the transaction is recognized, each asset, liability, revenue, expense, gain, or loss arising from the transaction shall be measured and recorded in the functional currency of the recording entity by use of the exchange rate in effect at that date as defined in ASC 830-10-20; and (b) at each balance sheet date, recorded balances that are denominated in currencies other than the functional currency or reporting currency of the recording entity shall be adjusted to reflect the current exchange rate.

Net gains and losses resulting from foreign exchange transactions, if any, are included in the Company's statements of operations.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**4. FACTORS AFFECTING OPERATIONS**

To date the Company has incurred recurring losses, negative cash flow from operations, and has accumulated a deficit of \$262,573,000 from the Company's inception through September 30, 2013. As of September 30, 2013, the Company had approximately \$23,104,000 in cash and cash equivalents.

The Company launched ILUVIEN in the United Kingdom and Germany in April and May of 2013, respectively, and currently plans to launch ILUVIEN in France in 2014. The Company does not expect to have positive cash flow from operations until late 2014, if at all. Due to the limited revenue generated by ILUVIEN to date, the Company may not be able to maintain compliance with covenants under its loan agreements. In an event of default, the Company's lender may call the 2013 Term Loan (Note 8) or restrict the availability of the 2013 Line of Credit (Note 8), and the Company will likely need to raise additional financing. If the Company is unable to obtain additional financing, the Company will need to adjust its commercial plans so that it can continue to operate with its existing cash resources or there may be substantial doubt about its ability to continue as a going concern.

The accompanying interim financial statements have been prepared assuming the Company will continue as a going concern. The interim financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**5. INVENTORY**

Inventory consisted of the following:

	September 30, 2013	December 31, 2012
	(In thousands)	
Component parts (1)	\$291	\$ 35
Work-in-process (2)	1,425	684
Finished goods	1,314	—
Total inventory	\$3,030	\$ 719

(1) Component parts inventory consisted of fluocinolone acetonide (FAc) and manufactured components of the ILUVIEN applicator.

(2) Work-in-process consisted of completed units of ILUVIEN that are undergoing, but have not completed, quality assurance testing as required by regulatory authorities.

**6. ACCRUED EXPENSES**

Accrued expenses consisted of the following:

	September 30, 2013	December 31, 2012
	(In thousands)	
Accrued clinical investigator expenses	\$815	\$ 897
Accrued other compensation expenses	593	237
Other accrued expenses	259	45
Total accrued expenses	\$1,667	\$ 1,179

**7. LICENSE AGREEMENTS**

The Company entered into an agreement with pSivida US, Inc. (pSivida) for the use of FAc in pSivida's proprietary delivery device in February 2005, which was subsequently amended and restated in March 2008. pSivida is a global drug delivery company committed to the biomedical sector and the development of drug delivery products. The Company's agreement with pSivida provides it with a worldwide exclusive license to develop and sell ILUVIEN.



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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

Upon commercialization of ILUVIEN, the Company must share 20% of net profits, by country, and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined by the agreement, with pSivida. In connection with this arrangement the Company is entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits, by country. As of September 30, 2013 and December 31, 2012, the Company was owed \$7,999,000 and \$5,565,000, respectively, in commercialization costs. Due to the uncertainty of future net profits, the Company has fully reserved these amounts in the accompanying interim financial statements. The Company will owe pSivida an additional milestone payment of \$25,000,000 if ILUVIEN is approved by the FDA.

In November 2007, the Company entered into a license agreement with Dainippon Sumitomo Pharma Co., Ltd. (Dainippon) whereby Dainippon granted the Company a non-exclusive, worldwide, royalty free license to patent rights under specific patents and patent applications. The Company paid \$200,000 to Dainippon shortly after the execution of this license agreement and will be required to make an additional payment in the amount of \$200,000 to Dainippon within 30 days following the regulatory approval of ILUVIEN in the United States by the FDA.

## 8. LOAN AGREEMENTS

### 2010 Term Loan

The Company entered into a loan and security agreement with Silicon Valley Bank (SVB) and MidCap Financial LLP (MidCap and together with SVB, the Lenders) in October 2010, which was subsequently amended in May 2011 (as amended, the 2010 Term Loan Agreement). Pursuant to the 2010 Term Loan Agreement, in October 2010 the Company borrowed an aggregate of \$6,250,000 from the Lenders (the 2010 Term Loan). The 2010 Term Loan Agreement also provided for the ability to drawdown an additional \$11,000,000 subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained.

In August 2011, the Company began repaying the outstanding principal under the 2010 Term Loan in 33 equal monthly installments plus interest at a rate of 11.5%. At maturity, the Company was also required to make an additional interest payment equal to 4% of the total amount borrowed. The Company paid to the Lenders an upfront fee of \$62,500 upon execution of the 2010 Term Loan Agreement and an additional fee of \$50,000 in connection with the May 2011 amendment. In accordance with ASC 470-50-40-17, Debt - Modifications and Extinguishments (ASC 470-50-40-17), the Company was amortizing the deferred financing costs on the 2010 Term Loan and the \$50,000 modification fee over the remaining term of the 2010 Term Loan, as modified.

In October 2010, in connection with entering into the 2010 Term Loan, the Company issued the Lenders warrants to purchase up to 39,773 shares of the Company's common stock. Each of the warrants were exercisable upon issuance, had a per-share exercise price of \$11.00 and a term of 10 years. The Company estimated the fair value of warrants granted using the Black-Scholes option pricing model to be \$389,000. The Company allocated a portion of the proceeds from the 2010 Term Loan to the warrants in accordance with ASC 470-20-25-2, Debt Instruments with Detachable Warrants. As a result, the Company recorded a discount of \$366,000 which was amortized to interest expense using the effective interest method. The Lenders were also issued warrants to purchase up to an aggregate of 69,999 additional shares of the Company's common stock, which were exercisable only upon the drawdown of the additional \$11,000,000 subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not



obtained.

In May 2013, the Company repaid all amounts owed to the Lenders under the 2010 Term Loan, including the final interest payment equal to 4% of the total amount borrowed, and a 1.0% prepayment penalty on the then outstanding principal owed to MidCap. In connection with the repayment of the 2010 Term Loan, and in accordance with ASC 470-50-40-17, the Company recognized a loss on early extinguishment of debt of \$153,000 associated with the remaining unamortized deferred

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

financing costs, unamortized discount associated with the Lenders' warrants, the final interest payment, the prepayment penalty and a lender fee and warrants associated with a new term loan.

**Working Capital Revolver**

In October 2010, the Company and SVB entered into a loan and security agreement, which was subsequently amended in May 2011 (as amended, the 2010 Revolving Loan Agreement), pursuant to which the Company obtained a secured revolving line of credit from SVB against eligible U.S. domestic accounts receivable with borrowing availability up to \$20,000,000. Upon entering into the 2010 Revolving Loan Agreement, the Company paid to SVB an upfront fee of \$100,000. As of December 31, 2012, no amounts under the 2010 Revolving Loan Agreement were outstanding or available to the Company. In May 2013, the Company and SVB terminated the 2010 Revolving Loan Agreement.

**2013 Loan Agreement**

In May 2013, Alimera Sciences Limited (Limited), a subsidiary of the Company, entered into a loan and security agreement (2013 Loan Agreement) with SVB to provide Limited with additional working capital for general corporate purposes. Under the 2013 Loan Agreement, SVB has made a term loan (2013 Term Loan) in the principal amount of \$5,000,000 to Limited and has agreed to provide up to an additional \$15,000,000 to Limited under a working capital line of credit (2013 Line of Credit). No advances were made at closing under the 2013 Line of Credit and no amounts were outstanding as of September 30, 2013.

