ALIMERA SCIENCES INC
Form 10-Q
November 09, 2015
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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 September 30, 2015
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 x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x
As of November 5, 2015 there were 44,545,623 shares of the registrant's Common Stock issued and outstanding.

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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 Alimera Sciences, Inc.'s (we, our, Alimera or the Company) 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,” “will,” “would,” “should,” “could,” or the 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 Economic Area (EEA) and the U.S.;
- our limited sales and marketing infrastructure;
- our ability to raise sufficient additional financing;
- uncertainty as to the pricing and reimbursement guidelines for ILUVIEN or any future products or product candidates, including ILUVIEN;
- 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;
- our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility;
- 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;
- the extent of government regulations; and
- dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality.

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, 2014, 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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PART I. FINANCIAL INFORMATION
ITEM 1. Interim Condensed Consolidated Financial Statements (unaudited)
ALIMERA SCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	September 30, 2015	December 31, 2014
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 39,340	$ 76,697
Accounts receivable, net	9,377	850
Prepaid expenses and other current assets	2,497	3,234
Inventory, net (Note 5)	1,716	1,734
Deferred financing costs	458	754
Total current assets	53,388	83,269
PROPERTY AND EQUIPMENT, net	2,587	1,653
INTANGIBLE ASSET, net (Note 6)	23,038	24,490
TOTAL ASSETS	$ 79,013	$ 109,412
CURRENT LIABILITIES:		
Accounts payable	$ 3,068	$ 5,021
Accrued expenses (Note 7)	3,238	954
Accrued milestone payments	—	2,000
Outsourced services payable	213	1,466
Note payable (Note 9)	—	1,023
Capital lease obligations	218	11
Total current liabilities	6,737	10,475
NON-CURRENT LIABILITIES:		
Derivative warrant liability	3,013	16,098
Note payable, net of discount — less current portion (Note 9)	34,448	33,065
Other non-current liabilities	1,454	255
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock, $.01 par value — 10,000,000 shares authorized at September 30, 2015 and December 31, 2014:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 600,000 issued and outstanding at September 30, 2015 and December 31, 2014; liquidation preference of $24,000 at September 30, 2015 and December 31, 2014	19,227	19,227
Series B Convertible Preferred Stock, 8,417 authorized and 8,416.251 issued and outstanding at September 30, 2015 and December 31, 2014; liquidation preference of $50,750 at September 30, 2015 and December 31, 2014	49,568	49,568
Common stock, $.01 par value — 100,000,000 shares authorized, 44,470,730 shares issued and outstanding at September 30, 2015 and 44,320,342 shares issued and outstanding at December 31, 2014	445	443
Additional paid-in capital	296,871	292,851
Common stock warrants	1,497	1,497
Accumulated deficit	(333,187)	(313,255)
Accumulated other comprehensive loss	(1,060)	(812)
TOTAL STOCKHOLDERS' EQUITY	33,361	49,519
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 79,013	$ 109,412

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands, except share and per share data)			
NET REVENUE	$6,901	$2,408	$16,615	$6,682
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(634)	(372)	(1,293)	(1,312)
GROSS PROFIT	6,267	2,036	15,322	5,370
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	4,078	4,145	11,222	8,840
GENERAL AND ADMINISTRATIVE EXPENSES	3,031	2,958	10,471	8,643
SALES AND MARKETING EXPENSES	6,949	3,476	21,003	9,763
DEPRECIATION AND AMORTIZATION	653	82	1,864	151
OPERATING EXPENSES	14,711	10,661	44,560	27,397
NET LOSS FROM OPERATIONS	(8,444)	(8,625)	(29,238)	(22,027)
INTEREST EXPENSE, NET AND OTHER	(1,317)	(408)	(3,590)	(862)
UNREALIZED FOREIGN CURRENCY LOSS, NET	(63)	(255)	(34)	(457)
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	8,363	2,324	13,085	(2,752)
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	—	—	(440)
NET LOSS BEFORE TAXES	(1,461)	(6,964)	(19,777)	(26,538)
PROVISION FOR TAXES	(82)	(45)	(155)	(114)
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	$(1,543)	$(7,009)	$(19,932)	$(26,652)
NET LOSS PER SHARE APPLICABLE TO COMMON STOCKHOLDERS — Basic and diluted	$(0.03)	$(0.17)	$(0.45)	$(0.68)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	44,436,224	41,062,814	44,393,831	39,083,187

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)			
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	$(1,543)	$(7,009)	$(19,932)	$(26,652)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	40	(197)	(248)	(175)
TOTAL OTHER COMPREHENSIVE INCOME (LOSS)	40	(197)	(248)	(175)
COMPREHENSIVE LOSS	$(1,503)	$(7,206)	$(20,180)	$(26,827)

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

	Nine Months Ended September 30,	
	2015	2014
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(19,932)	$(26,652)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,864	151
Unrealized foreign currency transaction loss	34	457
Loss from early extinguishment of debt	—	440
Amortization of deferred financing costs and debt discount	524	261
Stock-based compensation expense	3,702	2,833
Change in fair value of derivative warrant liability	(13,085)	2,752
Changes in assets and liabilities:		
Accounts receivable	(8,455)	(679)
Prepaid expenses and other current assets	627	1,307
Inventory	(88)	(9)
Accounts payable	(1,447)	1,341
Accrued expenses and other current liabilities	(828)	2,649
Other long-term liabilities	612	(2)
Net cash used in operating activities	(36,472)	(15,151)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(370)	(163)
Net cash used in investing activities	(370)	(163)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	278	709
Proceeds from sale of common stock	42	37,543
Payment of issuance cost of common stock	—	(2,389)
Payment of Series B Convertible Preferred Stock offering costs	(327)	—
Payment of principal on notes payable	—	(4,861)
Payment of debt extinguishment costs	—	(246)
Proceeds from issuance of notes payable	—	35,000
Payment of debt costs	—	(1,016)
Payment of capital lease obligations	(207)	(7)
Net cash (used in) provided by financing activities	(214)	64,733
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS	(301)	(623)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(37,357)	48,796
CASH AND CASH EQUIVALENTS — Beginning of period	76,697	12,628
CASH AND CASH EQUIVALENTS — End of period	$39,340	$61,424
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$2,904	$502

Cash paid for income taxes	$9	$—
Supplemental schedule of non-cash investing and financing activities:		
Property and equipment acquired under capital leases	$997	$—

There were no dividend payments made during the nine months ended September 30, 2015 and 2014.

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS

Alimera Sciences, Inc., and its subsidiaries (the Company), is a pharmaceutical 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 underserved market opportunity. The Company's only commercial product is ILUVIEN®, which has received marketing authorization in the United States (U.S.), Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, and the United Kingdom. In the U.S., ILUVIEN is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP). In the European Economic Area (EEA) countries in which ILUVIEN has received marketing authorization, it is indicated for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies. As part of the approval process in the EEA, the Company has committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients.

The Company launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015.

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 U.S. (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 the Company's management, the accompanying interim financial statements reflect all adjustments, which include normal recurring adjustments, necessary to present fairly the Company's interim financial information.

The accompanying interim financial statements and related notes should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2014 and related notes included in the Company's Annual Report on Form 10-K, which was filed with the SEC on March 13, 2015. The financial results for any interim period are not necessarily indicative of the expected financial results for the full year.

Reclassifications

Within the unaudited Consolidated Statements of Operations for the three and nine months ended September 30, 2014, the Company reclassified certain medical affairs support expenses of $204,000 and $464,000, respectively, from sales and marketing expenses to research, development and medical affairs expenses to conform to the current year presentation.

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 SEC for the year ended December 31, 2014. In addition, with the U.S. launch of ILUVIEN in the nine months ended September 30, 2015, the Company adopted the revenue recognition and segment reporting policies set forth below.

