ALIMERA SCIENCES INC
Form 10-Q
August 11, 2014
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q
(Mark One)

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

For the quarterly period ended June 30, 2014
or

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x
As of August 7, 2014 there were 40,424,241 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

	June 30, 2014	December 31, 2013
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 41,986	$ 12,628
Accounts receivable, net	1,020	500
Prepaid expenses and other current assets	2,560	3,474
Inventory, net (Note 5)	1,372	1,786
Deferred financing costs	597	250
Total current assets	47,535	18,638
PROPERTY AND EQUIPMENT — at cost less accumulated depreciation	1,123	982
TOTAL ASSETS	$ 48,658	$ 19,620
CURRENT LIABILITIES:		
Accounts payable	$ 1,851	$ 1,735
Accrued expenses (Note 6)	1,118	934
Outsourced services payable	1,236	603
Note payable (Note 8)	—	1,667
Capital lease obligations	10	10
Total current liabilities	4,215	4,949
NON-CURRENT LIABILITIES:		
Derivative warrant liability	21,457	16,381
Note payable, net of discount — less current portion (Note 8)	9,313	3,194
Other non-current liabilities	14	21
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock, $.01 par value — 10,000,000 shares authorized at June 30, 2014 and December 31, 2013:		
Series A convertible preferred stock, 1,300,000 authorized and 850,000 issued and outstanding at June 30, 2014 and 1,000,000 issued and outstanding at December 31, 2013; liquidation preference of $34,000 at June 30, 2014 and $40,000 at December 31, 2013	27,238	32,045
Common stock, $.01 par value — 100,000,000 shares authorized, 40,340,712 shares issued and outstanding at June 30, 2014 and 31,610,991 shares issued and outstanding at December 31, 2013	403	316
Additional paid-in capital	282,384	240,135
Common stock warrants	968	412
Accumulated deficit	(296,989)	(277,345)
Accumulated other comprehensive loss	(345)	(488)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	13,659	(4,925)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 48,658	$ 19,620

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2014 AND 2013

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands, except share and per share data)			
NET REVENUE	$2,190	$179	$4,274	$179
COST OF GOODS SOLD	(376)	(11)	(940)	(11)
GROSS MARGIN	1,814	168	3,334	168
RESEARCH AND DEVELOPMENT EXPENSES	1,809	2,180	4,435	4,203
GENERAL AND ADMINISTRATIVE EXPENSES	2,827	2,429	5,754	5,099
SALES AND MARKETING EXPENSES	3,136	4,898	6,547	8,461
OPERATING EXPENSES	7,772	9,507	16,736	17,763
INTEREST EXPENSE, NET AND OTHER	(325)	(129)	(454)	(263)
UNREALIZED FOREIGN CURRENCY LOSS, NET	(146)	—	(202)	—
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	8,054	(6,742)	(5,076)	(12,336)
LOSS ON EARLY EXTINGUISHMENT OF DEBT	(440)	(153)	(440)	(153)
NET INCOME (LOSS) BEFORE TAXES	1,185	(16,363)	(19,574)	(30,347)
PROVISION FOR TAXES	(69)	—	(69)	—
NET INCOME (LOSS)	$1,116	$(16,363)	$(19,643)	$(30,347)
ACCRETION OF PREFERRED STOCK BENEFICIAL CONVERSION FEATURE	—	(4,950)	—	(4,950)
NET INCOME (LOSS) APPLICABLE TO COMMON STOCKHOLDERS	$1,116	$(21,313)	$(19,643)	$(35,297)
NET INCOME (LOSS) PER SHARE APPLICABLE TO COMMON STOCKHOLDERS — Basic	$0.03	$(0.67)	$(0.52)	$(1.12)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic	40,275,638	31,574,858	38,076,968	31,560,294
NET LOSS PER SHARE APPLICABLE TO COMMON STOCKHOLDERS — Diluted	$(0.16)	$(0.67)	$(0.52)	$(1.12)
WEIGHTED AVERAGE SHARES OUTSTANDING — Diluted	42,548,254	31,574,858	38,076,968	31,560,294

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2014 AND 2013

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands, except share and per share data)			
NET INCOME (LOSS)	$1,116	$(16,363)	$(19,643)	$(30,347)
OTHER COMPREHENSIVE LOSS				
Foreign currency translation adjustments	139	37	143	45
TOTAL OTHER COMPREHENSIVE LOSS	139	37	143	45
COMPREHENSIVE INCOME (LOSS)	$1,255	$(16,326)	$(19,500)	$(30,302)

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013

	Six Months Ended June 30,	
	2014	2013
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(19,643)	$(30,347)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss from early extinguishment of debt	440	153
Depreciation and amortization	69	59
Unrealized foreign currency transaction loss	202	—
Amortization of deferred financing costs and debt discount	94	82
Stock-based compensation expense	1,849	990
Change in fair value of derivative warrant liability	5,076	12,336
Changes in assets and liabilities:		
Accounts receivable	(526)	(129)
Prepaid expenses and other current assets	894	(1,177)
Inventory	400	(1,094)
Accounts payable	122	1,132
Accrued expenses and other current liabilities	827	(902)
Other long-term liabilities	(2)	(201)
Net cash used in operating activities	(10,198)	(19,098)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(210)	(381)
Net cash used in investing activities	(210)	(381)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	334	59
Proceeds from sale of common stock	37,543	33
Payment of issuance cost of common stock	(2,389)	—
Payment of principal on notes payable	(4,861)	(3,067)
Payment of debt extinguishment costs	(246)	—
Proceeds from issuance of notes payable	10,000	5,000
Payment of debt costs	(645)	(223)
Payment of capital lease obligations	(5)	(7)
Net cash provided by financing activities	39,731	1,795
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS	35	45
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	29,358	(17,639)
CASH AND CASH EQUIVALENTS — Beginning of period	12,628	49,564
CASH AND CASH EQUIVALENTS — End of period	$41,986	$31,925
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$224	$183
Supplemental schedule of non-cash investing and financing activities:		
Property and equipment under capital leases	$—	$33

There were no income tax or dividend payments made for the six months ended June 30, 2014 and 2013.

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

The Company is presently focused on diseases affecting the back of the eye, or retina, because the Company's management believes these diseases are not well treated with current therapies and represent a significant market opportunity. The Company's only commercial product is ILUVIEN®, which has received marketing authorization in the United Kingdom, Austria, Portugal, France, Germany, Spain, Italy, Norway and Denmark, and has been recommended for marketing authorization in eight additional European Union (EU) countries, for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN is the first product approved for chronic DME in the EU. As part of the approval process in these countries, the Company has committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients treated per the labeled indication. ILUVIEN has not been approved by the U.S. Food and Drug Administration (FDA), but a New Drug Application (NDA) is currently under review with the FDA. 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 and Portugal in late 2014. 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 October 2013, the United Kingdom's National Institute for Health and Care Excellence (NICE) issued a positive Final Appraisal Determination recommending ILUVIEN funding, taking into consideration a simple patient access scheme (PAS) for the treatment of pseudophakic eyes (eyes with an artificial lens) in chronic DME patients considered insufficiently responsive to available therapies. The final technology appraisal guidance was published in November 2013. NICE requires clinical commissioning groups, National Health Service (NHS) England and Wales, and local public health authorities to comply with the recommendations in the final guidance within three months of its date of publication. The Company began receiving orders for ILUVIEN from several NHS facilities in January 2014, indicating early implementation of the NICE guidance in certain NHS facilities. Further, in February 2014, the Scottish Medicines Consortium, after completing its assessment and review of a similar simple PAS, announced that is has accepted ILUVIEN for restricted use within the NHS Scotland.

In July 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 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. The Company has not yet agreed on a price with the French authorities. When the Company and the French authorities agree on a price for ILUVIEN, 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 , the CT rated the product at "level IV" (Amelioration du Service Medical Rendu or ASMR) 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 (MHRA) in the United Kingdom, as the Reference Member State, for ten additional EU country approvals through the Mutual Recognition Procedure (MRP). In June 2014, the Company received a positive outcome from the Repeat-Use Procedure for ILUVIEN for the treatment of chronic DME in Ireland, the Netherlands, Belgium, Luxembourg, Sweden, Denmark, Finland, Norway, Poland and the Czech Republic. The regulatory process in these countries has entered the national phase in which each country grants marketing authorization. In July 2014, the

Company received the first marketing authorizations resulting from the MRP in Norway and Denmark.
The Company submitted a NDA in June 2010 for ILUVIEN in the U.S. with the 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 also 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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. 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 was notified of a January 2014 meeting of the Advisory Committee, shortly after the issuance of the third CRL. In a subsequent communication with the FDA, the Company believes it clarified that the purpose of the Advisory Committee meeting was to consider the benefits and risks of ILUVIEN based on existing data available from its two completed Phase 3 pivotal clinical trials. A meeting with the FDA in preparation for the Advisory Committee resulted in labeling discussions for ILUVIEN, and the Company and the FDA agreed that the Advisory Committee was no longer necessary.

In March 2014, the Company resubmitted its NDA for ILUVIEN in response to the third CRL. In the resubmission, the Company responded to questions raised in the third CRL, addressed deficiencies noted in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured and provided a safety update, which included commercial experience with ILUVIEN in Europe. In April 2014, the Company was notified by the FDA that the resubmission of its NDA for ILUVIEN had been acknowledged as received by the FDA as a complete class 2 response to the third CRL, and that a Prescription Drug User Fee Act (PDUFA) goal date of September 26, 2014 had been established. The Company does not plan to conduct any new clinical trials in connection with the FDA's review of this submission.

In the third CRL, the FDA also referenced deficiencies in the methods and controls used for the drug product at the third party facility where ILUVIEN is manufactured. In July 2014, the third party facility received a notification from the Los Angeles District of the Department of Health and Human Services (LA District) after their pre-approval and good manufacturing practice inspection of the facility in connection with the Company's NDA. In that notification, the LA District recommended approval of the NDA by the FDA. This is only a recommendation which the FDA is not obligated to follow. Only the FDA can issue an official approval of the NDA.

In July 2014, the Company reached agreement with INFARMED, the marketing authorization body of the Portuguese Ministry of Health, for the pricing and reimbursement of ILUVIEN for the public sector in Portugal. The Company currently plans to make ILUVIEN commercially available in Portugal in late 2014.

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 condensed consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary to present fairly the Company’s interim financial information.

The accompanying unaudited interim condensed consolidated financial statements and related notes should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2013 and related notes included in the Company’s Annual Report on Form 10-K, which was filed with the SEC on March 7, 2014. The financial results for any interim period are not necessarily indicative of the expected financial results for the full year.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

3. SUMMARY OF SIGNIFICANT 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, 2013.

Recent 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 May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)." ASU 2014-09 provides a single, comprehensive revenue recognition model for all contracts with customers. The revenue guidance contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016 for public entities, with no early adoption permitted. The Company is still evaluating the potential impact of adopting this guidance on the financial statements.

In June 2014, the FASB issued ASU 2014-12, "Compensation Stock - Compensation (Topic 718)." ASU 2014-12 applies to all reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. It requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition and follows existing accounting guidance for the treatment of performance conditions. The standard will be effective for annual periods and interim periods within those annual periods beginning after December 15, 2015, with early adoption permitted. The Company is still evaluating the potential impact of adopting this guidance on the financial statements.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. FACTORS AFFECTING OPERATIONS

To date the Company has incurred negative cash flow from operations, and has accumulated a deficit of $296,989,000 from the Company's inception through June 30, 2014. As of June 30, 2014, the Company had approximately $41,986,000 in cash and cash equivalents.