The 2013 Term Loan provides for interest only payments for six months followed by 36 monthly payments of interest, plus principal. Interest on outstanding borrowings under the 2013 Term Loan is payable at the rate of 7.50%. Borrowings under the 2013 Line of Credit will be advanced at 80% of eligible accounts receivable as defined in the 2013 Loan Agreement. Interest is payable on the balance of eligible accounts financed at the rate of 2.75% above SVB's most recently announced "prime rate." Limited is also required to pay SVB on a monthly basis an unused line fee equal to 0.25% per annum of the average unused portion of the 2013 Line of Credit during the preceding month. The maturity dates are June 30, 2015 with respect to the 2013 Line of Credit and October 31, 2016 with respect to the 2013 Term Loan.

In connection with entering into the 2013 Loan Agreement, Limited paid SVB a facility fee of \$25,000. Additionally, the Company re-priced warrants to purchase an aggregate of up to 31,818 shares of the Company's common stock previously issued to SVB in connection with the 2010 Term Loan; 15,909 of which were previously exercisable only upon the drawdown of the additional \$11,000,000 of the 2010 Term Loan subject to FDA approval of the NDA for ILUVIEN by December 31, 2011. Upon re-pricing, each of the warrants was exercisable immediately at a per-share exercise price of \$2.86 and had a remaining term of 7.4 years. The Company estimated the incremental fair value received by SVB using the Black-Scholes option pricing model to be \$46,000. In accordance with ASC 470-50-40-17, the Company expensed the facility fee and incremental value of the warrants associated with the 2013 Term Loan as part of the loss on early extinguishment of the 2010 Term Loan. Warrants to purchase up to an aggregate of 54,090 additional shares of the Company's common stock, which were exercisable only upon the draw down of the additional \$11,000,000 of the 2010 Term Loan subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained, remain outstanding.

In connection with the 2013 Line of Credit, Limited paid a commitment fee of \$100,000. In accordance with ASC 470-50-40-17, the Company capitalized the commitment fee and \$49,000 of deferred financing costs remaining on the 2010 Revolving Loan Agreement as deferred financing costs, which are being amortized over the remaining term of the 2013 Line of Credit.

If Limited repays the 2013 Term Loan prior to October 31, 2016, it will pay to SVB a prepayment penalty of 3% of the total principal amount if the prepayment occurs within one year after the funding date and 2% of the total principal amount if the prepayment occurs between one and two years after the funding date, provided in each case that such prepayment penalty will be reduced by 50% in the event of an acquisition of Limited (either alone, or in connection with the acquisition of the Company or any of its subsidiaries). In addition, if Limited terminates the 2013 Line of

Credit prior to June 30, 2015, it will pay to SVB a termination fee of \$112,500, which will be reduced by 50% in the event of an acquisition described above.

Limited also agreed to customary affirmative and negative covenants and events of default in connection with these arrangements, including, on a consolidated basis, maintenance of a minimum "adjusted quick ratio," tested as of the last day of each month, of at least 1.5:1.0. The adjusted quick ratio is the ratio of (x) the Company's consolidated, unrestricted and unencumbered cash plus net billed trade accounts receivable to (y) the Company's current liabilities (including all obligations owed to SVB) minus the current portion of deferred revenue. The occurrence of an event of default could result in the acceleration of Limited's obligations under the 2013 Loan Agreement and an increase to the applicable interest rate, and would permit SVB to exercise remedies with respect to the collateral under the 2013 Loan Agreement, including foreclosure on the

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Company's intellectual property. As of September 30, 2013, the Company, on a consolidated basis with its subsidiaries, was in compliance with all of the covenants of the 2013 Term Loan and 2013 Line of Credit. Limited's obligations to SVB are secured by a first priority security interest in substantially all of Limited's assets. The Company and certain of its subsidiaries are guarantors of the obligations of Limited to SVB under the 2013 Loan Agreement pursuant to separate guaranty agreements. Pursuant to the guaranties, the Company and these subsidiaries granted SVB a first priority security interest in substantially all of their respective assets.

The weighted average interest rates of the Company's notes payable approximate the rate at which the Company could obtain alternative financing; therefore, the carrying amount of the notes approximated their fair value at December 31, 2012 and September 30, 2013.

**9. LOSS PER SHARE (EPS)**

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

	Three Months Ended		Nine Months Ended	
	September 30, 2013	2012	September 30, 2013	2012
Preferred stock	15,037,594	—	15,037,594	—
Preferred stock warrants	1,352,727	—	737,480	—
Common stock warrants	17,356	3,555	7,743	3,584
Stock options	2,841,419	948,238	2,448,382	956,654
Total	19,249,096	951,793	18,231,199	960,238

**10. PREFERRED STOCK**

On October 2, 2012, the Company closed its preferred stock financing in which it sold units consisting of 1,000,000 shares of Series A Convertible Preferred Stock and warrants to purchase 300,000 shares of Series A Convertible Preferred Stock for gross proceeds of \$40,000,000, prior to the payment of approximately \$560,000 of related issuance costs. The rights, preferences, privileges and restrictions of the Series A Convertible Preferred Stock are set forth in the certificate of designation filed by the Company with the Secretary of State of the State of Delaware on October 1, 2012. Each share of Series A Convertible Preferred Stock, including any shares of Series A Convertible Preferred Stock issued upon exercise of the warrants, is convertible into shares of the Company's common stock at any time at the option of the holder at the rate equal to \$40.00 divided by the then current conversion price (Conversion Price). The initial Conversion Price of \$2.91 was subject to adjustment to \$3.16 or \$2.66 based on the occurrence or non-occurrence of certain events relating to guidance from NICE regarding ILUVIEN, in addition to certain customary price-based anti-dilution adjustments. Each share of Series A Convertible Preferred Stock shall automatically be converted into shares of common stock at the then-effective Conversion Price upon the occurrence of the later to occur of both (i) the Company receives and publicly announces the approval by the FDA of the Company's NDA for ILUVIEN and (ii) the date on which the Company consummates an equity financing transaction pursuant to which the Company sells to one or more third party investors either (a) shares of common stock or (b) other equity securities that are convertible into shares of common stock and that have rights, preference or privileges, senior to or on a parity with, the Series A Convertible Preferred Stock, in each case having an as-converted per share of common stock price of not less than \$10.00 and that results in total gross proceeds to the Company of at least \$30,000,000.

On June 30, 2013, the Conversion Price was automatically adjusted to \$2.66. As a result of the adjustment to the Conversion Price, the value of the common stock underlying the Series A Convertible Preferred Stock at issuance exceeded the amount of the net proceeds allocated to the Series A Convertible Preferred Stock at issuance. Therefore, the Company recorded the contingent beneficial conversion feature of \$4,950,000 as an increase in additional paid in capital. Because the Series A Convertible Preferred Stock was immediately convertible into common stock at the option of the holder on June 30, 2013, the Company immediately accreted the full value of the beneficial conversion feature to the carrying value of the Series A Convertible Preferred Stock on that date.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Each unit sold in the preferred stock financing included a warrant to purchase 0.30 shares of Series A Convertible Preferred Stock at an exercise price equal to \$44.00 per share. At the election of the holder of a warrant, the warrant may be exercised for the number of shares of common stock then issuable upon conversion of the Series A Convertible Preferred Stock that would otherwise be issued upon such exercise at the then-effective Conversion Price. These warrants are considered derivative instruments because the agreements provide for settlement in Series A Convertible Preferred Stock shares or common stock shares at the option of the holder, an adjustment to the warrant exercise price for common shares at some point in the future, and contain anti-dilution provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants are subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. Therefore the warrants were recorded as a liability at issuance. At September 30, 2013 and December 31, 2012, the fair market value of the warrant liability was estimated to be \$10,525,000 and \$4,418,000, respectively. The Company recorded a gain of \$6,229,000 and a loss of \$6,107,000 as a result of the change in fair value of the warrants in the three and nine month periods ended September 30, 2013, respectively.