Revenue Recognition

In the U.S., the Company sells ILUVIEN to a limited number of specialty distributors who in turn sell the product downstream to pharmacies and physician practices. Revenue from U.S. product sales is recorded upon sale to the specialty distributors net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees and other sales-related deductions. Calculating these provisions involves estimates and judgments. The Company reviews its estimates of rebates, chargebacks, and other applicable provisions each period

and records any necessary adjustments in the current period's net product sales.

Government Rebates and Chargebacks: The Company estimates reductions to product sales for Medicaid and Veterans' Administration (VA) programs, and for certain other qualifying federal and state government programs. Based upon the Company's contracts with government agencies, statutorily-defined discounts applicable to government-funded programs,

historical experience, and estimated payer mix, the Company estimates and records an allowance for rebates and chargebacks. The Company's liability for Medicaid rebates consists of estimates for claims that a state will make for a current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, and invoices received for claims from prior quarters that have not been paid. The Company's reserves related to discounted pricing to VA, Public Health Services, and other institutions (collectively qualified healthcare providers) represent the Company's estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices the Company charges to its customers (i.e., specialty distributors). The Company's customers charge the Company for the difference between what they pay for the products and the ultimate selling price to the qualified healthcare providers. The Company's reserve for this discounted pricing is based on expected sales to qualified healthcare providers and the chargebacks that customers have already claimed.

Distribution-Related Fees: The Company has written contracts with its customers that include terms for distribution-related fees. The Company estimates and records distribution and related fees due to its customers based on gross sales.

Product Returns: Consistent with industry practice, the Company offers its customers a limited right to return product purchased directly from the Company, which is principally based upon the product's expiration date. The Company will accept returns for three months prior to and up to nine months after the product expiration date. Depending on the circumstances, the Company may provide replacement products or cash credit for returns. Product returned is generally not resalable given the nature of the Company's products and method of administration. The Company develops estimates for product returns based upon historical experience, inventory levels, shelf life of the product, and other relevant factors. The Company monitors product supply levels in the distribution channel, as well as sales by its customers to healthcare providers using product-specific data provided by its customers. If necessary, the Company's estimates of product returns may be adjusted in the future based on actual returns experience, known or expected changes in the marketplace, or other factors.

Reporting Segments

The Company determines operating segments in accordance with its internal operating structure. The Company's chief operating decision maker is the Chief Executive Officer (CEO). While the CEO is apprised of a variety of financial metrics and information, the business is principally managed and organized based upon geographic and regulatory environment. Each segment is separately managed and is evaluated primarily upon net loss from operations. The Company does not report balance sheet information by segment since it is not reviewed by the Company's chief operating decision maker. The Company has two reportable segments, the U.S. and International.

Previously, the business was managed on an aggregate basis. As a result of the retrospective presentation and disclosure requirements under U.S. GAAP for changes in segment reporting, the Company is required to reflect the change in presentation and disclosure for all periods presented. As such, the Company has presented in Note 16, Segment Information, the financial results for the three and nine months ended September 30, 2014 in the same manner as for the three and nine months ended September 30, 2015.

During the three and nine months ended September 30, 2015, two individual customers within the U.S. segment accounted for 73% and 68% of the Company's consolidated revenues. As of September 30, 2015, two individual customers within the U.S. segment accounted for 83% of the Company's accounts receivable balances.

The accounting policies of these segments are the same as those described in Note 2, Summary of Significant Accounting Policies included in the Notes to Financial Statements included in the Company's Annual Report on Form 10-K.

Research and Development Expenses

Research and development expenses were $940,000 and $1,082,000 for the three months ended September 30, 2015 and 2014, respectively and $1,958,000 and $3,480,000 for the nine months ended September 30, 2015 and 2014, respectively.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (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 Accounting Standards Update (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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 is effective for the first interim period within annual reporting periods beginning after December 15, 2017 for public entities, with early adoption permitted in the annual reporting period beginning after December 15, 2016. The Company is still evaluating the potential impact of adopting this guidance on its financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern. ASU 2014-15 provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The Company is still evaluating the potential impact of adopting this guidance on its financial statements.

In April 2015, the FASB issued ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. ASU 2015-03 is intended to simplify the presentation of debt issuance costs. These amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted and the standard is to be retrospectively applied to all periods presented upon adoption. The Company is still evaluating the potential impact of adopting this guidance on its financial statements.

4. FACTORS AFFECTING OPERATIONS

To date, the Company has incurred negative cash flow from operations, and has accumulated a deficit of $333,187,000 from inception through September 30, 2015. As of September 30, 2015, the Company had approximately $39,340,000 in cash and cash equivalents.

The Company believes that it has sufficient funds available to fund its operations for the continued commercialization of ILUVIEN in the U.S., Germany, Portugal, and the United Kingdom. The Company does not expect to generate positive cash flow from operations until 2017, if at all. The Company may seek to raise additional financing to fund its working capital needs for the commercialization of ILUVIEN, the development and commercialization of future products and product candidates or in order to comply with certain financial covenants of the loan agreements. If the Company is unable to raise additional financing, then it may adjust its commercial plans so that it can continue to operate with its existing cash resources.

The accompanying interim 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

5. INVENTORY

Inventory consisted of the following:

	September 30, 2015	December 31, 2014
	(In thousands)	
Component parts (1)	$153	$76
Work-in-process (2)	693	219
Finished goods	1,185	1,972
Total inventory	2,031	2,267
Inventory reserve	(315)	(533)
Inventory — net	$1,716	$1,734

(1) Component parts inventory consists of manufactured components of the ILUVIEN applicator.

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

6. INTANGIBLE ASSETS

As a result of the United States Food and Drug Administration's (the FDA) approval of the New Drug Application for ILUVIEN in September 2014, the Company was required to pay pSivida US, Inc. (pSivida) a milestone payment of $25,000,000 (the pSivida Milestone Payment) in October 2014 (see Note 8). The Company had no intangible assets prior to September 2014.

The gross carrying amount of the intangible asset was $25,000,000, which is being amortized over approximately 13 years from the acquisition date. The amortization expense related to the intangible asset was $489,000 and $1,451,000 for the three and nine months ended September 30, 2015, respectively. The amortization expense related to the intangible asset was $49,000 for both the three and nine months ended September 30, 2014. The net book value of the intangible asset was $23,038,000 and $24,490,000 as of September 30, 2015 and December 31, 2014, respectively.

The estimated future amortization expense as of September 30, 2015 for the remaining periods in the next five years and thereafter is as follows (in thousands):

Years Ending December 31	
2015	$488
2016	1,940
2017	1,940
2018	1,940
2019	1,940
Thereafter	14,790
Total	$23,038

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

7. ACCRUED EXPENSES
Accrued expenses consisted of the following:

	September 30, 2015	December 31, 2014
	(In thousands)	
Accrued compensation expenses	$1,718	$226
Accrued clinical investigator expenses	453	309
Accrued rebate, chargeback and other revenue reserves	402	—
Other accrued expenses	665	419
Total accrued expenses	$3,238	$954

8. LICENSE AGREEMENTS
The Company entered into an agreement with pSivida for the use of fluocinolone acetonide (FAc) in pSivida's proprietary delivery device in February 2005, which was subsequently amended in 2008. The agreement with pSivida provides the Company with a worldwide exclusive license to utilize certain underlying technology used in the development and commercialization of 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, determined on a cash basis, 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 September 30, 2015 and December 31, 2014, the Company was owed approximately $19,997,000 and $12,956,000, 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. As a result of the FDA's approval of the NDA for ILUVIEN in September 2014, the Company made the pSivida Milestone Payment of $25,000,000 in October 2014.

9. LOAN AGREEMENTS
2013 Loan Agreement
In May 2013, Alimera Sciences Limited (Limited), a subsidiary of the Company, entered into a loan and security agreement (2013 Loan Agreement) with 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 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. 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 addition, 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.