The Company believes that it has sufficient funds available to fund its operations beyond the projected commercialization of ILUVIEN in Germany, the United Kingdom, Portugal and France. The Company does not expect the generation of positive cash flow from operations until late 2015, at the earliest, if at all. If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, the Company may adjust its commercial plans so that it can continue to operate with its existing cash resources or seek to raise additional financing.

The accompanying interim condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company's negative cash flow from operations and accumulated deficit raise substantial doubt about its ability to continue as a going concern. The interim condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

5. INVENTORY

Inventory consisted of the following:

	June 30, 2014	December 31, 2013
	(In thousands)	
Component parts (1)	$152	$266
Work-in-process (2)	607	587
Finished goods	1,267	1,343
Total inventory	2,026	2,196
Inventory reserve	(654)	(410)
Inventory — net	$1,372	$1,786

(1) Component parts inventory consisted of 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:

	June 30, 2014	December 31, 2013
	(In thousands)	
Accrued clinical investigator expenses	$327	$562
Accrued other compensation expenses	725	106
Other accrued expenses	66	266
Total accrued expenses	$1,118	$934

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

7. LICENSE AGREEMENTS

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

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

The Company must share 20% of the net profits of ILUVIEN and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined by the agreement, with pSivida. In connection with this arrangement the Company is entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits. As of June 30, 2014 and December 31, 2013, the Company was owed $12,971,000 and $12,219,000, respectively, in commercialization costs. Due to the uncertainty of future net profits, the Company has fully reserved these amounts in the accompanying interim condensed consolidated financial statements. The Company will owe pSivida an additional milestone payment of $25,000,000 if ILUVIEN is approved by the FDA (the pSivida Milestone Payment).

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

8. LOAN AGREEMENTS

2013 Loan Agreement

In May 2013, Alimera Sciences Limited (Limited) entered into a loan and security agreement (2013 Loan Agreement) with Silicon Valley Bank (SVB) to provide Limited with additional working capital for general corporate purposes. Under the 2013 Loan Agreement, SVB made a term loan (2013 Term Loan) in the principal amount of $5,000,000 to Limited and agreed to provide up to an additional $15,000,000 to Limited under a working capital line of credit (2013 Line of Credit). In connection with the 2013 Loan Agreement, a previous term loan was repaid in full and terminated. In accordance with ASC 470-50-40-17, the Company recognized a loss on early extinguishment of debt of $153,000 during the three and six months ended June 30, 2013, associated with the remaining unamortized deferred financing costs, unamortized discount associated with the warrants issued to the lenders, a final interest payment, a prepayment penalty and a lender fee and warrants associated with the 2013 Loan Agreement. No advances were made at closing under the 2013 Line of Credit and no amounts were outstanding as of December 31, 2013. In April 2014, the 2013 Term Loan was repaid and the 2013 Line of Credit was terminated in connection with the 2014 Loan Agreement described below.

The 2013 Term Loan provided for interest only payments for six months followed by 36 monthly payments of interest, plus principal. Limited made its first amortization payment on the 2013 Term Loan in December 2013. Interest on outstanding borrowings under the 2013 Term Loan were payable at the rate of 7.50%. Borrowings under the 2013 Line of Credit would have been advanced at 80% of eligible accounts receivable as defined in the 2013 Loan Agreement. Interest was payable on the balance of eligible accounts financed at the rate of 2.75% above SVB's most recently announced “prime rate.” Limited was 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 were 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 an earlier term loan. 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 earlier term loan. During the three and six months ended June 30, 2013 the Company incurred interest expense of $11,000 and $44,000, respectively, in connection with the earlier term loan.

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 an earlier line of credit as deferred financing costs, which were being amortized over the remaining term of the 2013 Line of Credit.

Upon repayment of the 2013 Term Loan in April 2014, Limited paid SVB an outstanding loan balance prepayment penalty of $133,000, and an early termination fee of $113,000 in connection with the termination of the 2013 Line of Credit in April 2014.

2014 Loan Agreement

In April 2014, Limited entered into a loan and security agreement (2014 Term Loan) with Hercules Technology Growth Capital, Inc. (Hercules). Under the 2014 Term Loan, Hercules made an advance in the initial principal amount of $10,000,000 to Limited at closing to provide Limited with additional working capital for general corporate purposes and to repay the 2013 Term Loan. Hercules also agreed to provide up to an additional $25,000,000 to Limited upon approval of ILUVIEN by the FDA on or prior to October 31, 2014 to fund the pSivida Milestone Payment. The 2014 Term Loan provides for interest only payments for 18 months. The interest only period may be extended by an additional 18 months if the Company realizes certain revenue thresholds and no event of default has

occurred under the 2014 Loan Agreement. Interest on the 2014 Term Loan accrues at a floating per annum rate equal to the greater of (i) 10.90%, or (ii) the sum of (A) 7.65%, plus (B) the prime rate. Following the interest only period the term loan will be due and payable to Hercules in equal monthly payments of principal and interest through May 1, 2018.

Limited paid to Hercules a facility charge of $262,500 and incurred legal and other fees of approximately $383,000 in connection with the 2014 Term Loan. If Limited repays the 2014 Term Loan prior to maturity, it will pay Hercules a prepayment penalty of 1.25% of the total principal amount repaid.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Limited and the Company, on a consolidated basis with its other subsidiaries, also agreed to customary affirmative and negative covenants and events of default in connection with these arrangements. The occurrence of an event of default could result in the acceleration of Limited's obligations under the Loan Agreement and an increase to the applicable interest rate, and would permit Hercules to exercise remedies with respect to the collateral under the Loan Agreement.

Limited's obligations to Hercules are secured by a first priority security interest in substantially all of Limited's assets, excluding intellectual property. Hercules does, however, maintain a negative pledge on Limited's intellectual property requiring Hercules' consent prior to the sale of such intellectual property. The Company and certain of the Company's other subsidiaries are guarantors of the obligations of Limited to Hercules under the Loan Agreement pursuant to separate guaranty agreements between Hercules and each of Limited and such subsidiaries (Guaranties). Pursuant to the Guaranties, the Company and these subsidiaries granted Hercules a first priority security interest in substantially all of their respective assets excluding intellectual property.

In connection with Limited entering into the 2014 Loan Agreement, the Company entered into a warrant agreement with Hercules to purchase up to 285,016 shares of the Company's common stock at an exercise price of $6.14 per share. Sixty percent of the warrants were exercisable at closing and the remaining 40% will become exercisable if the remaining $25,000,000 is advanced to the Company prior to October 31, 2014.

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 June 30, 2014 and December 31, 2013.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

9. EARNINGS (LOSS) PER SHARE (EPS)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Series A convertible preferred stock	12,781,954	15,037,593	12,781,954	15,037,593
Series A convertible preferred stock warrants	—	4,511,279	4,511,279	4,511,279
Common stock warrants	248,964	152,567	248,964	152,567
Stock options	7,599,768	5,895,838	7,599,768	5,895,838
Total	20,630,686	25,597,277	25,141,965	25,597,277

The following table sets forth the computation of basic and diluted EPS:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Numerator:				
Numerator for basic EPS - net income (loss) applicable to common stockholders	$1,116,000	$(21,313,000)	$(19,643,000)	$(35,297,000)
Effect of dilutive securities:				
Change in fair value of derivative warrant liability (Note 10)	(8,054,000)	—	—	—
Numerator for diluted EPS - net loss applicable to common stockholders after assumed conversions	$(6,938,000)	$(21,313,000)	$(19,643,000)	$(35,297,000)
Denominator:				
Denominator for basic EPS - weighted average shares outstanding	40,275,638	31,574,858	38,076,968	31,560,294
Effect of dilutive securities:				
Preferred stock warrants (Note 10)	2,272,616	—	—	—
Denominator for diluted EPS - adjusted weighted average shares and assumed conversions outstanding	42,548,254	31,574,858	38,076,968	31,560,294
Basic EPS	0.03	(0.67)	(0.52)	(1.12)
Diluted EPS	(0.16)	(0.67)	(0.52)	(1.12)

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

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 powers, preferences and rights 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 of the Series A Convertible Preferred Stock 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. The rights and preferences of Series A Convertible Preferred Stock also place limitations on the Company's ability to declare or pay any dividend or distribution on any shares of capital stock.

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.

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 June 30, 2014 and December 31, 2013, the fair market value of the warrants was estimated to be $21,457,000 and $16,381,000, respectively. During the three months ended June 30, 2014 and 2013, the Company recorded a gain of $8,054,000 and a loss of $6,742,000, respectively, as a result of the change in fair value of the warrants. During the six months ended June 30, 2014 and 2013, the Company recorded losses of $5,076,000 and $12,336,000, respectively, as a result of the change in fair value of the warrants.

In April 2014, 2,255,639 shares of common stock were issued pursuant to a conversion of 150,000 shares of Series A Preferred Stock held by an investor.

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

11. COMMON STOCK

In January 2014, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company sold an aggregate of 6,250,000 shares of its common stock at a purchase price of $6.00 per share. Gross proceeds from the offering were $37,500,000 prior to the payment of approximately $2,389,000 of related issuance costs. Proceeds from the private placement are expected to be used for general corporate and working capital purposes.

During the three and six months ended June 30, 2014 and 2013, 23,487 and 15,174 shares of the Company's common stock were acquired through its employee stock purchase plan resulting in proceeds of $43,000 and $33,000, respectively.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

12. STOCK INCENTIVE PLANS

Stock Option Plans

During the three months ended June 30, 2014 and 2013, the Company recorded compensation expense related to stock options of approximately $904,000 and $448,000, respectively. During the six months ended June 30, 2014 and 2013, the Company recorded compensation expense related to stock options of approximately $1,829,000 and $976,000, respectively. As of June 30, 2014, the total unrecognized compensation cost related to non-vested stock options granted was $5,668,000 and is expected to be recognized over a weighted average period of 2.63 years. The following table presents a summary of stock option activity for the three and six months ended June 30, 2014 and 2013:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2014		2013		2014		2013	
	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	7,408,977	$2.76	5,849,838	$2.63	7,566,438	$2.74	5,493,079	$2.67
Grants	315,000	5.66	172,500	5.26	315,000	5.66	560,000	3.09
Forfeitures	(99,167)	2.54	(106,500)	1.66	(99,167)	2.54	(122,412)	2.06
Exercises	(25,042)	1.88	(20,000)	1.33	(182,503)	1.83	(34,829)	1.70
Options outstanding at period end	7,599,768	2.88	5,895,838	2.73	7,599,768	2.88	5,895,838	2.73
Options exercisable at period end	3,903,668	3.15	2,836,201	3.05	3,903,668	3.15	2,836,201	3.05
Weighted average per share fair value of options granted during the period	$4.50		$4.01		$4.50		$2.38	

The following table provides additional information related to outstanding stock options, exercisable stock options, and stock options expected to vest as of June 30, 2014:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
				(In thousands)
Outstanding	7,599,768	$2.88	7.35 years	$25,657
Exercisable	3,903,668	3.15	5.79 years	12,963
Expected to vest	2,966,181	2.63	8.93 years	10,108

The following table provides additional information related to outstanding stock options, exercisable stock options, and stock options expected to vest as of December 31, 2013:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
				(In thousands)
Outstanding	7,566,438	$2.74	7.63 years	$17,759
Exercisable	3,304,981	3.09	5.45 years	7,589
Expected to vest	3,469,118	2.48	9.25 years	8,314

Employee Stock Purchase Plan

During the three months ended June 30, 2014 and 2013, the Company recorded compensation expense related to its employee stock purchase plan of approximately $12,000 and $7,000, respectively. During the six months ended June 30, 2014 and 2013, the Company recorded compensation expense related to its employee stock purchase plan of approximately $20,000 and $13,000, respectively.