In the second quarter of 2013, the Company concluded that it was appropriate to classify the derivative warrant liability as a non-current liability because the warrants do not provide for cash settlement, and will be settled in shares of either Series A Convertible Preferred Stock or common stock at the option of the holder. The prior period amount has been reclassified for consistency with the current period presentation. This reclassification had no effect on the reported results of operations.

**11. STOCK INCENTIVE PLANS****Stock Option Plans**

During the three months ended September 30, 2013 and 2012, the Company recorded compensation expense related to stock options of approximately \$599,000 and \$342,000, respectively. During the nine months ended September 30, 2013 and 2012, the Company recorded compensation expense related to stock options of approximately \$1,575,000 and \$1,136,000, respectively. As of September 30, 2013, the total unrecognized compensation cost related to non-vested stock options granted was \$3,722,000 and is expected to be recognized over a weighted average period of 2.50 years. The following table presents a summary of stock option transactions for the three and nine months ended September 30, 2013 and 2012:

	Three Months Ended September 30,		2012		Nine Months Ended September 30,		2012	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period	5,895,838	\$ 2.73	3,698,019	\$ 3.17	5,493,079	\$ 2.67	2,607,446	\$ 3.88
Grants	35,000	3.80	—	—	595,000	3.13	1,127,500	1.71
Forfeitures	(5,000 )	4.38	(9,146 )	6.91	(127,412 )	2.15	(46,073 )	8.32
Exercises	—	—	(2,245 )	1.33	(34,829 )	1.70	(2,245 )	1.33
Options outstanding at period end	5,925,838	2.74	3,686,628	3.16	5,925,838	2.74	3,686,628	3.16
Weighted average per share fair value of options granted during the period	\$ 3.01		\$ —		\$ 2.42		\$ 1.33	

The following table provides additional information related to outstanding stock options, fully vested stock options and stock options expected to vest as of September 30, 2013:

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	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value  (In thousands)
Outstanding	5,925,838	\$2.74	7.10 years	\$9,752
Exercisable	3,062,658	3.08	5.39 years	4,672
Expected to vest	2,157,245	2.54	8.97 years	3,653

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table provides additional information related to outstanding stock options, fully vested stock options and stock options expected to vest as of December 31, 2012:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value  (In thousands)
Outstanding	5,493,079	\$2.67	7.60 years	\$204
Exercisable	2,471,295	3.06	5.24 years	204
Expected to vest	2,172,678	2.55	9.52 years	—

**Restricted Stock Units**

In February 2012, the Company awarded 85,447 restricted stock units (RSUs), to executive officers and employees at a grant date fair value of \$1.70 per RSU. A RSU is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of the RSUs was determined on the date of grant based on the closing price of the Company's common stock on the date of grant, which equals the RSU's intrinsic value. The RSUs were to vest upon the receipt of marketing authorization of ILUVIEN in four of the seven EU countries in which ILUVIEN was recommended for marketing authorization (Note 1). During 2012, the vesting requirements were met and, as a result, the RSUs became fully vested. During the three and nine months ended September 30, 2012, the Company recognized \$36,000 and \$145,000 in compensation expense in connection with the RSUs. The Company did not recognize any compensation expense during the three and nine month periods ended September 30, 2013 in connection with the RSUs.

**12. INCOME TAXES**

In accordance with ASC 740, Income Taxes, the Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of its assets and liabilities. The Company records a valuation allowance against its net deferred tax asset to reduce the net carrying value to an amount that is more likely than not to be realized.

Income tax positions are considered for uncertainty in accordance with ASC 740, Income Taxes. The Company believes that its income tax filing positions and deductions are more likely than not of being sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position; therefore, no liabilities and no related penalties and interest have been recorded. Tax years since 2003 remain subject to examination in Georgia, Tennessee, and on the federal level. The Company does not anticipate any material changes to its uncertain tax positions within the next 12 months.

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

The Company has federal and state net operating loss (NOL) carry-forwards that are available to reduce future income unless otherwise taxable. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code (IRC) Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of the Company were to occur. The Company periodically evaluates its NOL carry-forwards and whether certain changes in ownership have occurred that would limit the Company's ability to utilize a portion of its NOL carry-forwards. If it is determined that significant ownership changes have occurred since the Company generated its NOL carry-forwards, it



may be subject to annual limitations on the use of these NOL carry-forwards under IRC Section 382 (or comparable provisions of state law). The issuance of the Series A Convertible Preferred Stock on October 2, 2012 constituted such a change in ownership. As a result of this change in ownership, the Company performed a formal analysis in connection with IRC Section 382 and determined that approximately \$13,700,000 of its NOLs generated prior to the change in ownership could not be utilized in the future.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 13. FAIR VALUE

The Company has adopted ASC 820, Fair Value Measurements. 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.

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, receivables, and current liabilities approximate their fair value because of their short maturities.

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

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

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

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

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

	September 30, 2013			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents(1)	\$ 16,943	\$—	\$—	\$ 16,943
Assets measured at fair value	\$ 16,943	\$—	\$—	\$ 16,943
Liabilities:				
Derivative warrant liability (2)	\$—	\$ 10,525	\$—	\$ 10,525
Liabilities measured at fair value	\$—	\$ 10,525	\$—	\$ 10,525
	December 31, 2012			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents(1)	\$ 48,943	\$—	\$—	\$ 48,943
Assets measured at fair value	\$ 48,943	\$—	\$—	\$ 48,943
Liabilities:				
Derivative warrant liability (2)	\$—	\$ 4,418	\$—	\$ 4,418
Liabilities measured at fair value	\$—	\$ 4,418	\$—	\$ 4,418

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

(2)The Company uses the Black-Scholes option pricing model and assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in

estimating fair value for the warrants considered to be derivative instruments.



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Overview

Alimera Sciences, Inc., and its subsidiaries (we, Alimera or the Company), is 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 only commercial product is ILUVIEN®, which has received marketing authorization in Austria, the United Kingdom, Portugal, France, Germany and Spain, and has been recommended for marketing authorization in Italy, for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies.

We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and currently plan to launch ILUVIEN in France in 2014. To date, the majority of our sales have been in Germany. We were able to launch in Germany without price restriction, but continue to work with the statutory health insurance funds in Germany to streamline reimbursement for ILUVIEN.

In January 2013, the United Kingdom's National Institute for Health and Care Excellence (NICE) published final guidance for England and Wales indicating that ILUVIEN does not satisfy NICE's definition of cost effectiveness for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies given the cost of £5,500. We submitted a simple patient access scheme (PAS) for ILUVIEN to NICE for consideration under its rapid review facility. In October 2013, the NICE Appraisal Committee issued a positive Final Appraisal Determination recommending ILUVIEN funding for the treatment of pseudophakic eyes in chronic DME patients that are insufficiently responsive to available therapies. The final draft guidance reverses the published guidance issued by NICE on January 23, 2013, and takes into consideration the PAS. The final technology appraisal guidance is expected to be published in November 2013.

On July 24, 2013, the Transparency Commission (Commission de la Transparence or CT) of the French National Health Authority (Haute Autorite de Sante) issued a favorable opinion for the reimbursement and hospital listing of ILUVIEN by the French National Health Insurance for the treatment of chronic DME considered insufficiently responsive to available therapies. In the opinion, ILUVIEN was deemed as providing a "moderate medical benefit" as defined by the Service Medical Rendu. As a result, patients will be reimbursed for 100% of the cost of ILUVIEN under the Affection de Longue Duree, a specific program for severe chronic diseases such as diabetes. When comparing the clinical benefit of ILUVIEN to existing therapies (Amelioration du Service Medical Rendu or ASMR), the CT rated the product at "level IV" which will be used in considering the price and any reimbursement conditions for ILUVIEN in France.