2014 Loan Agreement

In April 2014, Limited entered into a loan and security agreement (2014 Loan Agreement) with Hercules Technology Growth Capital, Inc. (Hercules) providing for a term loan of up to $35,000,000 (2014 Term Loan). Under the 2014 Loan

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Agreement, 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 made an additional advance of $25,000,000 to Limited in September 2014 following the approval of ILUVIEN by the FDA to fund the pSivida Milestone Payment. The 2014 Term Loan provided for interest only payments through November 2015. 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 2014 Term Loan was due and payable to Hercules in equal monthly payments of principal and interest through May 1, 2018. In November 2015, Limited and Hercules amended the 2014 Term Loan to extend the interest only payments through May 2017. Beginning in June 2017, Limited will make eleven equal monthly payments of principal and interest based upon a 30-month amortization schedule followed by a final payment of all remaining outstanding principal and interest in May 2018. In connection with the amendment, Limited paid to Hercules an amendment fee of $262,500 and agreed to make an additional payment of $1,050,000 equal to 3% of the 2014 Term Loan at the time of the final payment in May 2018.

In accordance with ASC 470-10-45, Debt, the balance sheet as of September 30, 2015 reflect the amended debt maturities.

In connection with the initial advance under the 2014 Term Loan, Limited paid to Hercules a facility charge of $262,500 and incurred legal and other fees of approximately $383,000. Limited incurred approximately $375,000 in additional fees in connection with the second advance. If Limited repays the 2014 Term Loan, as amended, prior to maturity, it will pay Hercules a prepayment penalty of 1.25% of the total principal amount repaid.

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 2014 Term Loan, as amended, and an increase to the applicable interest rate, and would permit Hercules to exercise remedies with respect to the collateral under the 2014 Term Loan, as amended.

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 2014 Loan Agreement, as amended, 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 the amendment, Limited agreed to covenants regarding certain revenue thresholds and liquidity for the Company. As of September 30, 2015, the Company, on a consolidated basis with its subsidiaries, was in compliance with the covenants of the 2014 Term Loan.

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 the closing in April 2014 and the remaining forty percent became exercisable upon the funding of the additional $25,000,000 to Limited in September 2014. Further, the Company agreed to amend the warrant agreement in connection with the amendment of the 2014 Loan Agreement to increase the number of shares issuable upon exercise to 660,377 and decrease the exercise price to $2.65 per share.

Fair Value of Debt

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 September 30, 2015 and December 31, 2014.

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10. 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Series A convertible preferred stock	9,022,556	9,022,556	9,022,556	9,022,556
Series B convertible preferred stock	8,416,251	—	8,416,251	—
Series A convertible preferred stock warrants	4,511,279	4,511,279	4,511,279	4,511,279
Common stock warrants	362,970	362,970	362,970	362,970
Stock options	9,094,716	7,582,462	9,094,716	7,582,462
Total	31,407,772	21,479,267	31,407,772	21,479,267

11. PREFERRED STOCK

Series A Convertible 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 $2.66 (Conversion Price). The initial Conversion Price was subject to adjustment based on certain customary price based anti-dilution adjustments. These adjustment features lapsed in September 2014. 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.

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. The warrant anti-dilution provisions lapsed in September 2014. At September 30, 2015 and December 31, 2014, the fair market value of the warrants was estimated to be $3,013,000 and $16,098,000, respectively. During the three months ended September 30, 2015 and 2014, the Company recorded gains of $8,363,000 and $2,324,000, respectively, as a

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result of the change in fair value of the warrants. During the nine months ended September 30, 2015 and 2014, the Company recorded gain of $13,085,000 and a loss of $2,752,000, 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 the conversion of 150,000 shares of Series A Convertible Preferred Stock held by an investor. In September 2014, 3,759,398 shares of common stock were issued pursuant to the conversion of 250,000 shares of Series A Convertible Preferred Stock held by another investor. As of September 30, 2015, there were 600,000 shares of Series A Convertible Preferred Stock issued and outstanding.

Series B Convertible Preferred Stock

On December 12, 2014, the Company closed a preferred stock financing in which it sold 8,291.873 shares of Series B Convertible Preferred Stock for a purchase price of $6,030 per share, or an aggregate purchase price of $50,000,000, prior to the payment of approximately $432,000 of related issuance costs. The Company issued an additional 124.378 shares of Series B Convertible Preferred Stock as a subscription premium to the purchasers. The powers, preferences and rights of the Series B 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. Each share of Series B Convertible Preferred Stock is convertible into 1,000 shares of the Company’s common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series B Convertible Preferred Stock into shares of the Company’s common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of the Company’s common stock then issued and outstanding. The Series B Convertible Preferred Stock ranks junior to the Company’s existing Series A Convertible Preferred Stock, and senior to the Company’s common stock, with respect to rights upon liquidation. The Series B Convertible Preferred Stock ranks junior to all existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions), the Series B Convertible Preferred Stock do not have voting rights. The Series B Preferred Stock is not redeemable at the option of the holder. The Series B Convertible Preferred Stock is not subject to any price-based or other anti-dilution protections and does not provide for any accruing dividends.

The Company determined that the conversion option of the Preferred Shares represented a beneficial conversion feature, as the conversion feature had intrinsic value to the holder on the commitment date as a result of the subscription premium. Therefore, the Company recorded a beneficial conversion feature of $750,000 as an increase in additional paid in capital. Because the Series B Convertible Preferred Stock was immediately convertible into common stock at the option of the holder at issuance, the Company immediately accreted the full value of the beneficial conversion feature to the carrying value of the Series B Convertible Preferred Stock on that date.

12. 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 were used for general corporate and working capital purposes.

In April 2014, 2,255,639 shares of common stock were issued pursuant to the conversion of 150,000 shares of Series A Convertible Preferred Stock held by an investor. In September 2014, 3,759,398 shares of common stock were issued pursuant to the conversion of 250,000 shares of Series A Convertible Preferred Stock held by another investor. During the nine months ended September 30, 2015 and 2014, 10,993 and 23,487 shares of the Company’s common stock were acquired through its employee stock purchase plan resulting in proceeds of $42,000 and $43,000, respectively.

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13. STOCK INCENTIVE PLANS

Stock Option Plans

During the three months ended September 30, 2015 and 2014, the Company recorded compensation expense related to stock options of approximately $1,355,000 and $970,000, respectively. During the nine months ended September 30, 2015 and 2014, the Company recorded compensation expense related to stock options of approximately $3,623,000 and $2,799,000, respectively. As of September 30, 2015, the total unrecognized compensation cost related to non-vested stock options granted was $10,496,000 and is expected to be recognized over a weighted average period of 2.93 years. The following table presents a summary of stock option activity for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2015		2014		2015		2014	
	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	9,292,947	$3.49	7,599,768	$2.89	7,681,256	$3.03	7,566,438	$2.74
Grants	69,000	4.39	165,000	5.66	1,902,500	5.38	480,000	5.66
Forfeitures	(200,260)	5.25	(10,208)	3.45	(349,645)	4.84	(109,375)	2.62
Exercises	(66,971)	2.09	(172,098)	2.18	(139,395)	1.99	(354,601)	2.00
Options outstanding at period end	9,094,716	3.47	7,582,462	2.96	9,094,716	3.47	7,582,462	2.96
Options exercisable at period end	5,510,064	3.19	4,148,647	3.18	5,510,064	3.19	4,148,647	3.18
Weighted average per share fair value of options granted during the period	$3.37		$4.55		$4.19		$4.71	

The following table provides additional information related to outstanding stock options, exercisable stock options, and stock options expected to vest as of September 30, 2015:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
				(In thousands)
Outstanding	9,094,716	$3.47	6.86 years	$2,025
Exercisable	5,510,064	3.19	5.72 years	1,699
Outstanding, vested and expected to vest	8,672,753	3.43	6.77 years	2,006

The following table provides additional information related to outstanding stock options, exercisable stock options, and stock options expected to vest as of December 31, 2014:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
				(In thousands)
Outstanding	7,681,256	$3.03	7.05 years	$21,710

Exercisable	4,452,274	3.17	5.87 years	12,887
Outstanding, vested and expected to vest	7,258,603	3.04	6.95 years	20,574

Employee Stock Purchase Plan

During the three months ended September 30, 2015 and 2014, the Company recorded compensation expense related to its employee stock purchase plan of approximately $38,000 and $14,000, respectively. During the nine months ended September 30, 2015 and 2014, the Company recorded compensation expense related to its employee stock purchase plan of approximately and $79,000 and $35,000, respectively.