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

13. 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 at the enacted tax rates in effect for the year in which the differences are expected to reverse. 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.

At the end of each interim period, the Company makes its best estimate of the effective tax rate expected to be applicable for the full fiscal year. This estimate reflects, among other items, the Company's best estimate of operating results and foreign currency exchange rates. The Company's quarterly income tax rate may differ from its estimated annual effective tax rate because accounting standards require the Company to exclude the actual results of certain entities expected to generate a pretax loss when applying the estimated annual effective tax rate to the Company's consolidated pretax results in interim periods. In estimating the annual effective tax rate, the Company does not include the estimated impact of unusual and/or infrequent items, including the reversal of valuation allowances, which may cause significant variations in the customary relationship between income tax expense (benefit) and pretax income (loss) in quarterly periods. The income tax expense (benefit) for such unusual and/or infrequent items is recorded in the quarterly period such items are incurred.

The Company's income tax expense and resulting effective tax rate are based upon the respective estimated annual effective tax rates applicable for the respective periods adjusted for the effects of items required to be treated as discrete to the period, including changes in tax laws, changes in estimated exposures for uncertain tax positions and other items. The Company's effective tax rate for the three months ended June 30, 2014 properly excluded tax benefits associated with year-to-date pre-tax losses generated in the U.S. and the Netherlands. Income tax positions are considered for uncertainty in accordance with ASC 740-10. The Company believes that its income tax filing positions and deductions are more likely than not to be sustained on audit and the Company does not anticipate any adjustments that will result in a material change in its financial position; therefore, no ASC 740-10 liabilities and no related penalties and interest have been recorded. The Company does not anticipate any material changes to its uncertain tax positions within the next 12 months. Tax years since 2003 remain subject to examination in Georgia, Tennessee, and at the federal level. The time period is longer than the standard statutory 3-year period due to net operating losses (NOLs) from 2003 being available for utilization. The statute of limitations on these years will close when the NOLs expire or when the statute closes on the years in which the NOLs are utilized.

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 its financial position and results of operations.

At December 31, 2013, the Company had federal NOL carryforwards of approximately $82,380,000 and state NOL carryforwards of approximately $65,840,000 available to reduce future income. The Company's federal NOL carry-forwards remain fully reserved as of June 30, 2014. If not utilized, the federal NOL carryforwards will expire at various dates between 2028 and 2032 and the state NOL carryforwards will expire at various dates between 2020 and 2032.

The Company's NOL carryforwards 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 carryforwards and whether certain changes in ownership,

including its IPO, have occurred that would limit its ability to utilize a portion of the Company's NOL carryforwards. If it is determined that significant ownership changes have occurred since the Company generated its NOL carryforwards, the Company may be subject to annual limitations on the use of these NOL carryforwards under IRC Section 382 (or comparable provisions of state law).

The Company's foreign subsidiaries commenced business during 2013. One of these subsidiaries has incurred losses to date, and the NOL carryforwards of this foreign entity are fully reserved as of June 30, 2014. The Company has not recorded a deferred tax asset for the excess of tax over book basis in the stock of its foreign subsidiaries. The Company intends to indefinitely reinvest in its foreign subsidiaries all undistributed earnings of and original investments in such subsidiaries. As a result, the Company does not expect to record deferred tax liabilities in the future related to excesses of book over tax basis in the stock of its foreign subsidiaries in accordance with ASC 740-30-25.

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

14. FAIR VALUE

The Company applies ASC 820, Fair Value Measurements, in determining the fair value of certain assets and liabilities. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date. In determining fair value, the Company uses various valuation approaches. The hierarchy of those valuation approaches is broken down into three levels based on the reliability of inputs as follows:

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

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

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

There have been no changes in the methodologies used at June 30, 2014 and December 31, 2013.

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

	June 30, 2014			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents (1)	$29,194	$—	$—	$29,194
Assets measured at fair value	$29,194	$—	$—	$29,194
Liabilities:				
Derivative warrant liability (2)	$—	$21,457	$—	$21,457
Liabilities measured at fair value	$—	$21,457	$—	$21,457

	December 31, 2013			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents (1)	$6,944	$—	$—	$6,944
Assets measured at fair value	$6,944	$—	$—	$6,944
Liabilities:				
Derivative warrant liability (2)	$—	$16,381	$—	$16,381
Liabilities measured at fair value	$—	$16,381	$—	$16,381

(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. Assumptions used are generally consistent with those disclosed for stock based compensation (see Note 12).

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND PROJECTIONS

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

- uncertainty as to our ability to successfully commercialize ILUVIEN in the European Union (EU);
- our limited sales and marketing infrastructure;
- delay in or failure to obtain regulatory approval of ILUVIEN in additional countries or any future products or product candidates;
- our inability to successfully market and sell ILUVIEN following regulatory approval in additional markets;
- uncertainty as to the pricing and reimbursement guidelines for ILUVIEN or any future products or product candidates, including ILUVIEN in the various EU countries;
- uncertainty as to the relationship between the benefits of ILUVIEN or any future products or product candidates and the risks of their side-effect profiles;
- dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality;
- the extent of government regulations;
- uncertainty of clinical trial results;
- our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility; and
- our ability to raise sufficient additional financing.

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

We encourage you to read the discussion and analysis of our financial condition and our unaudited interim financial statements contained in this report. We also encourage you to read Item 1A of Part II of this quarterly report on Form 10-Q entitled “Risk Factors” and Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of this quarterly report on Form 10-Q, other unknown or unpredictable factors also could affect our results. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

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Overview

Alimera Sciences, Inc., and its wholly-owned 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. We were formed on June 4, 2003 under the laws of the State of Delaware.

Our only commercial product is ILUVIEN®, which has received marketing authorization in the United Kingdom, Austria, Portugal, France, Germany, Spain, Italy, Norway and Denmark, and has been recommended for marketing authorization in eight additional European Union (EU) countries, for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN is the first product approved for chronic DME in the EU. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients treated per the labeled indication. ILUVIEN has not been approved by the U.S. Food and Drug Administration (FDA), but a New Drug Application (NDA) is currently under review with the FDA.

We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and currently plans to launch ILUVIEN in France and Portugal in late 2014. 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 (eyes with an artificial lens) in chronic DME patients considered insufficiently responsive to available therapies and the final technology appraisal guidance was published in November 2013. The technology appraisal guidance reverses the published guidance issued by NICE in January 2013, and takes into consideration the PAS. NICE requires clinical commissioning groups, National Health Service (NHS) England and Wales and local public health authorities to comply with the recommendations in the final guidance within three months of its date of publication. We began receiving orders for ILUVIEN from several NHS facilities in January 2014, indicating early implementation of the NICE guidance in certain NHS facilities. Further, in February 2014, the Scottish Medicines Consortium, after completing its assessment and review of a similar simple PAS, announced that is has accepted ILUVIEN for restricted use within the NHS Scotland.

In July 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 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. We have not yet agreed on a price with the French authorities. When we agree on a price with the French authorities, 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 , the CT rated the product at "level IV" (Amelioration du Service Medical Rendu or ASMR)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 ten additional EU country approvals through the Mutual Recognition Procedure (MRP). In June 2014, we received a positive outcome from the Repeat-Use Procedure for ILUVIEN for the treatment of chronic DME in Ireland, the Netherlands, Belgium, Luxembourg, Sweden, Denmark, Finland, Norway, Poland and the Czech Republic. The regulatory process in these countries has entered the national phase in which each country grants marketing authorization. In July 2014, we received the first marketing

authorizations resulting from the MRP in Norway and Denmark.

We submitted a NDA in June 2010 for ILUVIEN in the U.S. with the 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 also 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

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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. 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 were notified of a January 2014 meeting of the Advisory Committee shortly after the issuance of the third CRL. In a subsequent communication with the FDA, we believe we clarified that the purpose of the Advisory Committee meeting was to consider the benefits and risks of ILUVIEN based on existing data available from our two completed Phase 3 pivotal clinical trials (collectively, our FAME Study). A meeting with the FDA in preparation for the Advisory Committee resulted in labeling discussions for ILUVIEN, and we and the FDA agreed that the Advisory Committee was no longer necessary.

In March 2014, we resubmitted our NDA for ILUVIEN in response to the third CRL. In the resubmission, we responded to questions raised in the third CRL, addressed deficiencies noted in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured and provided a safety update, which included commercial experience with ILUVIEN in Europe. In April 2014, we were notified by the FDA that the resubmission of our NDA for ILUVIEN had been acknowledged as received by the FDA as a complete class 2 response to the third CRL, and that a Prescription Drug User Fee Act (PDUFA) goal date of September 26, 2014 had been established. We do not plan to conduct any new clinical trials in connection with the FDA's review of this submission.

In the third CRL, the FDA also referenced deficiencies in the methods and controls used for the drug product at the third party facility where ILUVIEN is manufactured. In July 2014, the third party facility received a notification from the Los Angeles District of the Department of Health and Human Services (LA District) after their pre-approval and good manufacturing practice inspection of the facility in connection with our NDA. In that notification, the LA District recommended approval of the NDA by the FDA. This is only a recommendation which the FDA is not obligated to follow. Only the FDA can issue an official approval of the NDA.

In July 2014, we reached agreement with INFARMED, the marketing authorization body of the Portuguese Ministry of Health, for the pricing and reimbursement of ILUVIEN for the public sector in Portugal. We currently plan to make ILUVIEN commercially available in Portugal in late 2014.

We commenced operations on June 4, 2003. Since our inception we have incurred significant losses. As of June 30, 2014, we have accumulated a deficit of $297.0 million. We expect to incur substantial losses as we:

- continue the commercialization of ILUVIEN in the EU;
- continue to seek regulatory approval of ILUVIEN in the U.S. and other jurisdictions;
- commercialize ILUVIEN in the U.S. if approved by the FDA;
- evaluate the use of ILUVIEN for the treatment of other diseases; and
- advance the clinical development of any future products or product candidates either currently in our pipeline, or that we may license or acquire in the future.

As of June 30, 2014, we had approximately $42.0 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 and Portugal in late 2014. We do not expect to have positive cash flow from operations until late 2015, 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 2014 Loan Agreement, and we would most 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.

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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. In connection with this arrangement we are entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits. As of June 30, 2014 and December 31, 2013, pSivida owed us $13.0 million and $12.2 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 condensed consolidated financial statements.

We will owe pSivida an additional milestone payment of $25.0 million if ILUVIEN is approved by the FDA (the pSivida Milestone Payment). 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

2013 Loan Agreement

In May 2013, Alimera Sciences Limited (Limited), our subsidiary, entered into a loan and security agreement (2013 Loan Agreement) with Silicon Valley Bank (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). In connection with the 2013 Loan Agreement, a previous term loan was repaid in full and terminated. In accordance with ASC 470-50-40-17, we recognized a loss on early extinguishment of debt of $153,000 during the three and six months ended June 30, 2013, associated with the remaining unamortized deferred financing costs, unamortized discount associated with the warrants issued to the lenders, a final interest payment, a prepayment penalty and a lender fee and warrants associated with the 2013 Loan Agreement. No advances were made at closing under the 2013 Line of Credit and no amounts were outstanding as of December 31, 2013, respectively. In April 2014, the 2013 Term Loan was repaid and the 2013 Line of Credit was terminated in connection with the 2014 Loan Agreement described below.

The 2013 Term Loan provided for interest only payments for six months followed by 36 monthly payments of interest, plus principal. We made our first amortization payment on the 2013 Term Loan in December 2013. Interest on outstanding borrowings under the 2013 Term Loan were payable at the rate of 7.50%. Borrowings under the 2013 Line of Credit would have been advanced at 80% of eligible accounts receivable as defined in the 2013 Loan Agreement. Interest was payable on the balance of eligible accounts financed at the rate of 2.75% above SVB's most recently announced "prime rate." Limited was 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 were 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 an earlier term loan. 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 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 earlier term loan.