In September 2013, we submitted an application to the Medicines and Healthcare Products Regulatory Agency in the United Kingdom, as the Reference Member State, for 10 additional European Union country approvals through the Mutual Recognition Procedure.

We submitted a New Drug Application (NDA) in June 2010 for ILUVIEN in the U.S. with the U.S. Food and Drug Administration (FDA). We resubmitted our NDA with revisions in May 2011 and April 2013 to address matters raised in the FDA's Complete Response Letters (CRLs) relating to the NDA. In October 2013, we received a third CRL from the FDA stating that the NDA could not be approved in its current form. In the third CRL, the FDA identified clinical and statistical deficiencies and indicated that the benefits of ILUVIEN did not outweigh its risks. Further, the FDA indicated that results from a new clinical trial would need to be submitted, together with at least 12 months of follow-up data for all enrolled patients, to support certain indications previously discussed with the FDA. The FDA suggested that a meeting with the Dermatologic and Ophthalmic Drugs Advisory Committee may be of assistance in addressing the deficiencies identified above and providing advice whether a patient population can be identified in which the benefits of the drug product might outweigh the risks.

We were notified of a January 2014 meeting of the Advisory Committee, shortly after the issuance of the CRL. In a subsequent communication with the FDA, we believe we clarified that the purpose of the Advisory Committee meeting is to consider the benefits and risks of ILUVIEN based on existing data available from our FAME Study. We believe that if this were a positive meeting, it could lead to further discussions with the FDA regarding the potential approvability of the NDA.

In the third CRL, the FDA also referenced deficiencies in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured. We do not believe that these deficiencies will affect our European commercial supply. We and our third-party manufacturer are in the process of resolving these deficiencies.

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We commenced operations on June 4, 2003. Since our inception we have incurred significant losses. As of September 30, 2013, we have accumulated a deficit of \$262.6 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

- complete the registration of ILUVIEN for DME;
- continue to execute the commercial launch of ILUVIEN in the European Union (EU);
- continue to seek regulatory approval of ILUVIEN in the U.S. and other jurisdictions;
- evaluate the use of ILUVIEN for the treatment of other diseases; and
- advance the clinical development of other new product candidates either currently in our pipeline, or that we may license or acquire in the future.

As of September 30, 2013, we had approximately \$23.1 million in cash and cash equivalents.

We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and currently plan to launch ILUVIEN in France in 2014. We do not expect to have positive cash flow from operations until late 2014, if at all. Due to the limited revenue generated by ILUVIEN to date, we may not be able to maintain compliance with covenants under our loan agreements. In an event of default, our lender may call the 2013 Term Loan or restrict the availability of the 2013 Line of Credit, and we will likely need to raise additional financing. If we are unable to obtain additional financing, we will need to adjust our commercial plans so that we can continue to operate with our existing cash resources or there may be substantial doubt about our ability to continue as a going concern.

### Our Agreement with pSivida US, Inc.

We entered into an agreement with pSivida US, Inc. (pSivida) in February 2005, which was subsequently amended and restated in March 2008, for the use of fluocinolone acetonide (FAc) in pSivida's proprietary delivery device. pSivida is a global drug delivery company committed to the biomedical sector and the development of drug delivery products. Our agreement with pSivida provides us with a worldwide exclusive license to develop and sell ILUVIEN, which consists of a tiny polyimide tube with membrane caps that is filled with FAc in a polyvinyl alcohol matrix for delivery to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis). This agreement also provides us with a worldwide non-exclusive license to develop and sell pSivida's proprietary delivery device to deliver other corticosteroids to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis) or to treat DME by delivering a compound to the back of the eye through a direct delivery method through an incision required for a 25-gauge or larger needle. We do not have the right to develop and sell pSivida's proprietary delivery device for indications for diseases outside of the eye or for the treatment of uveitis. Further, our agreement with pSivida permits pSivida to grant to any other party the right to use its intellectual property (i) to treat DME through an incision smaller than that required for a 25-gauge needle, unless using a corticosteroid delivered to the back of the eye, (ii) to deliver any compound outside the back of the eye unless it is to treat DME through an incision required for a 25-gauge or larger needle, or (iii) to deliver non-corticosteroids to the back of the eye, unless it is to treat DME through an incision required for a 25-gauge or larger needle.

The agreement provides that after commercialization of ILUVIEN, pSivida will be entitled to 20% of the net profits, by country, as defined in the amended and restated agreement. In connection with this arrangement we are entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits, by country. As of September 30, 2013 and December 31, 2012, pSivida owed us \$8.0 million and \$5.6 million, respectively, in commercialization costs. Due to the uncertainty of future profits from ILUVIEN, we have fully reserved these amounts in the accompanying unaudited interim financial statements.

We will owe pSivida an additional milestone payment of \$25.0 million if ILUVIEN is approved by the FDA. If we were to enter into any sub-license of ILUVIEN, we must share 20% of net profits and 33% of any lump sum milestone payments received from a sub-licensee, as defined in the agreement, with pSivida.

### Our Loan Agreements

#### 2010 Term Loan

We entered into a loan and security agreement with Silicon Valley Bank (SVB) and MidCap Financial LLP (MidCap and together with SVB, the Lenders) in October 2010, which was subsequently amended in May 2011 (as amended, the 2010 Term Loan Agreement). Pursuant to the 2010 Term Loan Agreement, in October 2010 we borrowed an aggregate of \$6.25 million from the Lenders (the 2010 Term Loan). The 2010 Term Loan Agreement also provided for the ability to drawdown an additional \$11.0 million subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained.

In August 2011, we began repaying the outstanding principal under the 2010 Term Loan in 33 equal monthly installments plus interest at a rate of 11.5%. At maturity, we were also required to make an additional interest payment equal to 4% of the total amount borrowed. We paid to the Lenders an upfront fee of \$62,500 upon execution of the 2010 Term Loan Agreement



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and an additional fee of \$50,000 in connection with the May 2011 amendment. In accordance with the Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) 470-50-40-17, Debt - Modifications and Extinguishments (ASC 470-50-40-17), we were amortizing the deferred financing costs on the 2010 Term Loan and the \$50,000 modification fee over the remaining term of the 2010 Term Loan, as modified.

In October 2010, in connection with entering into the 2010 Term Loan, we issued SVB a warrant to purchase up to 15,909 shares of our common stock and MidCap a warrant to purchase up to 23,864 shares of our common stock. Each of the warrants were exercisable upon issuance, had a per-share exercise price of \$11.00 and a term of 10 years. We estimated the fair value of warrants granted using the Black-Scholes option pricing model to be \$389,000. We allocated a portion of the proceeds from the 2010 Term Loan 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 was amortized to interest expense using the effective interest method. The Lenders were also issued warrants to purchase up to an aggregate of 69,999 additional shares of our common stock, which were exercisable only upon the drawdown of the additional \$11 million subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained. In May 2013, we repaid all amounts owed to the Lenders under the 2010 Term Loan, including the final interest payment equal to 4% of the total amount borrowed, and a 1.0% prepayment penalty on the then outstanding principal owed to MidCap. In connection with the repayment of the 2010 Term Loan, we recognized a loss on early extinguishment of debt of \$153,000 associated with the remaining unamortized deferred financing costs, unamortized discount associated with the Lenders' warrants, the final interest payment, the prepayment penalty and a lender fee and warrants associated with a new term loan.