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14. 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 September 30, 2015 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; 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. Tax years since 2012 remain subject to examination in the United Kingdom and the Netherlands. Tax years since 2013 remain subject to examination in Germany.

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, 2014, the Company had federal NOL carry-forwards of approximately $89,547,000 and state NOL carry-forwards of approximately $72,968,000 available to reduce future income. The Company's federal NOL carry-forwards remain fully reserved as of September 30, 2015. If not utilized, the federal NOL carry-forwards will expire at various dates between 2029 and 2033 and the state NOL carry-forwards will expire at various dates between 2020 and 2033.

The Company's NOL carry-forwards may be subject to annual limitations under Internal Revenue Code (IRC) Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of the Company

were to occur. The Company periodically evaluates its NOL carry-forwards and whether certain changes in ownership, including its IPO, have occurred that would limit its ability to utilize a portion of the Company's NOL carry-forwards. If it is determined that significant ownership changes have occurred since the Company generated its NOL carry-forwards, the Company may be subject to annual limitations on the use of these NOL carry-forwards under IRC Section 382 (or comparable provisions of state law).

As of December 31, 2014, the Company had cumulative book losses in foreign subsidiaries of $42,795,000. 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 anticipates that its foreign subsidiaries will be profitable and have earnings in the future. Once the foreign subsidiaries do have earnings, 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 has not recorded a deferred tax liability related to excess of book over tax basis in the stock of its foreign subsidiaries in accordance with ASC 740-30-25.

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15. 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 September 30, 2015 and December 31, 2014.

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

	September 30, 2015			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents (1)	$2,510	$—	$—	$2,510
Assets measured at fair value	$2,510	$—	$—	$2,510
Liabilities:				
Derivative warrant liability (2)	$—	$3,013	$—	$3,013
Liabilities measured at fair value	$—	$3,013	$—	$3,013

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents (1)	$65,509	$—	$—	$65,509
Assets measured at fair value	$65,509	$—	$—	$65,509
Liabilities:				
Derivative warrant liability (2)	$—	$16,098	$—	$16,098
Liabilities measured at fair value	$—	$16,098	$—	$16,098

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

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

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

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16. SEGMENT INFORMATION

The following table presents a summary of the Company's reporting segments for the three months ended September 30, 2015 and 2014:

	Three Months Ended September 30, 2015			Three Months Ended September 30, 2014		
	U.S.	International	Consolidated	U.S.	International	Consolidated
	(In thousands)					
NET REVENUE	$5,032	$1,869	$6,901	$—	$2,408	$2,408
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(245)	(389)	(634)	—	(372)	(372)
GROSS PROFIT	4,787	1,480	6,267	—	2,036	2,036
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	2,320	1,758	4,078	2,595	1,550	4,145
GENERAL AND ADMINISTRATIVE EXPENSES	1,712	1,319	3,031	1,788	1,170	2,958
SALES AND MARKETING EXPENSES	4,546	2,403	6,949	1,186	2,290	3,476
DEPRECIATION AND AMORTIZATION	639	14	653	82	—	82
OPERATING EXPENSES	9,217	5,494	14,711	5,651	5,010	10,661
NET LOSS FROM OPERATIONS	(4,430)	(4,014)	(8,444)	(5,651)	(2,974)	(8,625)
OTHER INCOME AND EXPENSES, NET			6,983			1,661
NET LOSS BEFORE TAXES			$(1,461)			$(6,964)

The following table presents a summary of the Company's reporting segments for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30, 2015			Nine Months Ended September 30, 2014		
	U.S.	International	Consolidated	U.S.	International	Consolidated
	(In thousands)					
NET REVENUE	$11,279	$5,336	$16,615	$—	$6,682	$6,682
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(573)	(720)	(1,293)	—	(1,312)	(1,312)
GROSS PROFIT	10,706	4,616	15,322	—	5,370	5,370
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	5,176	6,046	11,222	4,136	4,704	8,840
GENERAL AND ADMINISTRATIVE EXPENSES	6,080	4,391	10,471	5,103	3,540	8,643
SALES AND MARKETING EXPENSES	14,274	6,729	21,003	1,968	7,795	9,763
DEPRECIATION AND AMORTIZATION	1,819	45	1,864	151	—	151
OPERATING EXPENSES	27,349	17,211	44,560	11,358	16,039	27,397

NET LOSS FROM OPERATIONS	(16,643)	(12,595)	(29,238)	(11,358)	(10,669)	(22,027)
OTHER INCOME AND EXPENSES, NET			9,461			(4,511)
NET LOSS BEFORE TAXES			$ (19,777)			$ (26,538)

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17. SUBSEQUENT EVENT

As disclosed in Note 9, the Company entered into the first amendment to its 2014 Loan Agreement with Hercules in November 2015. The specific terms of the amendment are disclosed in detail Note 9.

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

Overview

Alimera Sciences, Inc., and its subsidiaries (we, Alimera or the Company) is a pharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. We are presently focused on diseases affecting the back of the eye, or retina, because we believe these diseases are not well treated with current therapies and represent a significant market opportunity.

Our only commercial product is ILUVIEN®, which has been developed to treat diabetic macular edema (DME). DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN has received marketing authorization in the United States (U.S.), Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, and the United Kingdom. In the U.S., ILUVIEN is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP). In the European Economic Area (EEA) countries in which ILUVIEN has received marketing authorization, it is indicated for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies. As part of the approval process in the EEA, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients.

We launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015.

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of September 30, 2015, we have accumulated a deficit of $333.2 million. We expect to continue to incur losses as we:

- continue the commercialization of ILUVIEN in the U.S. and the EEA;
- continue to seek regulatory approval of ILUVIEN in other jurisdictions;
- 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 September 30, 2015, we had approximately $39.3 million in cash and cash equivalents.

We do not expect to have positive cash flow from operations until 2017, if at all. Due to the limited revenue generated by ILUVIEN to date, or an inability to maintain compliance with covenants, including a $20.0 million liquidity covenant, under our loan and security agreement, as amended (2014 Loan Agreement), with Hercules Technology Growth Capital, Inc. (Hercules), we may 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

We 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, which was subsequently amended and restated in 2008. Our agreement with pSivida provides us with a worldwide exclusive license to utilize certain underlying technology used in the development and commercialization of ILUVIEN. ILUVIEN 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 utilize 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 utilize pSivida's proprietary delivery device in connection with 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, and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined in the amended and restated agreement. In connection with this arrangement we are entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits. As of September 30, 2015 and December 31, 2014, pSivida owed us $20.0 million and $13.0 million, respectively, in commercialization costs. Due to the uncertainty of future profits from ILUVIEN, we have fully reserved these amounts in the accompanying consolidated financial statements.

As a result of the United States Food and Drug Administration (the FDA) approval of ILUVIEN in September 2014, we paid pSivida a milestone payment of $25.0 million (the pSivida Milestone Payment) in October 2014.

Our Loan Agreements

2013 Loan Agreement

In May 2013, Alimera Sciences Limited (Limited), a subsidiary of ours, 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 agreed to provide up to an additional $15.0 million to Limited under a working capital line of credit (2013 Line of Credit). 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.

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 addition, 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 the loss on early extinguishment.