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In connection with the 2013 Line of Credit, Limited paid a 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 an earlier line of credit as deferred financing costs, which were being amortized over the remaining term of the 2013 Line of Credit. Upon repayment of the 2013 Term Loan in April 2014, Limited paid SVB an outstanding loan balance prepayment penalty of $133,000, and an early termination fee of $113,000 in connection with the termination of the 2013 Line of Credit in April 2014.

2014 Loan Agreement

In April 2014, Limited entered into a loan and security agreement (2014 Loan Agreement) with Hercules Technology Growth Capital, Inc. (Hercules). Under the 2014 Loan Agreement, Hercules made a term loan advance in the initial principal amount of $10.0 million to Limited at closing to provide Limited with additional working capital for general corporate purposes and to repay the 2013 Term Loan. Hercules also agreed to provide up to an additional $25.0 million to Limited upon approval of ILUVIEN by the FDA on or prior to October 31, 2014 to fund the pSivida Milestone Payment. The 2014 Term Loan provides for interest only payments for 18 months. The interest only period may be extended by an additional 18 months if we realize certain revenue thresholds and no event of default has occurred under the 2014 Loan Agreement. Interest on the 2014 Term Loan accrues at a floating per annum rate equal to the greater of (i) 10.90%, or (ii) the sum of (A) 7.65%, plus (B) the prime rate. Following the interest only period the term loan will be due and payable to Hercules in equal monthly payments of principal and interest through May 1, 2018.

Limited paid to Hercules a facility charge of $262,500 and incurred legal and other fees of approximately $383,000 in connection with the 2014 Term Loan. If Limited repays the Term Loan prior to maturity, it will pay Hercules a prepayment penalty of 1.25% of the total principal amount repaid.

We also agreed to customary affirmative and negative covenants and events of default in connection with these arrangements. The occurrence of an event of default could result in the acceleration of Limited’s obligations under the Loan Agreement and an increase to the applicable interest rate, and would permit Hercules to exercise remedies with respect to the collateral under the Loan Agreement.

Limited’s obligations to Hercules are secured by a first priority security interest in substantially all of Limited’s assets, excluding intellectual property. Hercules does, however, maintain a negative pledge on Limited’s intellectual property requiring Hercules' consent prior to the sale of such intellectual property. We and certain of our subsidiaries are guarantors of the obligations of Limited to Hercules under the Loan Agreement pursuant to separate guaranty agreements between Hercules and each of Limited and such subsidiaries (Guaranties). Pursuant to the Guaranties, we and these subsidiaries granted Hercules a first priority security interest in substantially all of their respective assets excluding intellectual property.

In connection with Limited entering into the 2014 Loan Agreement, we entered into a warrant agreement with Hercules to purchase up to 285,016 shares of our common stock at an exercise price of $6.14 per share. Sixty percent of the warrants were exercisable at closing and the remaining 40% will become exercisable if the remaining $25.0 million is advanced to us prior to October 31, 2014.

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 June 30, 2014 and December 31, 2013.

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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 2015, 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 ILUVIEN or any future 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 products or 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 products or product candidates;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- costs related to the provision of medical affairs support, including symposia development for physician education;
- costs related to compliance with FDA, EU or other regulatory requirements;
- consulting fees paid to third-parties involved in research and development activities; and
- costs related to stock options or other stock-based compensation granted to personnel in development functions.

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

Our only commercial product is ILUVIEN, which has received marketing authorization in the United Kingdom, Austria, France, Germany, Portugal, Spain, Italy, Norway and Denmark, and has been recommended for marketing authorization in eight additional EU countries, for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. ILUVIEN has not been approved in the U.S. by the FDA or in any jurisdiction other than as set forth above. In order to grant marketing approval, a health authority such as the FDA or foreign regulatory agencies must conclude that clinical and preclinical data establish the safety and efficacy of ILUVIEN or any future products or 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 whether ILUVIEN or any future products or 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

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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.

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 ILUVIEN or any future products or product candidates and maintaining public relations.

We launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013, and plan to launch ILUVIEN in Portugal and France in late 2014. We expect significant increases in our marketing and selling expenses as we continue the commercialization of ILUVIEN in these countries.

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. As of June 30, 2014, we had entered into eight 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 23 persons fully dedicated to Alimera as of June 30, 2014. Quintiles Commercial also employed three persons partially dedicated to Alimera in Germany, the United Kingdom and France, and five persons partially dedicated to develop market access in the United Kingdom as of June 30, 2014. In July 2014, seven of the project orders were amended, effective July 1, 2014, to align the terms with the actual staffing in place and provide for the early termination of the three project orders associated with Germany as of December 31, 2014 and transition of the German positions to our payroll effective January 1, 2015 or earlier. In accordance with the terms of these project orders and the July 2014 amendments, we expect to incur approximately $3.0 million and $4.9 million in costs with Quintiles Commercial for the six months ended December 31, 2014 and the year ended December 31, 2015, respectively. During the three and six months ended June 30, 2014, we incurred $1.4 million and $3.3 million, respectively, of expense associated with this agreement. At June 30, 2014, $1.2 million was included in outsourced services payable in our accompanying interim condensed consolidated financial statements in association with these project orders.

We have a European management team providing strategic oversight and operational management to the personnel provided by Quintiles Commercial.

Interest Expense

Interest expense consists primarily of interest and amortization of deferred financing costs and debt discounts associated with an earlier term loan entered into in 2010, our 2013 Term Loan and our 2014 Loan Agreement.

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 Income and Loss Applicable to Common Stockholders per Common Share

We calculated net income and loss per share in accordance with ASC 260, Earning per Share. 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. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive. Common stock equivalent securities that would potentially dilute basic earnings per share in the future, but were not included in the computation of diluted earnings per share because to do so would have been anti-dilutive totaled approximately 20,630,686 and 25,597,277 for the three months ended June 30, 2014 and 2013, respectively, and 25,141,965 and 25,597,277 for the six months ended

June 30, 2014 and 2013, respectively.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our interim condensed consolidated financial statements which have been prepared in accordance with accounting principles generally accepted in the

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

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 regulatory approval for ILUVIEN or any future products or 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 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 employee 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

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arrangements. We intend to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior will be more widely available.

Total stock-based compensation expense related to all our stock option awards for the three and six months ended June 30, 2014 and 2013, respectively, was comprised of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands)			
Sales and marketing	$101	$94	$246	$183
Research and development	264	95	519	189
General and administrative	539	258	1,064	604
Total employee stock option-based compensation expense	$904	$447	$1,829	$976

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 not utilized, the federal NOL carry-forwards will expire at various dates between 2023 and 2033 and the state NOL carry-forwards will expire at various dates between 2020 and 2033. We periodically evaluate our NOL carry-forwards and whether certain changes in ownership have occurred that would limit our ability to utilize a portion of our NOL carry-forwards. If it is determined that significant ownership changes have occurred since these NOLs were generated, we may be subject to annual limitations on the use of these NOLs under Internal Revenue Code (IRC) Section 382 (or comparable provisions of state law). 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.

Foreign Currency Translation

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

Our foreign currency assets and liabilities are remeasured into U.S. dollars at end-of-period exchange rates, except for nonmonetary 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.

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The financial statements of the foreign subsidiaries whose functional currency is not the U.S. dollar have been translated into U.S. Dollars in accordance with ASC 830-30, Translation of Financial Statements. For the subsidiaries operating 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 in which the activity took place. Equity is translated at historical rates and the resulting cumulative translation adjustments are included as a component of accumulated other comprehensive income.

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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 interim condensed consolidated financial statements.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
NET REVENUE	$2,190	$179	$4,274	$179
COST OF GOODS SOLD	(376)	(11)	(940)	(11)
GROSS MARGIN	1,814	168	3,334	168
RESEARCH AND DEVELOPMENT EXPENSES	1,809	2,180	4,435	4,203
GENERAL AND ADMINISTRATIVE EXPENSES	2,827	2,429	5,754	5,099
SALES AND MARKETING EXPENSES	3,136	4,898	6,547	8,461
OPERATING EXPENSES	7,772	9,507	16,736	17,763
INTEREST EXPENSE, NET AND OTHER	(325)	(129)	(454)	(263)
UNREALIZED FOREIGN CURRENCY LOSS, NET	(146)	—	(202)	—
LOSS ON EARLY EXTINGUISHMENT OF DEBT	(440)	(153)	(440)	(153)
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	8,054	(6,742)	(5,076)	(12,336)
NET INCOME (LOSS) BEFORE TAXES	1,185	(16,363)	(19,574)	(30,347)
PROVISION FOR TAXES	(69)	—	(69)	—
NET INCOME (LOSS)	$1,116	$(16,363)	$(19,643)	$(30,347)

Three months ended June 30, 2014 compared to the three months ended June 30, 2013

Net Revenue. Net revenue increased by approximately $2.0 million, or 1,111%, to approximately $2.2 million for the three months ended June 30, 2014 compared to approximately $180,000 for the three months ended June 30, 2013. The increase was primarily attributable to increased adoption of ILUVIEN in Germany and the United Kingdom following launches in both countries during the second quarter of 2013.

Cost of goods sold. Cost of goods sold increased by approximately $370,000 to approximately $380,000 for the three months ended June 30, 2014 compared to approximately $10,000 for the three months ended June 30, 2013. The increase was attributable to our increase in sales during the three months ended June 30, 2014 and a reserve of $210,000 for potential German inventory expiration due to a slower than expected initial sales.

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 June 30, 2014 compared to approximately $2.2 million for the three months ended June 30, 2013. The decrease was primarily attributable to decreases of approximately $500,000 in costs related to our domestic ancillary clinical studies including the physician utilization study which completed in the fourth quarter of 2013 and $380,000 in costs incurred related to a consultant engaged to assist with the continued pursuit of approval of ILUVIEN in the U.S. These costs were offset by an increase of approximately $270,000 in personnel costs as we expanded our medical affairs team in connection with the commercial launch of ILUVIEN in the EU.

General and administrative expenses. General and administrative expenses increased by approximately $400,000, or 17%, to approximately $2.8 million for the three months ended June 30, 2014 compared to approximately $2.4 million for the three months ended June 30, 2013. The increase was primarily attributable to an increase of approximately $570,000 in personnel costs as we expanded our team after the commercial lunch of ILUVIEN in the EU.

Sales and Marketing expenses. Sales and marketing expenses decreased by approximately $1.8 million, or 37%, to approximately $3.1 million for the three months ended June 30, 2014 compared to approximately $4.9 million for the three months ended June 30, 2013. The decrease was primarily attributable to decreases of approximately $690,000 in

costs incurred with Quintiles Commercial for market access assistance in the United Kingdom in 2013 in preparation for the implementation

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of the NICE guidance for reimbursement, $590,000 in non-recurring marketing and market access costs incurred in the first quarter of 2013 in preparation for the commercial launch of ILUVIEN in the EU in the second quarter of 2013 and $280,000 associated with the transition of several management and market access roles in Germany and the United Kingdom from Quintiles Commercial to Alimera that were contracted through Quintiles Commercial in 2013.

Interest expense, net and other. Interest expense, net and other increased by approximately $200,000, or 154%, to approximately $330,000 for the three months ended June 30, 2014 compared to approximately $130,000 for the three months ended June 30, 2013. The increase was primarily due to the increased note payable balance as a result of the 2014 Loan Agreement.

Unrealized foreign currency loss, net. We recorded a non-cash unrealized foreign currency loss of approximately $150,000 for the three months ended June 30, 2014. The unrealized foreign currency loss was primarily attributable to the change in value of the Euro and the British pound sterling during the three months ended June 30, 2014.