**2010 Revolving Loan Agreement**

In October 2010, we entered into a loan and security agreement with SVB, which was subsequently amended in May 2011 (as amended, the 2010 Revolving Loan Agreement), pursuant to which we obtained a secured revolving line of credit from SVB against eligible U.S. domestic accounts receivable with borrowing availability up to \$20.0 million. Upon entering into the 2010 Revolving Loan Agreement, we paid to SVB an upfront fee of \$100,000. As of December 31, 2012, no amounts under the 2010 Revolving Loan Agreement were outstanding or available to us. In May 2013, we terminated the 2010 Revolving Loan Agreement.

**2013 Loan Agreement**

On May 7, 2013, Alimera Sciences Limited (Limited), our subsidiary, entered into a loan and security agreement (2013 Loan Agreement) with SVB to provide Limited with additional working capital for general corporate purposes. Under the 2013 Loan Agreement, SVB has made a term loan (2013 Term Loan) in the principal amount of \$5.0 million to Limited and has agreed to provide up to an additional \$15.0 million to Limited under a working capital line of credit (2013 Line of Credit). No advances were made at closing under the 2013 Line of Credit.

The 2013 Term Loan provides for interest only payments for six months followed by 36 monthly payments of interest, plus principal. Interest on outstanding borrowings under the 2013 Term Loan is payable at the rate of 7.50%.

Borrowings under the 2013 Line of Credit will be advanced at 80% of eligible accounts receivable as defined in the 2013 Loan Agreement. Interest is payable on the balance of eligible accounts financed at the rate of 2.75% above SVB's most recently announced "prime rate." Limited is also required to pay SVB on a monthly basis an unused line fee equal to 0.25% per annum of the average unused portion of the 2013 Line of Credit during the preceding month. The maturity dates are June 30, 2015 with respect to the 2013 Line of Credit and October 31, 2016 with respect to the 2013 Term Loan.

In connection with entering into the 2013 Loan Agreement, Limited paid SVB a facility fee of \$25,000. Additionally, we re-priced warrants to purchase an aggregate of up to 31,818 shares of our common stock previously issued to SVB in connection with the 2010 Term Loan; 15,909 of which were previously exercisable only upon the drawdown of the additional \$11.0 million of the 2010 Term Loan subject to FDA approval of the NDA for ILUVIEN by December 31, 2011. Upon re-pricing, each of the warrants was exercisable immediately at a per-share exercise price of \$2.86 and had a remaining term of 7.4 years. We estimated the incremental fair value received by SVB using the Black-Scholes option pricing model to be \$46,000. In accordance with ASC 470-50-40-17, we classified the repayment of the 2010 Term Loan as an extinguishment of debt and expensed the facility fee and incremental value of the warrants associated with the 2013 Term Loan as part of a loss on early extinguishment of the 2010 Term Loan. Warrants to

purchase up to an aggregate of 54,090 additional shares of our common stock, which were exercisable only upon the drawdown of the additional \$11.0 million of the 2010 Term Loan subject to FDA approval of the NDA for ILUVIEN by December 31, 2011, which was not obtained, remain outstanding.

In connection with the 2013 Line of Credit, Limited paid commitment fee of \$100,000. In accordance with ASC 470-50-40-17, we capitalized the commitment fee and \$49,000 of deferred financing costs remaining on the 2010 Revolving Loan Agreement as deferred financing costs, which are being amortized over the remaining term of the 2013 Line of Credit.

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If Limited repays the 2013 Term Loan prior to October 31, 2016, it will pay to SVB a prepayment penalty of 3% of the total principal amount if the prepayment occurs within one year after the funding date and 2% of the total principal amount if the prepayment occurs between one and two years after the funding date, provided in each case that such prepayment penalty will be reduced by 50% in the event of an acquisition of Limited (either alone, or in connection with the acquisition of us or any of our subsidiaries). In addition, if Limited terminates the 2013 Line of Credit prior to June 30, 2015, it will pay to SVB a fee of \$112,500, which termination fee will be reduced by 50% in the event of an acquisition described above.

Limited also agreed to customary affirmative and negative covenants and events of default in connection with these arrangements. Further, we, on a consolidated basis with our subsidiaries, must maintain a minimum "adjusted quick ratio," tested as of the last day of each month, of at least 1.5:1.0. The adjusted quick ratio is the ratio of (x) our consolidated, unrestricted and unencumbered cash plus net billed trade accounts receivable to (y) our current liabilities (including all obligations owed to SVB) minus the current portion of deferred revenue. The occurrence of an event of default could result in the acceleration of Limited's obligations under the 2013 Loan Agreement and an increase to the applicable interest rate, and would permit SVB to exercise remedies with respect to the collateral under the 2013 Loan Agreement, including foreclosure on our intellectual property. As of September 30, 2013, we, on a consolidated basis with our subsidiaries, were in material compliance with all of the covenants of the 2013 Term Loan and 2013 Line of Credit.

Limited's obligations to SVB are secured by a first priority security interest in substantially all of Limited's assets. We and certain of our subsidiaries are guarantors of the obligations of Limited to SVB under the 2013 Loan Agreement pursuant to separate guaranty agreements. Pursuant to the guaranties, we and these subsidiaries granted SVB a first priority security interest in substantially all of our respective assets.

The weighted average interest rates of our notes payable approximate the rate at which we could obtain alternative financing; therefore, the carrying amount of the notes approximated their fair value at December 31, 2012 and September 30, 2013.

Financial Operations Overview

Revenue

We began generating revenue from ILUVIEN in the second quarter of 2013, but do not expect positive cash flow from operations until late 2014, if at all. In addition to generating revenue from product sales, we intend to seek to generate revenue from other sources such as upfront fees, milestone payments in connection with collaborative or strategic relationships, and royalties resulting from the licensing of our product candidates and other intellectual property. We expect any revenue we generate will fluctuate from quarter to quarter as a result of the nature, timing and amount of any milestone payments we may receive from potential collaborative and strategic relationships, as well as revenue we may receive upon the sale of our products to the extent any are successfully commercialized.

Research and Development Expenses

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

- salaries and related expenses for personnel;
- fees paid to consultants and contract research organizations (CRO) in conjunction with independently monitoring clinical trials and acquiring and evaluating data in conjunction with clinical trials, including all related fees such as investigator grants, patient screening, lab work and data compilation and statistical analysis;
- costs incurred with third parties related to the establishment of a commercially viable manufacturing process for our product candidates;
- costs related to production of clinical materials, including fees paid to contract manufacturers;

- costs related to upfront and milestone payments under in-licensing agreements;
- costs related to compliance with FDA, EU or other regulatory requirements;
- consulting fees paid to third-parties involved in research and development activities; and
- costs related to stock options or other stock-based compensation granted to personnel in development functions.

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

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

- the number of sites included in the trials;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the duration of patient follow-up;
- the phase of development the product candidate is in; and
- the efficacy and safety profile of the product candidate.

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

Our only commercial product is ILUVIEN, which has received marketing authorization in the United Kingdom, Austria, France, Germany, Portugal and Spain, and has been recommended for marketing authorization in Italy, for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. ILUVIEN was commercially launched in the United Kingdom and Germany in April and May of 2013, respectively. ILUVIEN has not been approved in the U.S. by the FDA or in any jurisdiction other than as set forth above. In order to grant marketing approval, a 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, information technology and human resources. Other significant costs include facilities costs and professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents. We expect to continue to incur significant costs to comply with the corporate governance, internal control and similar requirements applicable to public companies.