2014 Loan Agreement

In April 2014, Limited entered into a loan and security agreement (2014 Loan Agreement) with Hercules Technology Growth Capital, Inc. (Hercules) providing for a term loan up to $35.0 million (2014 Term Loan). 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 made an additional advance of $25.0 million to Limited in September 2014 as a result of the approval of ILUVIEN by the FDA to fund the pSivida Milestone Payment. The 2014 Term Loan provided for interest only payments through November 2015. 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 2014 Term Loan was due and payable to Hercules in equal monthly payments of principal and interest through May 1, 2018. In November 2015, Limited and Hercules amended the 2014 Term Loan to extend the interest only payments

through May 2017. Beginning in June 2017, Limited will make eleven equal monthly payments of principal and interest based upon a 30-month amortization schedule followed by a final payment of all remaining outstanding principal and interest in May 2018. In connection with the amendment, Limited paid to Hercules an amendment fee of $262,500 and agreed to make an additional payment of $1,050,000 equal to 3% of the 2014 Term Loan at the time of the final payment in May 2018.

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In accordance with ASC 470-10-45, Debt, the balance sheet as of September 30, 2015 reflect the amended debt maturities.

In connection with the initial advance under the 2014 Term Loan, Limited paid to Hercules a facility charge of $262,500 and incurred legal and other fees of approximately $383,000. Limited incurred approximately $375,000 in additional fees in connection with the second advance. If Limited repays the 2014 Term Loan, as amended, 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 2014 Loan Agreement and an increase to the applicable interest rate, and would permit Hercules to exercise remedies with respect to the collateral under the 2014 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 2014 Loan Agreement, as amended, 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 the amendment, Limited agreed to covenants regarding certain revenue thresholds and liquidity for the Company. As of September 30, 2015, we, on a consolidated basis with our subsidiaries, were in compliance with the covenants of the 2014 Term Loan Agreement.

In connection with Limited entering into the 2014 Loan Agreement, we entered into a warrant agreement with Hercules that allows 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 the closing in April 2014 and the remaining 40% became exercisable upon the funding of the additional $25.0 million to Limited in September 2014. Further, we agreed to amend the warrant agreement in connection with the amendment to increase the number of shares issuable upon exercise to 660,377 and decrease the exercise price to $2.65 per share.

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 September 30, 2015 and December 31, 2014.

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Financial Operations Overview

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)			
NET REVENUE	$6,901	$2,408	$16,615	$6,682
GROSS PROFIT	6,267	2,036	15,322	5,370
OPERATING EXPENSES	14,711	10,661	44,560	27,397
NET LOSS FROM OPERATIONS	(8,444)	(8,625)	(29,238)	(22,027)
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	(1,543)	(7,009)	(19,932)	(26,652)

Revenue

We began generating revenue from ILUVIEN in the second quarter of 2013, but do not expect positive cash flow from operations until 2017, 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 the revenue we generate in countries where we are commercialized will continue to fluctuate from quarter to quarter based on seasonality and the timing of orders from our customers. Specifically in the U.S., our revenue could fluctuate quarter over quarter, based on our distributors ordering patterns which may not correspond directly with their customers' ordering patterns. Further, 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.

Net revenue increased by approximately $4.5 million, or 188%, to approximately $6.9 million for the three months ended September 30, 2015 and by approximately $9.9 million, or 148%, to approximately $16.6 million for the nine months ended September 30, 2015 primarily as a result of our U.S. launch of ILUVIEN in 2015.

Operating Expenses

Operating expenses increased by approximately $4.0 million, or 37%, to approximately $14.7 million for the three months ended September 30, 2015 primarily as a result of increases in sales and marketing expenses of $3.4 million to support the marketing efforts of ILUVIEN in the U.S. Additionally, there was an increase in depreciation and amortization expense of $570,000.

Operating expenses increased by approximately $17.2 million, or 63%, to approximately $44.6 million for the nine months ended September 30, 2015 primarily as a result of increases in sales and marketing expenses of $11.2 million to support the marketing efforts of ILUVIEN in the U.S. Additionally, there were increases in research, development and medical affairs expenses of $2.4 million, in general and administrative expenses of $1.9 million and in depreciation and amortization expense of $1.7 million.

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Research, Development and Medical Affairs Expenses

Substantially all of our research, development and medical affairs expenses incurred to date related to our continuing operations have been related to the development of ILUVIEN. We anticipate that we will incur additional research, development and medical affairs 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, development and medical affairs expenses as they are incurred. Our research, development and medical affairs expenses consist primarily of:

- salaries and related expenses for personnel, including medical sales liaisons;
- costs related to the provision of medical affairs support, including symposia development for physician education;
- costs related to compliance with FDA, EEA or other regulatory requirements;
- 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;
- consulting fees paid to third-parties involved in research, development and medical affairs activities; and
- costs related to stock options or other stock-based compensation granted to personnel in development functions.

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

We expect that a large percentage of our research, development and medical affairs expenses in the future will be incurred in support of our current and future technical, preclinical and clinical development programs.

Within the Operating expenses section of the unaudited Consolidated Statements of Operations for the three and nine months ended September 30, 2014, we reclassified certain medical affairs support expenses of $204,000 and $464,000, respectively, from sales and marketing expenses to research, development and medical affairs expenses to conform to the current year presentation.

General and Administrative Expenses

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

Sales and Marketing Expenses

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

We launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015.

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) provided certain services to us in relation to the commercialization of ILUVIEN, in France, Germany and the United Kingdom. In December 2013 and January 2014, respectively, we transitioned our German and United Kingdom country manager positions in-house. In April 2015, we terminated the project orders associated with France and Germany and transitioned the covered positions employed by Quintiles Commercial to our payroll. In July 2015, we terminated the project orders associated with the United Kingdom and transitioned the covered positions employed by Quintiles Commercial to our payroll.

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For the nine months ended September 30, 2015, we incurred $1.0 million of expense associated with these project orders. No expense was recognized during the three months ended September 30, 2015. At September 30, 2015, approximately $210,000 is included in outsourced services payable in our accompanying consolidated financial statements in association with these project orders.

We have a European management team, local management teams and commercial personnel in France, Germany, Portugal and the United Kingdom totaling 29 persons at September 30, 2015, of which five are consultants. As of September 30, 2015, we had a U.S. field force of approximately 47 persons, including sales personnel, reimbursement specialists, and payor relations directors.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our unaudited interim condensed consolidated financial statements and notes (interim financial statements) which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these interim 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 discuss our critical accounting policies in the Management's Discussion and Analysis section of the Company's Annual Report on Form 10-K. There have been no significant changes in our critical accounting policies except as follows.

Revenue Recognition - U.S. Product Sales

Product sales consist of U.S. sales of ILUVIEN. In the U.S., we sell ILUVIEN to a limited number of specialty distributors who in turn sell the product downstream to pharmacies and physician practices. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss have passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, we have no further performance obligations, and returns can be reasonably estimated. We record revenue from product sales upon delivery to our specialty distributors.

Revenue from U.S. product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, such as Medicaid and Veterans' Administration, distribution-related fees and other sales-related deductions. We estimate reductions to product sales based upon contracts with customers and government agencies, statutorily-defined discounts applicable to government-funded programs, estimated payer mix, inventory levels, shelf life of the product, and other relevant factors. Calculating these provisions involves estimates and judgments. We review our estimates of rebates, chargebacks, and other applicable provisions each period and record any necessary adjustments in the current period's net product sales.

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Results of Operations - Segment Review

The following selected unaudited financial and operating data are derived from our interim financial statements and should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements. The results and discussions that follow are reflective of how our executive management monitors the performance of our reporting segments.

Certain operating expenses are allocated between our reporting segments based on activity-based costing methods. These activity-based costing methods require us to make estimates that impact the amount of each expense category that is attributed to each segment. Changes in these estimates will directly impact the amount of expense allocated to each segment, and therefore the operating profit of each reporting segment. There were no significant changes in our expense allocation methodology during 2015 or 2014.