Change in fair value of derivative warrant liability. A decrease in the fair value of our derivative warrant liability resulted in non-cash gain of approximately $8.1 million for the three months ended June 30, 2014 compared to an increase in the fair value of our derivative warrant liability, which resulted in non-cash expense of approximately $6.7 million for the three months ended June 30, 2013. The decreased value of the derivative warrant liability for the three months ended June 30, 2014 was primarily due to the decrease in fair market value of our underlying common stock in the second quarter of 2014 and the increased value for the three months ended June 30, 2013 was primarily due to the increase in fair market value of our underlying common stock in the second quarter of 2013.

Six months ended June 30, 2014 compared to the six months ended June 30, 2013

Net Revenue. Net revenue increased by approximately $4.1 million, or 2,278%, to approximately $4.3 million for the six months ended June 30, 2014 compared to approximately $180,000 for the six months ended June 30, 2013. The increase was primarily attributable to increased adoption of ILUVIEN in Germany and the United Kingdom following launches in both countries during the second quarter of 2013.

Cost of goods sold. Cost of goods sold increased by approximately $930,000 to approximately $940,000 for the six months ended June 30, 2014 compared to approximately $10,000 for the six months ended June 30, 2013. The increase was attributable to our increase in sales during the six months ended June 30, 2014 and a reserve of $650,000 for potential German inventory expiration due to a slower than expected initial sales.

Research and development expenses. Research and development expenses increased by approximately $200,000, or 5%, to approximately $4.4 million for the six months ended June 30, 2014 compared to approximately $4.2 million for the six months ended June 30, 2013. The increase was primarily attributable to increases of approximately $680,000 in personnel costs as we expanded our medical affairs team in connection with the commercial launch of ILUVIEN in the EU, $400,000 in costs associated with the submission of our response to the third CRL from the FDA in March 2014 and $360,000 in costs associated with new clinical studies being performed in the EU including costs associated with a five-year, post-authorization, open label registry study of ILUVIEN. These costs were offset by decreases of approximately $760,000 in costs related to our domestic ancillary clinical studies including the physician utilization study which completed in the fourth quarter of 2013 and $530,000 in costs incurred related to a consultant engaged to assist with the continued pursuit of approval of ILUVIEN in the U.S.

General and administrative expenses. General and administrative expenses increased by approximately $700,000, or 14%, to approximately $5.8 million for the six months ended June 30, 2014 compared to approximately $5.1 million for the six months ended June 30, 2013. The increase was primarily attributable to increases of approximately $1.0 million in personnel costs as we expanded our team after the commercial launch of ILUVIEN in the EU and $150,000 in travel and entertainment related to the U.S. team providing support for the ongoing activities in Europe. These costs were offset by a decrease of approximately $440,000 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 incurred in the six months ended June 30, 2013.

Sales and Marketing expenses. Marketing expenses decreased by approximately $2.0 million, or 24%, to approximately $6.5 million for the six months ended June 30, 2014 compared to approximately $8.5 million for the six months ended June 30, 2013. The decrease was primarily attributable to decreases of non-recurring marketing and market access costs of approximately $1.2 million incurred in the first half of 2013 in preparation for the commercial

launch of ILUVIEN in the EU in the second quarter of 2013 and $1.0 million in costs incurred with Quintiles Commercial for market access assistance in the United Kingdom in 2013 in preparation for the implementation of the NICE guidance for reimbursement, $200,000 associated with the transition of several management and market access roles in Germany and the United Kingdom from Quintiles Commercial to Alimera that were contracted through Quintiles Commercial in 2013, offset by an increase of $720,000 for costs incurred with Quintiles Commercial for the French commercial team that was engaged in the second half of 2013.

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Interest expense, net and other. Interest expense, net and other increased by approximately $190,000, or 73%, to approximately $450,000 for the six months ended June 30, 2014 compared to approximately $260,000 for the six months ended June 30, 2013. The increase was primarily due to the increased note payable balance as a result of the 2014 Loan Agreement.

Unrealized foreign currency loss, net. We recorded a non-cash unrealized foreign currency loss of approximately $200,000 for the six months ended June 30, 2014. The unrealized foreign currency loss was primarily attributable to the change in value of the Euro and the British pound sterling during the six months ended June 30, 2014.

Change in fair value of derivative warrant liability. Increases in the fair value of our derivative warrant liability resulted in non-cash expense of approximately $5.1 million and $12.3 million for the six months ended June 30, 2014 and 2013, respectively. The increased value of the derivative warrant liability for both periods was primarily due to increases in the fair market value of our underlying common stock during the respective periods.

Liquidity and Capital Resources

To date we have incurred negative cash flow from operations, and have accumulated a deficit of $297.0 million from our inception through June 30, 2014.

As of June 30, 2014, we had approximately $42.0 million in cash and cash equivalents.

We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and plan to launch ILUVIEN in Portugal and France in late 2014. We do not expect to have positive cash flow from operations until late 2015, 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 2014 Loan Agreement, 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 ILUVIEN or any future products or 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 six months ended June 30, 2014, cash used in our operations of $10.2 million was primarily due to our net loss of $19.6 million offset by a non-cash loss of $5.1 million for the change in our derivative warrant liability, $1.9 million of stock-based compensation expense, $440,000 for the loss from early extinguishment of debt and $200,000 for unrealized foreign currency transaction loss. Further impacting cash from operations was an increase in accounts receivable of approximately $530,000, offset by decreases of $890,000 in prepaid expenses and other current assets and $400,000 in inventory, and an increase in accounts payable and accrued expenses and other current liabilities of $950,000. Accounts payable and accrued expenses and other current liabilities increased primarily due to an increase of $790,000 in amounts payable to Quintiles Commercial. Prepaid expenses and other current assets decreased primarily due to a decrease of $1.3 million in amounts owed to us from Quintiles Commercial that were applied in lieu of payments for billings in the six months ended June 30, 2014, offset by increases of $160,000 in amounts prepaid to our CROs and $130,000 in prepaid marketing expense for meetings and conventions.

For the six months ended June 30, 2013, cash used in our operations of $19.1 million was primarily due to our net loss of $30.3 million offset by a non-cash loss of $12.3 million for the change in our derivative warrant liability, $990,000 of stock-based compensation expense and $150,000 for the loss from early extinguishment of debt. Further impacting our cash used in operations were increases of approximately $1.2 million in prepaid expenses and other current assets, $1.1 million in inventory and $130,000 in accounts receivables, offset by an increase in accounts payable, accrued expenses and other current liabilities of approximately $230,000. Prepaid expenses and other currents increased

primarily due to increases of $340,000 in credits receivable from Quintiles Commercial for excess billings during the second quarter of 2013 and $190,000 of prepaid insurance. Inventory increased primarily due to an increase of $1.1 million in ILUVIEN inventory as we launched our product in Germany and the United Kingdom in the second quarter of 2013.

For the six months ended June 30, 2014, net cash used in our investing activities was $210,000, which was primarily due to the purchase of back-up manufacturing equipment for ILUVIEN.

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For the six months ended June 30, 2013, net cash used by our investing activities was approximately $380,000, which was due to the purchase of back-up manufacturing equipment for ILUVIEN.

For the six months ended June 30, 2014, net cash provided by our financing activities was approximately $39.7 million. In January 2014, we entered into a securities purchase agreement with investors pursuant to which we sold an aggregate of 6,250,000 shares of our common stock at a purchase price of $6.00 per share. Gross proceeds from the offering were $37.5 million prior to the payment of approximately $2.4 million of related issuance costs. In April 2014, we entered into a term loan agreement with Hercules, which resulted in proceeds of $10.0 million prior to the payment of approximately $650,000 in related costs, and $4.9 million used to prepay and terminate our 2013 Term Loan. Further increasing cash from our financing activities was $330,000 from the proceeds from exercises of stock options.

For the six months ended June 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 $3.1 million to repay the 2010 Term Loan.

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 $75,000 and $450,000 during the three months ended June 30, 2014 and 2013, respectively, and $375,000 and $900,000 during the six months ended June 30, 2014 and 2013, respectively. We expect to record an additional $75,000 in charges in connection with this agreement through September 30, 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 eight project orders with Quintiles Commercial for the provision of services in Germany, the United Kingdom and France. In July 2014, seven of the project orders were amended, effective July 1, 2014, to align the terms with the actual staffing in place and provide for the early termination of the three project orders associated with Germany as of December 31, 2014 and transition of the German positions to our payroll effective January 1, 2015 or earlier. In accordance with the terms of these project orders and the July 2014 amendments, we expect to incur approximately $3.0 million and $4.9 million in costs with Quintiles Commercial for the six months ended December 31, 2014 and the year ended December 31, 2015, respectively. During the three and six months ended June 30, 2014, we recorded charges of $1.4 million and $3.3 million, respectively, in connection with this agreement. At June 30, 2014, $1.2 million was included in outsourced services payable.

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, 2013, filed with the SEC on March 7, 2014.

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.

Recent 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 May 2014, the FASB issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606).” ASU 2014-09 provides a single, comprehensive revenue recognition model for all contracts with customers. The revenue guidance contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an

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amount that the entity expects to be entitled to in exchange for those goods or services. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016 for public entities, with no early adoption permitted. Our management is still evaluating the potential impact of adopting this guidance on our financial statements.

In June 2014, the FASB issued ASU 2014-12, “Compensation Stock - Compensation (Topic 718).” ASU 2014-12 applies to all reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. It requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition and follows existing accounting guidance for the treatment of performance conditions. The standard will be effective for annual periods and interim periods within those annual periods beginning after December 15, 2015, with early adoption permitted. Our management is still evaluating the potential impact of adopting this guidance on our financial statements.

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ITEM 3. Quantitative and Qualitative 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 June 30, 2014. 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 June 30, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the three months ended June 30, 2014 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

The following description of risk factors include any material changes to, and supersedes the description of, risk factors associated with our business previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 7, 2014, under the heading "Risk Factors." Our business, financial condition and operating results can be affected by a number of factors, whether current known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding any statement in this Quarterly Report on Form 10-Q or elsewhere. The following information should be read in conjunction with the interim condensed consolidated financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's, Discussion and Analysis of Financial Condition and Results of Operations."

Because of the following factors, as well as other factors affecting our financial condition and operating results, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

Risks Related to Our Dependence on ILUVIEN

We are heavily dependent on the commercial success of our lead product, ILUVIEN, which has received marketing authorizations in Austria, the United Kingdom, Portugal, France, Germany, Spain, Italy, Norway and Denmark, and on the regulatory approval of ILUVIEN for the treatment of chronic diabetic macular edema (DME) in the U.S. and other countries, which may never occur.

We are a pharmaceutical company with only one product available for commercial sale in a limited number of markets. As a result, our future success is currently dependent upon the commercial and regulatory success of ILUVIEN. ILUVIEN has received marketing authorization from governing regulatory bodies in Austria, the United Kingdom, Portugal, France, Germany, Spain, Italy, Norway and Denmark and has been recommended for marketing authorization in eight additional European Union (EU) countries to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies. We cannot be certain if, or when, ILUVIEN will receive marketing authorization in the eight additional EU countries. ILUVIEN has not been approved by the FDA in the U.S. and may never receive such approval. We launched ILUVIEN in the United Kingdom and Germany in April and May of 2013, respectively, and currently plan to launch ILUVIEN in Portugal and France in late 2014. The timing of the commercial launch of ILUVIEN in the EU countries is dependent upon each specific EU country's pricing and reimbursement timelines. Because we do not currently have any products or product candidates available for sale or in clinical development other than ILUVIEN, our future success is dependent upon building a commercial operation in the EU to successfully commercialize ILUVIEN in the EU, and/or obtaining regulatory approval from the FDA to market ILUVIEN for the treatment of DME in the U.S., and if approved by the FDA, successfully commercializing ILUVIEN in the U.S.