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### Sales and Marketing Expenses

Sales and marketing expenses consist primarily of professional fees and compensation for employees for the assessment of the commercial opportunity of, the development of market awareness for, the pursuit of market reimbursement and the execution of launch plans for ILUVIEN. Other costs include professional fees associated with developing plans for our product candidates and maintaining public relations.

We launched ILUVIEN in the United Kingdom and Germany, in the second quarter of 2013, and currently plan to launch ILUVIEN in France in 2014. We have hired a European management team and, through outsourced third party providers, are developing a commercial infrastructure of approximately thirty people, in the United Kingdom, Germany and France, in management and the field combined including sales representatives, market access personnel and medical science liaisons.

In November 2012, we entered into an agreement with Quintiles Commercial Europe Limited. Under the Agreement, Quintiles Commercial Europe Limited and its affiliates (collectively, Quintiles Commercial) will provide certain services to us in relation to the commercialization of ILUVIEN, in certain countries in Europe under subsequent project orders. Such services may include marketing, brand management, sales promotion and detailing, market access, pricing and reimbursement support, regulatory, medical science liaison and communications and/or other advisory services. Currently we have entered into seven project orders with Quintiles Commercial for the provision of sales, marketing, management, market access and medical science personnel in Germany, the United Kingdom and France. Under these project orders Quintiles Commercial employed 21 persons fully dedicated to Alimera as of September 30, 2013 and expects this number to grow to 30 by December 2013. Quintiles Commercial also employed 8 persons partially dedicated to Alimera in Germany, the United Kingdom and France, and 12 persons partially dedicated to develop market access in the United Kingdom as of September 30, 2013. In accordance with the terms of these project orders, we will incur approximately \$27.2 million in costs with Quintiles Commercial through 2015. During the three and nine month periods ended September 30, 2013, we incurred \$2.1 million and \$6.1 million, respectively, of expense associated with this agreement. At September 30, 2013, \$1.2 million is included in outsourced services payable and \$1.9 million is included in prepaid expenses and other current assets in our accompanying interim financial statements in association with these project orders.

### Interest Expense

Interest expense consists primarily of interest and amortization of deferred financing costs and debt discounts associated with our 2010 Term Loan and 2013 Term Loan.

### Change in Fair Value of Derivative Warrant Liability

Warrants to purchase our Series A Convertible Preferred Stock or common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the Financial Accounting Standards Board Accounting Standards Codification, are classified as liabilities. We record these derivative financial instruments as liabilities in our balance sheet measured at their fair value. We record the changes in fair value of such instruments as non-cash gains or losses in the consolidated statements of operations.

### Basic and Diluted Net Loss Applicable to Common Stockholders per Common Share

We calculated net loss per share in accordance with ASC 260, Earning Per Share. We had a net loss for all periods presented. 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 19,249,096 and 951,793 for the three months ended September 30, 2013 and 2012, respectively, and 18,231,199 and 960,238 for the nine months ended September 30, 2013 and 2012, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods of net loss because of their anti-dilutive effect. Therefore, for the three and nine months ended September 30, 2013 and 2012, the weighted average shares used to calculate both basic and diluted loss per share are the same.

### Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our interim 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



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evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our interim financial statements.

### Clinical Trial Prepaid and Accrued Expenses

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

### Research and Development Costs

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

### Stock-Based Compensation

We have stock option plans which provide for grants of stock options to employees, directors and consultants or other service providers to purchase shares of our common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. Compensation cost is recognized for all stock-based awards based on the grant date fair value in accordance with the provisions of ASC 718, Compensation — Stock Compensation. We recognize the grant date fair value as compensation cost of employee stock-based awards using the straight-line method over the actual vesting period, adjusted for our estimates of forfeiture. Typically, we grant stock options with a requisite service period of four years from the grant date. We have elected to use the Black-Scholes option pricing model to determine the fair value of stock-based awards.

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

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

To estimate the expected term, we utilize the “simplified” method for “plain vanilla” options as discussed within the Securities and Exchange Commission’s (SEC) Statement of Accounting Bulletin (SAB) 107. We believe that all

factors listed within SAB 107 as pre-requisites for utilizing the simplified method are true for us and for our share-based payment arrangements. We intend to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior will be more widely available.

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Total stock-based compensation expense related to all our stock option awards for the three and nine months ended September 30, 2013 and 2012, respectively, was comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
	(in thousands)			
Sales and marketing	\$97	\$57	\$280	\$172
Research and development	96	92	285	277
General and administrative	406	193	1,010	687
Total employee stock option-based compensation expense	\$599	\$342	\$1,575	\$1,136

## Restricted Stock Units

In February 2012, we awarded 85,437 restricted stock units (RSUs), to our executive officers and employees at a grant date fair value of \$1.70 per RSU. A RSU is a stock award that entitles the holder to receive shares of our common stock as the award vests. The fair value of the RSUs was determined on the date of grant based on the closing price of our common stock on the date of grant, which equals the RSU's intrinsic value. The RSUs would vest upon the receipt of marketing approval of ILUVIEN in four of the seven EU countries in which ILUVIEN was recommended for marketing authorization. During 2012, the vesting requirements were met and, as a result, the RSUs became fully vested. During the three and nine months ended September 30, 2012, we recognized \$36,000 and \$145,000 in compensation expense in connection with the RSUs. We did not recognize any compensation expense during the three and nine month periods ended September 30, 2013 in connection with the RSUs.

## Income Taxes

We recognize deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of our assets and liabilities in accordance with ASC 740, Income Taxes. We evaluate the positive and negative evidence bearing upon the realizability of our deferred tax assets on an annual basis. Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of our deferred tax assets due to our history of operating losses, a valuation allowance has been established against our deferred tax asset balances to reduce the net carrying value to an amount that is more likely than not to be realized. As a result we have fully reserved 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. If it is determined that significant ownership changes have occurred since these NOLs were generated, we may be subject to annual limitations on the use of these NOLs under Internal Revenue Code (IRC) Section 382 (or comparable provisions of state law). The issuance of the Series A Convertible Preferred Stock on October 2, 2012 constituted such a change in ownership. As a result of this change in ownership, we performed a formal analysis in connection with IRC Section 382 and determined that approximately \$13.7 million of our NOLs generated prior to the change in ownership could not be utilized in the future. Our remaining NOLs remain subject to future limitation under IRC Section 382. Because our deferred tax assets were fully reserved, there was no impact on our financial statements. In the event that we were to determine that we are able to realize any of our net deferred tax assets in the future, an adjustment to the valuation allowance would increase net income in the period such determination was made. We believe that the most significant uncertainty that will impact the determination of our valuation allowance will be our estimation of the extent and timing of future net income, if any.

We considered our income tax positions for uncertainty in accordance with ASC 740. We believe our income tax filing positions and deductions are more likely than not of being sustained on audit and do not anticipate any adjustments that will result in a material change to our financial position; therefore, we have not recorded ASC 740

liabilities. We recognize accrued interest and penalties related to unrecognized tax benefits as interest expense and income tax expense, respectively, in our statements of operations. Our tax years since 2003 remain subject to examination in Georgia, Tennessee, and on the federal level. We do not anticipate any material changes to our uncertain tax positions within the next 12 months.