U.S. Segment

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)			
NET REVENUE	$5,032	$—	$11,279	$—
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(245)	—	(573)	—
GROSS PROFIT	4,787	—	10,706	—
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	2,320	2,595	5,176	4,136
GENERAL AND ADMINISTRATIVE EXPENSES	1,712	1,788	6,080	5,103
SALES AND MARKETING EXPENSES	4,546	1,186	14,274	1,968
DEPRECIATION AND AMORTIZATION	639	82	1,819	151
OPERATING EXPENSES	9,217	5,651	27,349	11,358
NET LOSS FROM OPERATIONS	$(4,430)	$(5,651)	$(16,643)	$(11,358)

Three months ended September 30, 2015 compared to the three months ended September 30, 2014

Net Revenue. Net revenue of approximately $5.0 million was recognized for the three months ended September 30, 2015 after the U.S. launch of ILUVIEN during the first quarter of 2015. No U.S. revenue was recognized during the three months ended September 30, 2014.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization of approximately $250,000, was recognized for the three months ended September 30, 2015, as a result of the U.S. launch of ILUVIEN during the first quarter of 2015. No U.S. cost of goods sold was recognized during the three months ended September 30, 2014.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately $300,000, or 12%, to approximately $2.3 million for the three months ended September 30, 2015 compared to approximately $2.6 million for the three months ended September 30, 2014. The decrease was primarily attributable to a decrease associated with a $2.0 million milestone payment payable to a consultant engaged to assist with the approval of ILUVIEN in the U.S. incurred in 2014 offset by increases of approximately $690,000 in costs incurred with third parties related to product enhancements, $500,000 for scientific communications, $470,000 for U.S. regulatory compliance costs and $240,000 in personnel and related costs associated with our medical science liaison team engaging physicians in the study of ILUVIEN.

General and administrative expenses. General and administrative expenses decreased by approximately $100,000, or 6%, to approximately $1.7 million for the three months ended September 30, 2015 compared to approximately $1.8 million for the three months ended September 30, 2014. The decrease was primarily attributable to a reduction in professional and legal fees of $100,000 due to the addition of in-house counsel in 2015.

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Sales and Marketing expenses. Sales and marketing expenses increased by approximately $3.3 million, or 275%, to approximately $4.5 million for the three months ended September 30, 2015 compared to approximately $1.2 million for the three months ended September 30, 2014. The increase was primarily attributable to increases of $2.9 million costs of the commercial team hired for the launch of ILUVIEN in the U.S. in the first quarter of 2015 and $430,000 in costs associated with providing reimbursement support for ILUVIEN in the U.S.

Depreciation and amortization. Depreciation and amortization increased by approximately $560,000, or 700%, to approximately $640,000 for the three months ended September 30, 2015 compared to approximately $80,000 for the three months ended September 30, 2014. The increase was primarily attributable to amortization of $490,000 associated with an intangible asset which was capitalized in connection with the pSivida Milestone Payment which was payable upon FDA approval of ILUVIEN in September 2014.

Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

Net Revenue. Net revenue of approximately $11.3 million was recognized for the nine months ended September 30, 2015 following the U.S. launch of ILUVIEN in the first quarter of 2015. No U.S. revenue was recognized during the nine months ended September 30, 2014.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold excluding depreciation and amortization of approximately $570,000, was recognized for the nine months ended September 30, 2015 following the U.S. launch of ILUVIEN during the first quarter of 2015. No U.S. cost of goods sold was recognized during the nine months ended September 30, 2014.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately $1.1 million, or 27%, to approximately $5.2 million for the nine months ended September 30, 2015 compared to approximately $4.1 million for the nine months ended September 30, 2014. The increase was primarily attributable to increases of approximately $1.3 million in costs incurred with third parties related to product enhancements, $750,000 in scientific communications costs, $530,000 in ongoing scientific study costs, $470,000 in U.S. regulatory compliance costs and $370,000 in personnel and related costs associated with our medical science liaison team engaging physicians in the study of ILUVIEN. These costs were offset by a decrease of approximately $2.5 million in costs incurred with a consultant engaged to assist with the approval of ILUVIEN in the U.S. incurred in 2014, which included a milestone payment of $2.0 million payable upon FDA approval of ILUVIEN in September 2014.

General and administrative expenses. General and administrative expenses increased by approximately $1.0 million, or 20%, to approximately $6.1 million for the nine months ended September 30, 2015 compared to approximately $5.1 million for the nine months ended September 30, 2014. The increase was primarily attributable to increases of approximately $610,000 in personnel and related costs, and $160,000 in office expenses due to our growth to support the launch and commercialization of ILUVIEN in the U.S and $170,000 in professional and legal fees.

Sales and Marketing expenses. Sales and marketing expenses increased by approximately $12.3 million, or 615%, to approximately $14.3 million for the nine months ended September 30, 2015 compared to approximately $2.0 million for the nine months ended September 30, 2014. The increase was primarily attributable to increases of approximately $8.8 million in personnel and travel costs associated with the commercial team hired for the launch of ILUVIEN in the U.S. in the first quarter of 2015, $2.1 million in promotional costs, $1.2 million in costs associated with establishing reimbursement in the U.S. and $460,000 of media and public relations costs incurred to support the launch and commercialization of ILUVIEN in the U.S.

Depreciation and amortization. Depreciation and amortization increased by approximately $1.7 million, or 1,133%, to approximately $1.8 million for the nine months ended September 30, 2015 compared to approximately $150,000 for the nine months ended September 30, 2014. The increase was primarily attributable to amortization of $1.5 million associated with an intangible asset which was capitalized in connection with the pSivida Milestone Payment which was payable upon FDA approval of ILUVIEN in September 2014.

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International Segment

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)			
NET REVENUE	$1,869	$2,408	$5,336	$6,682
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(389)	(372)	(720)	(1,312)
GROSS PROFIT	1,480	2,036	4,616	5,370
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	1,758	1,550	6,046	4,704
GENERAL AND ADMINISTRATIVE EXPENSES	1,319	1,170	4,391	3,540
SALES AND MARKETING EXPENSES	2,403	2,290	6,729	7,795
DEPRECIATION AND AMORTIZATION	14	—	45	—
OPERATING EXPENSES	5,494	5,010	17,211	16,039
NET LOSS FROM OPERATIONS	$(4,014)	$(2,974)	$(12,595)	$(10,669)

Three months ended September 30, 2015 compared to the three months ended September 30, 2014

Net Revenue. Net revenue decreased by approximately $500,000, or 21%, to approximately $1.9 million for the three months ended September 30, 2015 compared to approximately $2.4 million for the three months ended September 30, 2014. The decrease was primarily attributable to decreases in the value of the British pound sterling and the Euro which impacted reported revenue by $290,000 and lower sales volume in Germany compared to the three months ended September 30, 2014.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately $20,000, or 5%, to approximately $390,000 for the three months ended September 30, 2015 compared to approximately $370,000 for the three months ended September 30, 2014. The increase was primarily attributable to charges for expiring inventory of approximately $260,000 recorded in 2015 compared with $190,000 recorded in 2014, offset by a decrease as a result of lower sales volume.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately $200,000, or 13%, to approximately $1.8 million for the three months ended September 30, 2015 compared to approximately $1.6 million for the three months ended September 30, 2014. The increase was primarily attributable to increases of $290,000 in ongoing scientific study and pharmacovigilence costs.

General and administrative expenses. General and administrative expenses increased by approximately $100,000, or 8%, to approximately $1.3 million for the three months ended September 30, 2015 compared to approximately $1.2 million for the three months ended September 30, 2014. The increase was primarily attributable to an increase in employee costs to support our business in the International Segment.

Sales and Marketing expenses. Sales and marketing expenses increased by approximately $100,000, or 4%, to approximately $2.4 million for the three months ended September 30, 2015 compared to approximately $2.3 million for the three months ended September 30, 2014. The increase was primarily attributable to increases in marketing expenses of $830,000 for market research, consultants and market access. This increase was offset by a decrease of approximately $680,000 in costs associated with the transition of several management and market access roles that were contracted from Quintiles Commercial in 2014 and brought in-house in 2015.

Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

Net Revenue. Net revenue decreased by approximately $1.4 million, or 21%, to approximately $5.3 million for the nine months ended September 30, 2015 compared to approximately $6.7 million for the nine months ended September 30, 2014. The decrease was primarily attributable to decreases in the value of the British pound sterling and the Euro which impacted reported revenue by $890,000 and lower sales volume in Germany compared to the nine months ended September 30, 2014.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization, decreased by approximately $580,000, or 45%, to approximately $720,000 for the nine months ended September 30, 2015 compared to approximately $1.3 million for the nine months ended September 30, 2014. The decrease was primarily

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attributable to charges for expiring inventory of approximately $320,000 recorded in 2015 compared with $830,000 recorded in 2014 and lower sales volume.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately $1.3 million, or 28%, to approximately $6.0 million for the nine months ended September 30, 2015 compared to approximately $4.7 million for the nine months ended September 30, 2014. The increase was primarily attributable to increases of approximately $710,000 in personnel and related costs to support ongoing clinical studies and $630,000 in ongoing scientific study and pharmacovigilence costs.

General and administrative expenses. General and administrative expenses increased by approximately $900,000, or 26%, to approximately $4.4 million for the nine months ended September 30, 2015 compared to approximately $3.5 million for the nine months ended September 30, 2014. The increase was primarily attributable to increases of approximately $790,000 in personnel and travel costs to support our business in the International segment.

Sales and Marketing expenses. Sales and marketing expenses decreased by approximately $1.1 million, or 14%, to approximately $6.7 million for the nine months ended September 30, 2015 compared to approximately $7.8 million for the nine months ended September 30, 2014. The decrease was primarily attributable to decreases of $2.8 million associated with the transition of several management and market access roles that were contracted from Quintiles Commercial in 2014 and brought in-house in 2015 and a reallocation of corporate resources to the U.S. following FDA approval of ILUVIEN in September 2014, offset by increases of approximately $1.1 million for congresses and marketing costs and $350,000 in costs associated with outside consultants.

Consolidated other income and expense

The following selected unaudited financial and operating data are derived from our consolidated 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)			
NET LOSS FROM OPERATIONS	$(8,444)	$(8,625)	$(29,238)	$(22,027)
INTEREST EXPENSE, NET AND OTHER	(1,317)	(408)	(3,590)	(862)
UNREALIZED FOREIGN CURRENCY LOSS, NET	(63)	(255)	(34)	(457)
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	8,363	2,324	13,085	(2,752)
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	—	—	(440)
NET LOSS BEFORE TAXES	(1,461)	(6,964)	(19,777)	(26,538)
PROVISION FOR TAXES	(82)	(45)	(155)	(114)
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	$(1,543)	$(7,009)	$(19,932)	$(26,652)

Interest expense, net and other.

Interest expense, net and other increased by approximately $900,000, or 225%, to approximately $1.3 million for the three months ended September 30, 2015 compared to approximately $400,000 for the three months ended September 30, 2014. The increase was primarily attributable to the increased notes payable balance as a result of the $25.0 million advance under the 2014 Loan Agreement as a result of the FDA approval of ILUVIEN in September of 2014.

Interest expense, net and other increased by approximately $2.7 million, or 314%, to approximately $3.6 million for the nine months ended September 30, 2015 compared to approximately $860,000 for the nine months ended September 30, 2014. The increase was primarily attributable to the increased notes payable balance as a result of the $25.0 million advance under the 2014 Loan Agreement as a result of the FDA approval of ILUVIEN in September of 2014.

Unrealized foreign currency loss, net.

We recorded a non-cash unrealized foreign currency loss of approximately $60,000 for the three months ended September 30, 2015 compared to approximately $260,000 for the three months ended September 30, 2014. The

unrealized

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foreign currency loss in 2014 was primarily attributable to the declining value of the Euro and the British pound sterling during the three months ended September 30, 2014.

We recorded a non-cash unrealized foreign currency loss of approximately $30,000 for the nine months ended September 30, 2015 compared to approximately $460,000 for the nine months ended September 30, 2014. The unrealized foreign currency loss in 2014 was primarily attributable to the change in value of the Euro and the British pound sterling during the nine months ended September 30, 2014.

Change in fair value of derivative warrant liability.

A decrease in the fair value of our derivative warrant liability resulted in a non-cash gains of approximately $8.4 million and $2.3 million for the three months ended September 30, 2015 and 2014, respectively. The change in fair value was primarily attributable to decreases in the fair market value of our underlying common stock during both the three-month periods ended September 30, 2015 and 2014.

A decrease in the fair value of our derivative warrant liability resulted in a non-cash gain of approximately $13.1 million for the nine months ended September 30, 2015. The gain was primarily attributable to the decrease in fair market value of our underlying common stock during the period. During the nine months ended September 30, 2014, we recognized a loss of approximately $2.8 million related to the increase in the fair value of our derivative warrant liability. The loss was primarily attributable to an increase in the fair market value of our underlying common stock during the period.

Liquidity and Capital Resources

To date, we have incurred negative cash flow from operations, and have accumulated a deficit of $333.2 million from our inception through September 30, 2015.

As of September 30, 2015, we had approximately $39.3 million in cash and cash equivalents. We launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015. Based on our current plans, we do not expect to generate positive cash flow from operations until 2017, if at all. We believe our cash and cash equivalents will be sufficient to fund our operations for the continued commercialization of ILUVIEN in the United Kingdom, Germany, Portugal and the U.S. However, due to the covenants contained in the 2014 Loan Agreement, as amended, including a $20.0 million liquidity covenant, we may need to raise additional funds to support our operations for the continued commercialization of ILUVIEN. 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. If ILUVIEN does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

In the event additional financing is needed or desired, we may seek to fund our operations through the sale of equity securities, strategic collaboration agreements and debt financing. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result and the terms of any new equity securities may have a preference over our common stock. If we attempt to raise additional funds through strategic collaboration agreements and debt financing, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize ILUVIEN or any future products or product candidates or operate our business.

For the nine months ended September 30, 2015, cash used by our operations of $36.5 million was primarily due to our net loss of $19.9 million, $8.5 million increase in accounts receivable and $2.3 million decrease in accounts payable, accrued expenses and other current liabilities offset by a decrease in prepaid expenses and other current assets of $630,000, an increase in other non-current liabilities of $610,000 and by the impact of non-cash items on our net operating loss. Accounts receivable increased primarily due to the U.S. launch of ILUVIEN during the first quarter of 2015. Accounts payable and accrued expenses and other current liabilities decreased primarily due to the milestone payment of $2.0 million to a consultant that was engaged to assist with the pursuit of approval of ILUVIEN in the U.S. and a decrease of $1.2 million in amounts payable to Quintiles Commercial offset by increases of $1.5 million in

accrued payroll and related costs including bonuses. Prepaid expenses and other current assets decreased by approximately $700,000 associated with the termination of the Quintiles Commercial project orders. Other non-current liabilities increased primarily due to receipt of $500,000 upon the execution of a distribution agreement, which is deferred over the service period. Non-cash items included a gain of $13.1 million for the change in our derivative warrant liability offset by $3.7 million of stock-based compensation expense, $1.9 million for depreciation and amortization and $520,000 for non-cash interest expense associated with deferred financing costs and our debt discount.

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For the nine months ended September 30, 2014, cash used by our operations of $15.2 million was primarily due to our net loss of $26.7 million offset by non-cash items including $2.8 million of stock-based compensation expense, a loss of $2.8 million for the change in our derivative warrant liability, $460,000 for unrealized foreign currency transaction loss and $440,000 for the loss from early extinguishment of debt. Further impacting cash from operations was an increase in accounts receivable of approximately $680,000, offset by increases of $4.0 million in accounts payable and accrued expenses and other current liabilities and a decrease of $1.3 million in prepaid expenses and other current assets. Accounts payable and accrued expenses and other current liabilities increased primarily due to a $2.0 million success fee payable to a consultant for services related to the continued pursuit of approval of ILUVIEN in the U.S. and $530,000 in amounts payable to our legal and professional accounting firms. Prepaid expenses and other current assets decreased primarily due to a decrease of $1.9 million in amounts owed to us from Quintiles Commercial that were applied in lieu of payments for billings in the nine months ended September 30, 2014, offset by increases of $120,000 in prepaid amounts to the CRO of our five-year, post-authorization, open label registry study of ILUVIEN in 800 patients treated per the labeled indication in the EEA and $100,000 of prepaid insurance.