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom, Portugal and France. If we do not successfully commercialize ILUVIEN in these countries or other countries in the EU or receive regulatory approval in the U.S. for ILUVIEN for the treatment of DME, our ability to generate revenue may be jeopardized and, consequently, our business may be seriously harmed. We may not succeed in our commercial efforts in the EU; we

may not receive regulatory approval in the U.S. for ILUVIEN; and if we do receive regulatory approval in the U.S. for ILUVIEN, we may not be able to commercialize ILUVIEN successfully, all of which would have a material adverse effect on our business and prospects. In the near term, we may experience delays and unforeseen difficulties in the launch of ILUVIEN in one or more of the EU countries, including obtaining unfavorable pricing and/or reimbursement, which could negatively affect our stock price. We may continue to experience delays in obtaining regulatory approval in the U.S. for ILUVIEN, if it is approved at all, and our stock price may be negatively affected.

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

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

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

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

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

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom, Portugal and France. We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and currently plan to launch ILUVIEN in Portugal and France in late 2014. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources.

Although we have engaged Quintiles Commercial Europe Limited (together with its affiliates, Quintiles Commercial) to provide services to help facilitate the launch of ILUVIEN in the EU, expansion of our business into the EU continues to require significant management attention and additional financial resources. We may not be able to maintain and expand our commercial operation in a cost-effective manner or realize a positive return on this investment even with the assistance of Quintiles Commercial. In addition, we have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products include:

•our or Quintiles Commercial's inability to recruit and retain adequate numbers of effective personnel;

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

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

•the inability of market access personnel to obtain sufficient levels of pricing and reimbursement in each jurisdiction; and

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

If we or Quintiles Commercial are not successful in recruiting and retaining sales and marketing personnel or in expanding our sales and marketing infrastructure or if we do not successfully enter into additional collaboration arrangements with third-parties, we will have difficulty commercializing ILUVIEN or any future products or product candidates, which would adversely affect our business, operating results and financial condition.

Even with the assistance of Quintiles Commercial or other third-party collaborators, we may not be successful in maintaining and expanding our commercial operation in the EU for numerous reasons, including, but not limited to, failing to attract, retain

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and motivate the necessary skilled personnel and failing to develop a successful marketing strategy. Failure to maintain and expand our commercial operation in the EU will have a negative outcome on our ability to commercialize ILUVIEN and generate revenue.

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

ILUVIEN may not be commercially successful.

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

•cost of treatment;

•pricing and availability of alternative products;

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

•perceived efficacy relative to other available therapies;

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

•relative convenience and ease of administration; and

•prevalence and severity of adverse side effects associated with treatment.

Because we only recently initiated the commercialization of ILUVIEN, we have limited information with regard to the market acceptance of ILUVIEN in the EU or elsewhere. As a result, we may have to revise our estimates regarding the acceptance of ILUVIEN under our anticipated pricing structure, reevaluate and/or change the anticipated pricing for ILUVIEN.

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

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

•are more effective;

•have fewer or less severe adverse side effects;

•are better tolerated;

•receive better reimbursement terms;

•are more accepted by physicians;

•are more adaptable to various modes of dosing;

•have better distribution channels;

•are easier to administer; or

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

We expect that ILUVIEN may compete in the EU, and, if approved by the FDA, in the U.S., with other products that have been or are being developed for the treatment of diabetic macular edema (DME). There are three biological products, Lucentis, Eylea and Avastin, expected to provide competition for ILUVIEN. Lucentis is currently approved for the treatment of DME, the treatment of neovascular wet age-related macular degeneration (AMD) and the treatment of macular edema following retinal vein occlusion (RVO) in the U.S. and the EU. Lucentis is marketed in the U.S. by Genentech and in the EU by Novartis. Eylea is

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currently approved for the treatment of DME, the treatment of neovascular wet AMD and the treatment of macular edema following RVO in the U.S. and the EU. Eylea is marketed in the U.S. by Regeneron and in the EU by Bayer. Avastin, an oncology product marketed by the Roche Group, is used by retinal specialists in both the U.S. and in certain countries of the EU in the treatment of numerous retinal diseases but is not formulated or approved for any ophthalmic use.

Within the corticosteroid class, Ozurdex is expected to provide competition for ILUVIEN. Ozurdex has recently been approved by the FDA for use in adult patients with DME who have had an artificial lens implant or are scheduled for cataract surgery. In Europe, the CHMP has recommended extending the Marketing Authorization for Ozurdex to treat adult patients with vision loss due to diabetic macular edema (DME) who are pseudophakic (have an artificial lens implant), or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy. Ozurdex is indicated for macular edema resulting from RVO and for uveitis in the U.S and the EU.

Retinal specialists are currently using laser photocoagulation and off-label therapies for the treatment of DME, and may continue to use these therapies in competition with ILUVIEN. Other laser, surgical or pharmaceutical treatments for DME may also compete against ILUVIEN. These competitive therapies may result in pricing pressure even if ILUVIEN is otherwise viewed as a preferable therapy.

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

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

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

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

•multiple legal systems and unexpected changes in legal requirements;

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

•trade laws and business practices favoring local competition;

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

•weaker intellectual property protection in some countries;

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

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

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

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Risks Related to Our Business and Industry

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

We launched ILUVIEN in the United Kingdom and Germany in April and May of 2013, respectively, and currently plan to launch ILUVIEN in Portugal and France in late 2014. We are not currently generating significant revenues and we cannot estimate with precision the extent of our future losses. ILUVIEN is our only product currently approved for commercial sale and it is only approved in limited markets in the EU. We may never achieve profitability. We expect to continue to incur substantial and increasing losses. ILUVIEN has not been approved for marketing in the U.S. and may never receive such approval. As a result of these factors, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. As of June 30, 2014, we have accumulated a deficit of $297.0 million. Our ability to achieve revenue and profitability is dependent on our ability to obtain necessary regulatory approvals, have our products manufactured, successfully marketed and sold and to complete the development of any future products or product candidates. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

As of June 30, 2014, we had approximately $42.0 million in cash and cash equivalents. 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 our term loan or restrict the availability of our line of credit, and we will likely need to raise additional financing. If ILUVIEN does not generate sufficient revenue in the EU, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

Our operating results may fluctuate significantly.

Our operating results will continue to be subject to fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including:

- product sales;
- cost of product sales;
- marketing and other expenses;
- manufacturing or supply issues;
- regulatory developments affecting our products or those of our competitors;
- variations in the level of expenses related to our products or future development programs;
- the timing and amount of royalties or milestone payments;
- our addition or termination of development programs;
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;

- any intellectual property infringement or other lawsuit in which we may become involved; and

- the timing and recognition of stock-based compensation expense.

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

Prolonged economic uncertainties or downturns, as well as unstable market, credit and financial conditions, may exacerbate certain risks affecting our business and have serious adverse consequences on our business.

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The global economic downturn and market instability has made the business climate more volatile and more costly. These economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control. Sales of our products will be dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations in Germany, the United Kingdom, Portugal and France. As a result of negative trends in the general economy in the EU or other jurisdictions in which we may do business, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, health authorities in some jurisdictions may reduce reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue.

In addition, we rely on third parties for several important aspects of our business. During challenging and uncertain economic times and in tight credit markets, there may be a disruption or delay in the performance of our third party contractors, suppliers or partners. If such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected. Moreover, two customers in Europe accounted for approximately 23% of our total consolidated revenues for the year ended December 31, 2013 and for approximately 6% of our total consolidated revenues for the six months ended June 30, 2014. The loss of or a substantial reduction in activity by one or more of these customers could have an adverse effect on our business, financial condition and results of operations.

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

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

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

•a drug candidate may not be safe or effective;

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

•they may not approve of our manufacturing processes;

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

•they may change their approval policies or adopt new regulations.

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

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

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

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

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

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

Our license rights to pSivida US, Inc.'s (pSivida) proprietary delivery device could revert to pSivida if we (i) fail twice to cure our breach of an obligation to make certain payments to pSivida following receipt of written notice thereof; (ii) fail to cure other breaches of material terms of our agreement with pSivida within 30 days after notice of such breaches or such longer period (up to 90 days) as may be reasonably necessary if the breach cannot be cured within such 30-day period; (iii) file for protection under the bankruptcy laws, make an assignment for the benefit of creditors,

appoint or suffer appointment of a receiver or trustee over our property, file a petition under any bankruptcy or insolvency act or have any such petition filed against us and such proceeding remains undismissed or unstayed for a period of more than 60 days; or (iv) notify pSivida in writing of our decision to abandon our license with respect to a certain product using pSivida's proprietary delivery device. If our agreement with pSivida were terminated, we would lose our rights to develop and commercialize ILUVIEN, which would materially and adversely affect our business, results of operations and future prospects.

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

We do not have, nor currently intend to have, in-house manufacturing capability and depend completely on a single third-party manufacturer for the manufacture of the ILUVIEN implant (Alliance Medical Products, Inc. (Alliance)), a single third-party manufacturer for the manufacture of the ILUVIEN applicator (Flextronics International, Ltd. or an affiliate of Flextronics

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International, Ltd. (Flextronics)), a single third-party manufacturer for the manufacture of ILUVIEN's active pharmaceutical ingredient (FARMABIOS SpA./Byron Chemical Company Inc. (FARMABIOS)) and a single third-party manufacturer for the quality release testing of ILUVIEN in the EU (Brecon Pharmaceuticals Limited (Brecon)). Although we have agreements for the manufacture of the ILUVIEN implant (with Alliance), the manufacture of the ILUVIEN applicator (with Flextronics), for the supply of ILUVIEN's active pharmaceutical ingredient (with FARMABIOS) and for the quality release testing of ILUVIEN in the EU (with Brecon), if any of the third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with them or get them approved by the applicable regulatory authorities, such as the FDA in the U.S., in a timely manner. Further, all of our manufacturers rely on additional third-parties for the manufacture of component parts. Any inability to acquire sufficient quantities of ILUVIEN implants, the ILUVIEN applicator or the active pharmaceutical ingredient in a timely manner from these third-parties could delay commercial production of, and impact our ability to fulfill demand for, ILUVIEN, if any.

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

We rely on our manufacturers to purchase materials from third-party suppliers necessary to produce ILUVIEN. Suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. If our manufacturers are unable to obtain these materials, the commercial launch of ILUVIEN would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of ILUVIEN. Moreover, although we have entered into agreements for the commercial production of the ILUVIEN implant, the commercial production of the ILUVIEN applicator, and the supply of the active pharmaceutical ingredient in ILUVIEN, the suppliers may be unable or choose not to supply us in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain these supplies, our ability to manufacture ILUVIEN for commercial sale would be delayed, significantly impacting our ability to generate revenue from the sale of ILUVIEN.