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## Results of Operations

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
	(In thousands)			
REVENUE	\$758	\$—	\$937	\$—
COST OF GOODS SOLD	(57	) —	(68	) —
GROSS MARGIN	701	—	869	—
RESEARCH AND DEVELOPMENT EXPENSES	1,780	2,199	5,983	5,636
GENERAL AND ADMINISTRATIVE EXPENSES	2,113	1,506	7,252	4,488
SALES AND MARKETING EXPENSES	4,524	1,503	12,985	3,704
OPERATING EXPENSES	8,417	5,208	26,220	13,828
INTEREST EXPENSE AND OTHER	(134	) (186	) (397	) (629
UNREALIZED FOREIGN CURRENCY GAIN, NET	508	—	552	—
CHANGE IN FAIR VALUE OF DERIVATIVE	6,229	—	(6,107	) —
WARRANT LIABILITY	—	—	(153	) —
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	—	(153	) —
NET LOSS	\$(1,113	) \$(5,394	) \$(31,456	) \$(14,457

Three months ended September 30, 2013 compared to the three months ended September 30, 2012

Revenue. Revenue of approximately \$760,000 was recognized for the three months ended September 30, 2013 in connection with the launch of ILUVIEN in Germany and the United Kingdom in the second quarter of 2013. No revenue was recognized during the three months ended September 30, 2012.

Research and development expenses. Research and development expenses decreased by approximately \$400,000, or 18%, to approximately \$1.8 million for the three months ended September 30, 2013 compared to approximately \$2.2 million for the three months ended September 30, 2012. The decrease was primarily attributable to decreases of \$320,000 in costs related to the completion of the enrollment of the physician utilization study in the fourth quarter of 2012, which was conducted to assess the safety and utility of the commercial version of the applicator for ILUVIEN, and a reduction of \$250,000 in costs related to a consultant engaged to assist with the continued pursuit of approval of ILUVIEN in the U.S., which was offset by an increase of \$210,000 in costs associated with contracting medical science liaisons to engage with retina specialists in the discussion of ILUVIEN in Germany, the United Kingdom and France.

General and administrative expenses. General and administrative expenses increased by approximately \$600,000, or 40%, to approximately \$2.1 million for the three months ended September 30, 2013 compared to approximately \$1.5 million for the three months ended September 30, 2012. The increase was primarily attributable to increases of approximately \$370,000 in costs associated with the hiring of a new managing director of Europe, executive director of finance and other personnel in the first quarter of 2013, \$220,000 in professional and legal fees associated with the establishment of our infrastructure and tax planning for our expansion in Europe, and the registration of common stock underlying our Series A Convertible Preferred Stock issued in October 2012 and \$100,000 in costs for new offices in Germany and the United Kingdom.

Sales and Marketing expenses. Sales and marketing expenses increased by approximately \$3.0 million, or 200%, to approximately \$4.5 million for the three months ended September 30, 2013 compared to approximately \$1.5 million for the three months ended September 30, 2012. The increase was primarily attributable to increases of approximately \$1.9 million in costs associated with contracting with Quintiles Commercial for marketing, brand management, sales

promotion and detailing, market access, pricing and reimbursement support, and communications and/or other advisory services in the EU beginning in the fourth quarter of 2012, \$490,000 in costs associated with conducting local business in the EU as we expand our marketing presence, \$260,000 in advertising and promotion costs in connection with the commercial launch of ILUVIEN in Germany and the United Kingdom, \$210,000 in costs associated with the hiring of new marketing and medical marketing directors in the fourth quarter of 2012 and a market access director in the first quarter of 2013 to support the EU launch of ILUVIEN and

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\$200,000 in costs to pursue pricing and reimbursement for ILUVIEN in the seven countries in which it has received or been recommended for marketing authorization.

Interest expense and other. Interest expense decreased by approximately \$60,000, or 32%, to approximately \$130,000 for the three months ended September 30, 2013 compared to approximately \$190,000 for the three months ended September 30, 2012. Interest expense for the three months ended September 30, 2013 was incurred in connection with our 2013 Term Loan. Interest expense for the three months ended September 30, 2012 was incurred in connection with our 2010 Term Loan. The decrease was primarily attributable to the lower interest rate on the 2013 Term Loan in comparison to the 2010 Term Loan.

Unrealized foreign currency gain, net. We recorded a non-cash unrealized foreign currency gain of approximately \$510,000 for the three months ended September 30, 2013. The unrealized foreign currency gain was primarily attributable to the strengthening of the Euro and the British pound sterling over the third quarter of 2013.

Change in fair value of derivative warrant liability. A decrease in the fair value of our derivative warrant liability resulted in non-cash income of approximately \$6.2 million for the three months ended September 30, 2013. The decreased value of the derivative warrant liability was primarily due to a decrease in the fair market value of our underlying common stock since June 30, 2013.

Nine months ended September 30, 2013 compared to the nine months ended September 30, 2012

Revenue. Revenue of approximately \$940,000 was recognized for the nine months ended September 30, 2013 in connection with the launch of ILUVIEN in Germany and the United Kingdom in the second quarter of 2013. No revenue was recognized during the nine months ended September 30, 2012.

Research and development expenses. Research and development expenses increased by approximately \$400,000, or 7%, to approximately \$6.0 million for the nine months ended September 30, 2013 compared to approximately \$5.6 million for the nine months ended September 30, 2012. The increase was primarily attributable to increases of approximately \$700,000 in costs associated with contracting medical science liaisons to engage with retina specialists in the study of ILUVIEN in Germany, the United Kingdom and France, \$280,000 in costs associated with regulatory consultants engaged to assist with labeling, compliance and maintenance of our marketing authorizations and \$170,000 in costs associated with expanding the manufacturing capabilities for the ILUVIEN inserter to commercial scale in 2013, offset by decreases of \$480,000 in costs related to a consultant engaged to assist with the continued pursuit of approval of ILUVIEN in the U.S. and \$350,000 in costs related to the completion of the enrollment of the physician utilization study, conducted to assess the safety and utility of the commercial version of the applicator for ILUVIEN, in the fourth quarter of 2012.

General and administrative expenses. General and administrative expenses increased by approximately \$2.8 million, or 62%, to approximately \$7.3 million for the nine months ended September 30, 2013 compared to approximately \$4.5 million for the nine months ended September 30, 2012. The increase was primarily attributable to increases of approximately \$870,000 in professional and legal fees associated with the establishment of our infrastructure and tax planning for our expansion in Europe, and the registration of common stock underlying our Series A Convertible Preferred Stock issued in October 2012, \$760,000 in costs associated with the hiring of a new managing director of Europe, executive director of finance and other personnel in the first quarter of 2013, \$260,000 in costs for new offices in Germany and the United Kingdom and \$150,000 in costs associated with our third party logistics provider to support the commercialization of ILUVIEN in Europe.

Sales and Marketing expenses. Sales and marketing expenses increased by approximately \$9.3 million, or 251%, to approximately \$13.0 million for the nine months ended September 30, 2013 compared to approximately \$3.7 million for the nine months ended September 30, 2012. The increase was primarily attributable to increases of approximately \$5.5 million in costs associated with contracting with Quintiles Commercial for marketing, brand management, sales promotion and detailing, market access, pricing and reimbursement support, and communications and/or other advisory services in the EU beginning in the fourth quarter of 2012, \$1.2 million in costs associated with conducting local business in the EU as we expand our marketing presence, \$1.2 million in advertising and promotion costs in connection with the commercial launch of ILUVIEN in Germany and the United Kingdom in 2013, \$460,000 in costs to pursue pricing and reimbursement for ILUVIEN in the seven countries in which it has received or been recommended for marketing authorization, \$420,000 in costs associated with the hiring of new marketing and medical

marketing directors in the fourth quarter of 2012 and a market access director in the first quarter of 2013 to support the EU launch of ILUVIEN and \$210,000 in medical marketing costs.

Interest expense and other. Interest expense decreased by approximately \$230,000, or 37%, to approximately \$400,000 for the nine months ended September 30, 2013 compared to approximately \$630,000 for the nine months ended September 30, 2012. Interest expense for the nine months ended September 30, 2013 was incurred in connection with our 2010 Term Loan and our 2013 Term Loan. Interest expense for the nine months ended September 30, 2012 was incurred in connection with our 2010 Term Loan. The decrease was primarily attributable to lower principal balances on the 2010 Term Loan due to amortization



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payments which began in August 2011, and the lower interest rate on the 2013 Term Loan in comparison to the 2010 Term Loan.