For the nine months ended September 30, 2015, net cash used in our investing activities was approximately $370,000, which was due to the purchase of property and equipment, which was primarily due to the purchase of drug safety management software.

For the nine months ended September 30, 2014, net cash used in our investing activities was approximately $160,000, which was primarily due to the purchase of customer relationship management software for $110,000.

For the nine months ended September 30, 2015, net cash used in our financing activities was approximately $210,000 due to the payment of issuance costs of approximately $330,000 in January 2015 associated with the sale of our Series B Convertible Preferred Stock in December 2014 and approximately $210,000 in payments on capital leases offset by cash received of approximately $280,000 from the proceeds from exercises of stock options.

For the nine months ended September 30, 2014, net cash provided by our financing activities was approximately $64.7 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 in April of 2014 and $25.0 million in September of 2014 prior to the payment of approximately $1.0 million in related costs, and $4.9 million used to prepay and terminate our 2013 Term Loan. Further increasing cash from our financing activities was $710,000 from the proceeds from exercises of stock options.

Contractual Obligations and Commitments

In November 2012, we entered into an agreement with Quintiles Commercial Europe Limited. Under the agreement, Quintiles Commercial provided certain services to us in relation to the commercialization of ILUVIEN, in France, Germany and the United Kingdom. In December 2013 and January 2014, respectively, we transitioned our German and United Kingdom country manager positions in-house. In April 2015, we terminated the project orders associated with France and Germany and transitioned the covered positions employed by Quintiles Commercial to our payroll. In July 2015, we terminated the project orders associated with the United Kingdom and transitioned the covered positions employed by Quintiles Commercial to our payroll.

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, 2014, filed with the SEC on March 13, 2015.

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

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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 is effective for the first interim period within annual reporting periods beginning after December 15, 2017 for public entities, with early adoption permitted in the annual reporting period beginning after December 15, 2016. Our management is still evaluating the potential impact of adopting this guidance on our financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern. ASU 2014-15 provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. Our management is still evaluating the potential impact of adopting this guidance on its financial statements.

In April 2015, the FASB issued ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. ASU 2015-03 is intended to simplify the presentation of debt issuance costs. These amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU.The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted and the standard is to be retrospectively applied to all periods presented upon adoption. Our management is still evaluating the potential impact of adopting this guidance on its financial statements.

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ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Liquidity

See the “Liquidity and Capital Resources” section of this Quarterly Report on Form 10-Q for additional discussion of liquidity and related risks.

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our loan agreement with Hercules. We do not believe we are materially exposed to changes in interest rates. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a 100 basis point, or 1%, unfavorable change in interest rates would have resulted in approximately a $90,000 and $270,000 increase in interest expense for the three and nine months ended September 30, 2015, respectively.

Credit Quality Risk

We are subject to credit risk in connection with accounts receivable from our product sales of ILUVIEN. We have contractual payment terms with each of our customers, and we monitor our customers’ financial performance and credit worthiness so that we can properly assess and respond to any changes in their credit profile. During the three and nine months ended September 30, 2015 and September 30, 2014, we did not recognize any charges for write-offs of accounts receivable. As of September 30, 2015, two individual customers accounted for 83% of our accounts receivable balances. There were no customers that accounted for more than 10% of accounts receivable at December 31, 2014.

Foreign Exchange Risk

As discussed further above, we market ILUVIEN outside the U.S. Therefore, significant changes in foreign exchange rates of the countries outside the U.S. where our product is sold can impact our operating results and financial condition. As sales outside the U.S. continue to grow, and as we expand our international operations, we will continue to assess potential steps, including foreign currency hedging and other strategies, to mitigate our foreign exchange risk.

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ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2015. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the three months ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

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

ITEM 1A. Risk Factors

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 13, 2015, we identify under Item 1A of Part I important factors which could affect our business, financial condition, results of operations and future operations and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report on Form 10-Q.

However, the risks described herein and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

The following description of risk factors includes any material changes to, and supersedes the description of, risk factors associated with our business previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 as a result of the amendment to our loan agreement with Hercules Technology Growth Capital, Inc. 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.”

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

We do not expect to have positive cash flow from operations until 2017, if at all. At September 30, 2015, we had approximately $39.3 million in cash and cash equivalents. We believe our cash and cash equivalents will be sufficient to fund our operations for the continued commercialization of ILUVIEN in Germany and the United Kingdom, and the launch of ILUVIEN in Portugal and the U.S. However, due to the covenants contained in the 2014 Loan Agreement, as amended, including a $20.0 million liquidity covenant, we may need to raise additional funds to support our operations for the continued commercialization of ILUVIEN. We will seek to raise additional financing to fund our working capital needs associated with the commercialization of ILUVIEN in the U.S., if necessary. If we are unable to raise additional financing, then we may adjust our commercial plans so that we can continue to operate with our existing cash resources. 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 level of success of the initial commercial launch of ILUVIEN in Germany, the United Kingdom, Portugal and the U.S.;
- the amount of our research and development, marketing and general and administrative expenses;
- the amount of our future operating losses;
- third party expenses relating to the commercialization of ILUVIEN;
- the need and cost of conducting additional clinical trials for ILUVIEN;
- the timing of approvals, if any, of ILUVIEN in additional jurisdictions;

- 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.

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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 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 our loan and security agreement, as amended (Amended Loan Agreement) with Hercules Technology Growth Capital, Inc. (Hercules), under which our subsidiary, Alimera Sciences Limited (Limited), obtained a term loan of $35.0 million (2014 Term Loan). We and certain of our subsidiaries are subject to a variety of affirmative and negative covenants, including required financial reporting, revenue and liquidity requirements, 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 the Amended Loan Agreement. In an event of default, Hercules may call the 2014 Term Loan, and we will likely need to raise additional financing. To secure the performance of our obligations under the Amended Loan Agreement, Limited pledged all of its assets to Hercules. Our or Limited’s failure to comply with the covenants under the Amended Loan Agreement 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 Hercules under the Amended Loan Agreement (Guaranties). Pursuant to the Guaranties, we and these subsidiaries granted Hercules 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.

The terms of our Amended Loan Agreement require us to meet certain operating covenants and place restrictions on our operating and financial flexibility.

Due to the limited revenue generated by ILUVIEN to date, we may not be able to maintain compliance with covenants under our Amended Loan Agreement with Hercules. The 2014 Term Loan is secured by a lien covering all of our assets, other than our intellectual property. The Amended Loan Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to satisfy certain financial covenants, including revenue requirements, maintain liquidity including cash at certain levels, maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. Negative covenants include, among others, restrictions on transferring any part of our business or property, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets and other financial covenants, in each case subject to customary exceptions.

In an event of default under our Amended Loan Agreement, including failure to satisfy our operating covenants, Hercules may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to raise additional financing, renegotiate the Amended Loan Agreement on terms less favorable to us or to immediately cease operations. Any declaration by Hercules of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Further, if we are liquidated, Hercules' right to repayment would be senior to the rights of the holders of our common stock.

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ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds
None.

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ITEM 3. Defaults Upon Senior Securities
None.
ITEM 4. Mine Safety Disclosures
Not applicable.
ITEM 5. Other Information
None.

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ITEM 6. Exhibits

Exhibit Number	Description
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	XBRL Instance Document.
101.SCH+	XBRL Taxonomy Extension Schema Document.
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	XBRL Taxonomy Extension Label Link Document.
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document.

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

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

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Signatures

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

ALIMERA SCIENCES, INC.

November 6, 2015	By: /s/ C. Daniel Myers C. Daniel Myers Chief Executive Officer and President (Principal Executive Officer)
November 6, 2015	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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EXHIBIT INDEX

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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.