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

The manufacture and packaging of pharmaceutical products such as ILUVIEN and any future product candidates are regulated by the FDA and similar foreign regulatory agencies and must be conducted in accordance with the FDA's cGMP and comparable requirements of foreign regulatory agencies. There are a limited number of manufacturers that operate under these cGMP regulations which are both capable of manufacturing ILUVIEN and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of ILUVIEN or any future products or product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. Failure of our manufacturers to maintain compliance could interrupt the production of ILUVIEN , resulting in delays and additional costs which could significantly and adversely affect our business. For example, during routine manufacturing inspection, we identified a quality issue related to one of our suppliers that affected certain batches of work in process, which resulted in a write-off of $1.4 million during the year ended December 31, 2013. Any significant delays in the manufacture of ILUVIEN or the quality of the product could materially harm our business and prospects.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, will require prior FDA review and/or approval of the manufacturing process and procedures in accordance with the FDA's cGMP regulations. There are comparable foreign requirements as well. This review may be costly and time consuming and could delay or prevent the launch of a product. If we elect to manufacture products in our own facility or at the facility of another third-party, we would need to ensure that the new facility and the manufacturing process are in substantial compliance with cGMP and comparable foreign regulations. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA or a foreign regulatory agency may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

Furthermore, in order to obtain approval of ILUVIEN or any future products or product candidates by the FDA and foreign regulatory agencies, we need to complete testing on both the active pharmaceutical ingredient and on the finished product in the packaging that we propose for commercial sales. This includes testing of stability, identification of impurities and testing of other product specifications by validated test methods. In addition, we will be required to consistently produce in commercial quantities and of specified quality in a reproducible manner and document our ability to do so. This requirement is referred to as process

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validation. The FDA and similar foreign regulatory agencies may also implement new standards, or change their interpretation and enforcement of existing standards and requirements, for the manufacture, packaging, or testing of products at any time. For example, in the CRL we received in October 2013, the FDA referenced deficiencies in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured. If we are unable to comply, ILUVIEN may not be approved, or we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business.

In order to expand our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of June 30, 2014, we had 30 employees, 24 of whom were located in the U.S. and six of whom were located in the United Kingdom or Germany. Recognizing that we would need resources beyond this core management team to commercialize ILUVIEN on our own in the EU, in November 2012 we entered into a master services agreement with Quintiles Commercial to provide additional personnel for our planned launch of ILUVIEN, and subsequent operations, in Germany, the United Kingdom and France. Under this agreement and its related project orders, Quintiles Commercial, as of June 30, 2014, employed six persons fully dedicated to Alimera. Quintiles Commercial also employed 24 persons partially dedicated to Alimera in Germany, the United Kingdom and France, as of June 30, 2014. While these individuals are employed by Quintiles Commercial, and are not employed directly by us, we will not be able to operate effectively unless we integrate them into our organization, which may be difficult. For example, we have determined that Quintiles Commercial is not as effective in filling certain positions in certain geographies as we believe that we can be in hiring directly. Therefore, in July 2014, the project orders with Quintiles Commercial in Germany, the United Kingdom and France were amended, effective July 1, 2014, to align the terms with the actual staffing in place, account for positions that have been hired directly into Alimera and provide for the early termination of the project orders associated with Germany as of December 31, 2014 and transition of the German positions to our payroll effective January 1, 2015 or earlier. As our development and commercialization plans and strategies evolve beyond our initial planned EU launches, we will need to further expand the size of our organization by recruiting additional managerial, operational, sales, marketing, financial and other personnel, who may be hired directly by us or through Quintiles Commercial or other similar organizations. This future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional personnel. Also, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize ILUVIEN and our future products or product candidates and compete effectively will depend, in part, on our ability to effectively manage any such future growth and related costs. We may not be able to effectively manage a rapid pace of growth and timely implement improvements to our management infrastructure and control systems.

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

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

In many countries, the pricing of prescription pharmaceuticals is subject to governmental control. In the EU, each country has a different reviewing body that evaluates reimbursement dossiers submitted by marketing authorization holders of new drugs and then makes recommendations as to whether or not the drug should be reimbursed. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of

regulatory approval, or delay regulatory approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including ILUVIEN, to other available therapies. Limitations on reimbursement could be imposed at the national, regional or local level or by fiscal intermediaries in each country. Our business could be materially adversely affected if such limitations were imposed. Our business also could be adversely affected if retinal specialists are not reimbursed for the cost of the procedure in which they administer ILUVIEN on a basis satisfactory to the administering retinal specialists.

In the U.S., in the event that ILUVIEN is approved, we will need to obtain approvals for payment for ILUVIEN from private insurers, including managed care organizations, and from the Medicare program. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. These reforms could significantly reduce payments from Medicare and Medicaid over the next ten years. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling of payments or the imposition of enrollment limitations on new providers, may change the availability, methods and

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rates of reimbursements from Medicare, private insurers and other third-party payers for ILUVIEN and our other potential products. Some of these changes and proposed changes could result in reduced reimbursement rates for ILUVIEN and our other potential products, which would adversely affect our business strategy, operations and financial results.

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

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

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

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

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

incision required for a 25-gauge or larger needle, or (iii) to deliver non-corticosteroids to the back of the eye, unless it is to treat DME through an incision required for a 25-gauge or larger needle.

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

Other than the master services agreement entered into with Quintiles Commercial in November 2012, we currently do not have any collaboration agreements with third-parties. We expect to depend on collaborations to develop and commercialize our products. If we are unable to identify or enter into an agreement with any material third-party collaborator, if our collaborations with any such third-party are not scientifically or commercially successful or if our agreement with any such

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third-party is terminated or allowed to expire, we could be adversely affected financially or our business reputation could be harmed.

Our business strategy includes entering into collaborations with corporate and academic collaborators for the research, development and commercialization of ILUVIEN and any future products or product candidates. Other than the master services agreement entered into with Quintiles Commercial in November 2012, we currently do not have any collaboration agreements with third-parties. Areas in which we may potentially enter into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing of ILUVIEN in certain EU countries and elsewhere outside of North America, and future product development arrangements. If we are unable to identify or enter into an agreement with any material third-party collaborator we could be adversely affected financially or our business reputation could be harmed. Any arrangements we do enter into may not be scientifically or commercially successful. The termination of any of these arrangements might adversely affect our ability to develop, commercialize and market our products.

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

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

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

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

•our collaborators may change the focus of their development and commercialization efforts. In recent years there have been a significant number of mergers and consolidations in the pharmaceutical and biotechnology industries, some of which have resulted in the participant companies reevaluating and shifting the focus of their business following the completion of these transactions. The ability of our products to reach their potential could be limited if any of our future collaborators decreases or fails to increase spending relating to such products.

Collaborations with pharmaceutical companies and other third-parties often are terminated or allowed to expire by the other party. With respect to our future collaborations, any such termination or expiration could adversely affect us financially as well as harm our business reputation.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to identify, develop and commercialize ILUVIEN and any future products or product candidates.

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

market ILUVIEN and any future products or product candidates.

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

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

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

• restrictions on such products or manufacturing processes;

• withdrawal of the products from the market;

• voluntary or mandatory recall;

• fines;

• suspension of regulatory approvals;

• product seizure; and

• injunctions or the imposition of civil or criminal penalties.

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

Failure to obtain regulatory approval in additional foreign jurisdictions would prevent us from marketing ILUVIEN in additional markets.

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

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

Our business exposes us to the risk of product liability claims, which is inherent in the manufacturing, testing and marketing of drugs and related products. If the use of one or more of our products harms people, we may be subject to costly and damaging product liability claims. We maintain product liability insurance covering our clinical trial

activities and our product sales. The insurance provides worldwide coverage where allowed by law. As product revenue is generated in new countries, we intend to obtain compulsory coverage in those countries that require it. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our product development and commercialization efforts.

We may not be successful in our efforts to expand our portfolio of products.

In the future, we may choose to commercialize a portfolio of new ophthalmic drugs in addition to ILUVIEN. We may seek to do so through our internal research programs and through licensing or otherwise acquiring the rights to potential new drugs and drug targets for the treatment of ophthalmic disease.

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A significant portion of the research that we may choose to conduct may involve new and unproven technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. Any future research programs may initially show promise in identifying potential products or product candidates, yet fail to yield products or product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential products or product candidates; or
- potential products or product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

We may be unable to license or acquire suitable products or product candidates or products from third-parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is a competitive area. Several more established companies are also pursuing strategies to license or acquire products in the ophthalmic field. These established companies may have a competitive advantage over us due to their size, cash resources and greater development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable products or product candidates include the following:

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

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

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

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

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

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

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

Any future products or product candidates may never achieve market acceptance even if we obtain regulatory approvals.

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

depend on a number of factors, including, among other things:

• the demonstration of its safety and efficacy;

• its cost-effectiveness;

• its potential advantages over other therapies;

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

• the effectiveness of our marketing and distribution capabilities.

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

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

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

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

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

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

• poor effectiveness of product candidates during clinical trials;

• unforeseen safety issues or side effects; and

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

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

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

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

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

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

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

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

any of this occurs, our business will be materially harmed.

If our contract research organizations (CROs), third-party vendors and investigators do not successfully carry out their duties or if we lose our relationships with them, our development efforts with respect to any future product candidates could be delayed.

We expect to be dependent on CROs, third-party vendors and investigators for preclinical testing and clinical trials related to our discovery and development efforts with respect to any future product candidates. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our development programs with respect to our product candidates or if their performance is substandard, it will delay the development and commercialization of our product candidates. The parties with which we contract for execution of clinical

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trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

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

Risks Related to Intellectual Property and Other Legal Matters

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

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

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

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

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

or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

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

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both.

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These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

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

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

Our licenses are material to our business, and we expect to enter into additional licenses in the future. We hold a license from pSivida to intellectual property relating to ILUVIEN. This license imposes various commercialization, milestone payment, profit sharing, insurance and other obligations on us. We also hold a license from Dainippon Sumitomo Pharma Co., Ltd. to patents relating to ILUVIEN. This license imposes a milestone payment and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the applicable license, in which event we would not be able to market products, such as ILUVIEN, that may be covered by such license.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure or misappropriation by third-parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third-parties. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff were previously employed by other pharmaceutical or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their drug development activities for us.

If our efforts to protect the proprietary nature of the intellectual property related to our products are not adequate, we may not be able to compete effectively in our markets.

The strength of our patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. In addition to the rights we have licensed from pSivida relating to ILUVIEN, we rely upon intellectual property we own, including patents, patent applications and trade secrets. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third-parties from developing or designing around these patents. As of June 30, 2014, the patent rights relating to ILUVIEN licensed to us from pSivida include five U.S. patents that expire between March 2019 and April 2020, two European patents expiring in April of 2021 and October of 2024, and counterpart filings to these patents in a number of other jurisdictions. No patent term extension will be available for any of these U.S. patents, European patent or any of our licensed U.S. or European pending patent applications. After these patents expire in April 2020 in the U.S. and October of 2024 in Europe, we will not be able to block others from marketing FAc in an implant similar to ILUVIEN. Moreover, it is possible that a third-party could successfully challenge the scope (i.e., whether a patent is infringed), validity and enforceability of our licensed patents prior to patent expiration and obtain approval to market a competitive product.

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

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

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

Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to ILUVIEN, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may in the future allege that our activities infringe their patents or that we are employing their proprietary technology without authorization. We may not have identified all the patents, patent applications or published literature that affect our business either by blocking our ability to commercialize our products or product candidates, by preventing the patentability of one or more aspects of our products or those of our licensors or by covering the same or similar technologies that may affect our ability to market our product. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, if at all. Any inability to obtain such a license under the applicable patents on commercially reasonable terms, or at all, may have a material adverse effect on our ability to commercialize ILUVIEN or any future products or product candidates until such patents expire.

In addition, third-parties may obtain patents in the future and claim that use of ILUVIEN, our technologies or future products or product candidates infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further commercialize ILUVIEN or

develop and commercialize any future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third-parties or pay royalties, or we may be enjoined from further commercializing ILUVIEN or developing and commercializing any future product candidates or technologies. In addition, even in the absence of litigation, we may need to obtain licenses from third-parties to advance our research or allow commercialization of ILUVIEN or any future product candidate, and we have done so from time to time. We may fail to obtain future licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be unable to further commercialize ILUVIEN or develop and commercialize any future product candidates, which could harm our business significantly.