Unrealized foreign currency gain, net. We recorded a non-cash unrealized foreign currency gain of approximately \$550,000 for the nine months ended September 30, 2013. The unrealized foreign currency gain was primarily attributable to the strengthening of the Euro and the British pound sterling over the third quarter of 2013.

Change in fair value of derivative warrant liability. An increase in the fair value of our derivative warrant liability resulted in non-cash expense of approximately \$6.1 million for the nine months ended September 30, 2013. The increased value of the derivative warrant liability was primarily due to an increase in the fair market value of our underlying common stock since December 31, 2012.

**Liquidity and Capital Resources**

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of \$262.6 million from our inception through September 30, 2013. Prior to our IPO in April 2010, we funded our operations through the private placement of common stock, preferred stock, preferred stock warrants and convertible debt, as well as by the sale of certain assets of the non-prescription business in which we were previously engaged. As of September 30, 2013, we had approximately \$23.1 million in cash and cash equivalents. We launched ILUVIEN in the United Kingdom and Germany, in the second quarter of 2013, respectively, and currently plan to launch ILUVIEN in France in 2014. We do not expect to have positive cash flow from operations until late 2014, if at all. Due to the limited revenue generated by ILUVIEN to date, we may not be able to maintain compliance with covenants under our loan agreements. In an event of default, our lender may call the 2013 Term Loan or restrict the availability of the 2013 Line of Credit, and we will likely need to raise additional financing. 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 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 preferred or 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. If we are unable to obtain additional financing, we will need to adjust our commercial plans so that we can continue to operate with our existing cash resources or there may be substantial doubt about our ability to continue as a going concern.

For the nine months ended September 30, 2013, cash used in our operations of \$28.1 million was primarily due to our net loss of \$31.5 million and unrealized foreign currency gain, net of \$550,000 decreased by a non-cash expense of \$6.1 million for a change in our derivative warrant liability and by non-cash stock-based compensation and other expense of \$1.6 million. Further increasing our cash used in operations were net increases of \$2.2 million in inventory as we built ILUVIEN inventory for our commercial launch in Europe, \$590,000 in credits receivable from Quintiles Commercial for excess billings during the third quarter of 2013, \$450,000 in accounts receivable associated with our initial sales of ILUVIEN and \$140,000 of prepaid insurance included in prepaid expenses and other current assets. For the nine months ended September 30, 2012, cash used in our operations of \$14.5 million was primarily due to our net loss of \$14.5 million offset by stock-based compensation and other non-cash expense of \$1.5 million. Further decreasing cash was a decrease in accounts payable, accrued expenses and other current liabilities of \$740,000, and increases in inventory and prepaid expenses and other current assets of \$880,000. The change in accounts payable, accrued expenses and other current liabilities was primarily due to decreases of approximately \$540,000 paid to the administrator of our U.S. reimbursement and patient assistance programs for a termination payment and final billing due to the suspension of our commercialization of ILUVIEN in the U.S., \$500,000 in amounts paid to our CROs, \$240,000 in amounts paid to our legal and professional accounting firms, and \$210,000 in severance payments made to terminated employees associated with our fourth quarter 2011 reduction in force and \$140,000 in amounts paid to vendors performing pharmacoeconomic studies to evaluate the pricing of ILUVIEN in the EU, offset by increases of

approximately \$460,000 in amounts payable to our third party manufacturers of ILUVIEN for inventory and \$240,000 in amounts payable to vendors assisting us in growing our market presence in the EU as the expected launch of ILUVIEN in the EU approaches. The increases in inventory and prepaid expenses and other current assets were primarily due to increases of approximately \$670,000 for inventory and \$110,000 of prepaid insurance. For the nine months ended September 30, 2013, net cash used by our investing activities was approximately \$390,000, which was due to the purchase of back up manufacturing equipment for ILUVIEN.

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

For the nine months ended September 30, 2013, net cash provided by our financing activities was approximately \$1.8 million, which was primarily due to proceeds from the 2013 Term Loan of \$5.0 million offset by the use of approximately \$3.0 million to repay the 2010 Term Loan.

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

### Contractual Obligations and Commitments

In connection with our efforts to obtain the approval of ILUVIEN from the FDA, in February 2012, we engaged a consultant for services related to the continued pursuit of approval of ILUVIEN in the U.S. We recorded charges pertaining to consulting fees related to our agreement with this consultant of \$450,000 and \$700,000 during the three months ended September 30, 2013 and 2012, respectively, and \$1.4 million and \$1.8 million during the nine months ended September 30, 2013 and 2012, respectively. We expect to record an additional \$600,000 in charges in connection with this agreement through March 31, 2014. In addition, we have agreed to pay the consultant \$2.0 million, if, and only if, the FDA approves our NDA for ILUVIEN.

In November 2012, we entered into an agreement with Quintiles Commercial Europe Limited. Under the agreement, Quintiles Commercial Europe Limited and its affiliates (collectively, Quintiles Commercial) will provide certain services to us in connection with the commercialization of ILUVIEN in certain countries in Europe under subsequent project orders. Such services may include marketing, brand management, sales promotion and detailing, market access, pricing and reimbursement support, regulatory, medical science liaison and communications and/or other advisory services. Currently, we have entered into seven project orders with Quintiles Commercial for the provision of services in Germany, the United Kingdom and France. Under the existing project orders, we will incur approximately \$27.2 million in costs with Quintiles Commercial through 2015. During the three and nine month periods ended September 30, 2013 we recorded charges of \$2.1 million and \$6.1 million, respectively, in connection with this agreement. At September 30, 2013, \$1.2 million is included in outsourced services payable and \$1.9 million is included in prepaid expenses and other current assets.

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, 2012, filed with the SEC on March 28, 2013.

### Off-Balance Sheet Arrangements

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

### New Accounting Pronouncements

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

In March 2013, the FASB issued Accounting Standard Update (ASU) No. 2013-05: Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity (ASU 2013-05), which applies to the release of the cumulative translation adjustment resulting from certain events occurring in foreign subsidiaries. ASU 2013-05 is effective for fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2012. The adoption of ASU 2013-05 did not have a material impact on our interim financial statements.

In February 2013, the FASB issued ASU No. 2013-02: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02), which adds new disclosure requirements for items reclassified out of

accumulated other comprehensive income. ASU 2013-02 is effective for fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2012. The adoption of ASU 2013-02 did not have a material impact on our interim financial statements.

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ITEM 3. Qualitative and Quantitative Disclosures About Market Risk

Not applicable.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2013. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2013, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the three months ended September 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

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

ITEM 1A. Risk Factors

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the SEC on March 28, 2013, 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, 2012. However, the risks described in our Form 10-K are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

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

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

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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.
101.INS+	XBRL Instance Document.
101.SCH+	XBRL Taxonomy Extension Schema Document.
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	XBRL Taxonomy Extension Label Link Document.
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document.

+ Users of this data are advised pursuant to Rule 406T of Regulation S-T that this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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

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Signatures

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

ALIMERA SCIENCES, INC.

November 13, 2013

By: /s/ C. Daniel Myers  
C. Daniel Myers  
Chief Executive Officer and President  
(Principal Executive Officer)

November 13, 2013

By: /s/ Richard S. Eiswirth, Jr.  
Richard S. Eiswirth, Jr.  
Chief Operating Officer and Chief Financial Officer  
(Principal Financial and Accounting Officer)



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