We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding,

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a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

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

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

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

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. We face an increased risk of product liability as we further commercialize ILUVIEN. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our products are inserted into the eye, and it is possible that we may be held liable for eye injuries of patients who receive our product. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products. Although we maintain product liability insurance covering our clinical trial activities and our product sales, our aggregate coverage limit under these insurance policies is limited to $10.0 million in most jurisdictions, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover potential liabilities. The insurance provides worldwide coverage where allowed by law. As product revenue is generated in new countries, we intend to obtain compulsory coverage in those countries that require it. However, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products.

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

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

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

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

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

•Pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company’s market share of prior year total sales of branded products to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense. The aggregate industry-wide fee is expected to total $28

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billion through 2019, of which $3.0 billion will be payable in 2014. Since we expect our branded pharmaceutical sales to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

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

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

The Physician Payment Sunshine Act also imposes new reporting and disclosure requirements on device and drug manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. In addition, device and drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in significant civil monetary penalties.

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

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

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

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

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

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

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At December 31, 2013, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $82.4 million and $65.8 million, respectively, which expire at various dates beginning in 2020 through 2033. Section 382 of the Internal Revenue Code limits the annual utilization of NOL carry-forwards and tax credit carry-forwards following an ownership change in our company. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of our company were to occur. In general, an ownership change occurs for purposes of Section 382 if there is a more than 50% change in ownership of a company over a 3-year testing period. The issuance of the Series A Convertible Preferred Stock in October 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.

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

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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), we expect to be required as of December 31, 2014 and thereafter to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, if required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 would require us to continue to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Risks Relating to Our Financial Results and Need for Financing

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

We expect our operating results and cash flows to be subject to quarterly fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including, but not limited to:

•the commercial success of ILUVIEN in the EU;

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

•the emergence of products that compete with ILUVIEN;

•variations in the level of expenses related to ILUVIEN;

•the status of our preclinical and clinical development programs;

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

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

•regulatory developments affecting our products or those of our competitors.

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

Exchange rate fluctuations could cause a decline in our financial condition and results of operations.

As a result of our European operations, we are subject to increased risk because we incur a significant portion of our operating expenses and receive revenues in multiple currencies other than the U.S. dollar. For example, in Europe where we have operating costs in a foreign currency, we are subject to risk if the foreign currency in which our costs are paid appreciates against the currency in which we generate revenue because the appreciation effectively increases our cost in that country.

The financial condition and results of operations of some of our operating entities are reported in foreign currencies and then translated into U.S. dollars at the applicable exchange rate for inclusion in our consolidated financial statements. As a result, appreciation of the U.S. dollar against these foreign currencies generally will have a negative impact on our reported operating losses while depreciation of the U.S. dollar against these foreign currencies will generally have a positive effect on reported operating losses. We do not seek to mitigate this translation effect through the use of derivative financial instruments. To the extent we are unable to match revenues received in foreign currencies with costs paid in the same currency, exchange rate fluctuations in that currency could have a material adverse effect on our business and results of operations.

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

Our business may require additional capital that we have not yet secured. At June 30, 2014, we had approximately $42.0 million in cash and cash equivalents. We believe our cash and cash equivalents will be sufficient to fund our operations beyond the projected commercialization of ILUVIEN in Germany, the United Kingdom, Portugal and France and the expected generation of positive cash flow in late 2015, at the earliest. However, the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control, and we may need funds sooner than currently anticipated. These factors include but are not limited to:

•the amount of our future operating losses;

•third party expenses relating to the commercialization of ILUVIEN;

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

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

•the $25 million milestone payment owed to pSivida in the event that ILUVIEN is approved in the U.S.;

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

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

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

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

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

•regulatory changes and technological developments in our markets.

General market conditions or the market price of our common stock may not support capital raising transactions such as an additional public or private offering of our common stock or other securities. In addition, our ability to raise additional capital may be dependent upon our stock being quoted on the NASDAQ Global Market or upon obtaining stockholder approval. There can be no assurance that we will be able to satisfy the criteria for continued listing on NASDAQ or that we will be able to obtain

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stockholder approval if it is necessary. If we are unable to obtain additional funds on a timely basis or on terms favorable to us, we may be required to cease or reduce further commercialization of ILUVIEN, to cease or reduce certain research and development projects, to sell some or all of our technology or assets or business units or to merge all or a portion of our business with another entity. In the event additional financing is needed or advisable, we may seek to fund our operations through the sale of equity securities, additional debt financing and strategic collaboration agreements. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders especially in light of the current difficult financial environment. If we raise additional funds by selling shares of our capital stock, the ownership interest of our current stockholders will be diluted. In addition, our Series A Convertible Preferred Stock is entitled to price-based anti-dilution protection in connection with certain financings, which has the potential to further dilute our other stockholders. If we attempt to raise additional funds through strategic collaboration agreements, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize ILUVIEN or any future products or product candidates or operate our business. For example, under the secured credit facility, which Alimera Sciences Limited (Limited), our subsidiary, entered into in April 2014 (Credit Facility), we and certain of our subsidiaries are subject to a variety of affirmative and negative covenants, including required financial reporting, limitations on our cash balances, limitations on the disposition of assets, limitations on the incurrence of additional debt, and other requirements. 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 our term loan or restrict the availability of our line of credit, and we will likely need to raise additional financing. To secure the performance of our obligations under the Credit Facility, Limited pledged all of its assets to the lender. Our or Limited's failure to comply with the covenants under the Credit Facility could result in an event of default, the acceleration of our debt and the loss of our assets. We and certain of our subsidiaries are guarantors of the obligations of Limited to the lender under the Credit Facility (Guaranties). Pursuant to the Guaranties, we and these subsidiaries granted the lender a first priority security interest in substantially all of our respective assets. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there may be substantial doubt about our ability to continue as a going concern.

Risks Related to the Ownership of Our Common Stock

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

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

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

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

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

•FDA or international regulatory actions, including failure to receive regulatory approval for ILUVIEN or any future products or product candidates;

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

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

•third-party coverage and reimbursement policies;

•additions or departures of key personnel;

•commencement of, or our involvement in, litigation;

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•our ability to meet our repayment and other obligations under our loan agreements;

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

•changes in earnings estimates or recommendations by securities analysts;

•any major change in our board of directors or management;

•results from our clinical trial programs;

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

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

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

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

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

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

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

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

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

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

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In addition to our outstanding common stock, as of June 30, 2014, there were a total of 7,599,768 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options granted under our equity incentive plans. Upon the exercise of these options, in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under the SEC's Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

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

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

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

Pursuant to our 2010 Equity Incentive Plan, our Board of Directors is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2010 Equity Incentive Plan increases each year by an amount equal to the lesser of 4% of all shares of our capital stock outstanding as of January 1st of each year, 2,000,000 shares, or such lesser number as determined by our Board of Directors. On January 1, 2014, an additional 1,264,440 shares became available for future issuance under our 2010 Equity Incentive Plan in accordance with the annual increase. In addition, we have reserved 494,422 shares of our common stock for issuance under our 2010 Employee Stock Purchase Plan. The number of shares eligible for purchase is replenished as of January 1st of each year in an amount equal to the shares purchased under the plan in the preceding year. As such, on January 1, 2014, an additional 26,123 shares became available for future issuance under our 2010 Employee Stock Purchase Plan.

The Series A Convertible Preferred Stock contains covenants that may limit our business flexibility.

For so long as at least 37.5% of the shares of Series A Convertible Preferred Stock originally issued to the investors at the closing of our Series A Convertible Preferred Stock financing in October 2012 are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock: (i) increase or decrease the authorized number of shares of Series A Convertible Preferred Stock; (ii) authorize, create, issue or obligate us to issue (by reclassification, merger or otherwise) any security (or any class or series thereof) or any indebtedness, in each case that has any rights, preferences or privileges senior to, or on a parity with, the Series A Convertible Preferred Stock, or any security convertible into or exercisable for any such security or indebtedness, subject to limited exceptions for certain debt transactions; (iii) amend our certificate of incorporation or the certificate of designation of the Series A Convertible Preferred Stock, in each case in a manner that adversely affects the rights, preference or privileges of the Series A Convertible Preferred Stock; (iv) redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of common stock or preferred stock; provided, however, that this restriction shall not apply

to (A) the redemption of rights issued pursuant to any "poison pill" rights plan or similar plan adopted by us after the closing of the Series A Convertible Preferred Stock financing or (B) the repurchases of stock from former employees, officers, directors or consultants who performed services for us in connection with the cessation of such employment or service pursuant to the terms of existing agreements with such individuals; (v) declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (A) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Convertible Preferred Stock is made pursuant to the certificate of designation or (B) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with the implementation of a "poison pill" rights plan or similar plan by us; (vi) authorize or approve any increase to the number of aggregate shares of capital stock reserved for issuance pursuant to stock option, stock purchase plans or other equity incentive plans such that the total aggregate number of shares issued under such plans and reserved for issuance under such plans (on an as-converted basis) exceeds the number of shares issued and reserved for issuance under such plans (on an as-converted basis) on the date of the closing of the Series A Convertible Preferred Stock financing by more than 20% (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like), provided that any increases resulting solely from the annual increases resulting

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from the "evergreen" provisions of equity incentive plans in effect on the date of the closing of the Series A Convertible Preferred Stock financing shall not be subject to this restriction and shall not be included for purposes of determining whether such 20% increase has occurred; (vii) issue stock or other equity securities of any subsidiary (other than to us or another of our wholly-owned subsidiaries or declare or pay any dividend or other distribution of cash, shares or other assets or redemption or repurchase of shares of any subsidiary; or (viii) incur any secured indebtedness other than certain limited debt transactions. There is no guarantee that the holders of the Series A Convertible Preferred Stock would approve any such restricted action, even where such an action would be in the best interests of our stockholders. Any failure to obtain such approval could harm our business and result in a decrease in the value of our common stock.

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

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

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

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

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

•require that directors only be removed from office for cause;

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

•contain certain protective provisions in favor of the holders of Series A Convertible Preferred Stock;
•limit who may call special meetings of stockholders;

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

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

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us

downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

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

During the three months ended June 30, 2014, we issued the following securities which were not registered under the Securities Act of 1933, as amended, and have not been included previously in a Current Report on Form 8-K. We did not employ any form of general solicitation or advertising in connection with the offer and sale of the securities described below. In addition, we believe the purchasers of the securities are “accredited investors” for the purpose of Rule 501 of the Securities Act. For these reasons, among others, the offer and sale of the following securities were made in reliance on the exemption from registration provided by Section 4(2) of the Securities Act or Regulation D promulgated by the SEC under the Securities Act of 1933, as amended (the Securities Act):

Conversion of Preferred Stock

In April 2014, we issued 2,255,639 shares of our common stock pursuant to a conversion of 150,000 shares of Series A Preferred Stock held by an investor.

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
4.11	Warrant Agreement dated as of April 24, 2014 issued to Hercules Technology Growth Capital, Inc.
10.49	Loan and Security Agreement dated as of April 24, 2014 by and among Alimera Sciences Limited, the several banks and other financial institutions or entities from time to time parties thereto and Hercules Technology Growth Capital, Inc.
10.50	Unconditional Guaranty entered into as of April 24, 2014 by Alimera Sciences, Inc. in favor of Hercules Technology Growth Capital, Inc.
10.51	Unconditional Guaranty entered into as of April 24, 2014 by Alimera Sciences B.V. in favor of Hercules Technology Growth Capital, Inc.
10.52	Unconditional Guaranty entered into as of April 24, 2014 by AS C.V. in favor of Hercules Technology Growth Capital, Inc.
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.

August 11, 2014	By: /s/ C. Daniel Myers C. Daniel Myers Chief Executive Officer and President (Principal Executive Officer)
August 11, 2014	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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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.

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incorporation language contained in such filing.

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