

ALIMERA SCIENCES INC  
Form 10-Q  
August 05, 2016  
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q  
(Mark One)

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

For the quarterly period ended June 30, 2016  
or

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

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

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

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

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

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

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

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

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

As of August 4, 2016 there were 45,759,253 shares of the registrant's Common Stock issued and outstanding.



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See the Exhibit Index immediately following the signature page of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

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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 achieve profitability and positive cash flow through the commercialization of ILUVIEN® in the European Economic Area (EEA) and the United States (U.S.);
- our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility;
- our ability to raise sufficient additional financing and our need to raise such financing;
- our limited sales and marketing infrastructure;
- uncertainty as to the pricing and reimbursement guidelines for ILUVIEN or any future products or product candidates, including ILUVIEN in new markets;
- delay in or failure to obtain regulatory approval of ILUVIEN in additional countries or any future products or product candidates;
- our ability to successfully commercialize ILUVIEN following regulatory approval in additional markets;
- 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, 2015, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above, 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

	June 30, 2016	December 31, 2015
	(In thousands, except share and per share data)	
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 16,627	\$ 31,075
Restricted cash	38	37
Accounts receivable, net	13,257	9,799
Prepaid expenses and other current assets	3,532	2,696
Inventory, net (Note 5)	1,210	1,552
Total current assets	34,664	45,159
<b>NON-CURRENT ASSETS:</b>		
Property and equipment, net	2,293	2,553
Intangible asset, net (Note 6)	21,582	22,549
Deferred tax asset, net	227	223
<b>TOTAL ASSETS</b>	<b>\$ 58,766</b>	<b>\$ 70,484</b>
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 5,651	\$ 4,002
Accrued expenses (Note 7)	5,483	3,911
Note payable, net of discount (Note 9)	33,809	31,786
Capital lease obligations	245	234
Total current liabilities	45,188	39,933
<b>NON-CURRENT LIABILITIES:</b>		
Derivative warrant liability	472	2,815
Capital lease obligations — less current portion	486	582
Other non-current liabilities	817	834
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$.01 par value — 10,000,000 shares authorized at June 30, 2016 and December 31, 2015:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 600,000 issued and outstanding at June 30, 2016 and December 31, 2015; liquidation preference of \$24,000 at June 30, 2016 and December 31, 2015	19,227	19,227
Series B Convertible Preferred Stock, 8,417 authorized and 8,416.251 issued and outstanding at June 30, 2016 and December 31, 2015; liquidation preference of \$50,750 at June 30, 2016 and December 31, 2015	49,568	49,568
Common stock, \$.01 par value — 100,000,000 shares authorized, 45,375,439 shares issued and outstanding at June 30, 2016 and 45,005,833 shares issued and outstanding at December 31, 2015	454	450
Additional paid-in capital	302,507	299,376
Common stock warrants	3,049	2,747
Accumulated deficit	(361,903)	(343,900)
Accumulated other comprehensive loss	(1,099)	(1,148)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>11,803</b>	<b>26,320</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 58,766</b>	<b>\$ 70,484</b>

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.  
CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2016 AND 2015

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands, except share and per share data)			
NET REVENUE	\$9,557	\$ 5,776	\$15,358	\$ 9,714
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(556 )	(376 )	(934 )	(659 )
GROSS PROFIT	9,001	5,400	14,424	9,055
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	3,205	3,815	6,225	7,144
GENERAL AND ADMINISTRATIVE EXPENSES	4,039	3,821	7,434	7,440
SALES AND MARKETING EXPENSES	7,510	6,925	14,619	14,054
DEPRECIATION AND AMORTIZATION	696	639	1,385	1,211
OPERATING EXPENSES	15,450	15,200	29,663	29,849
NET LOSS FROM OPERATIONS	(6,449 )	(9,800 )	(15,239 )	(20,794 )
INTEREST EXPENSE, NET AND OTHER	(1,177 )	(1,151 )	(2,512 )	(2,273 )
UNREALIZED FOREIGN CURRENCY (LOSS) GAIN, NET	(14 )	143	20	29
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	824	2,216	2,343	4,722
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	—	(2,564 )	—
NET LOSS BEFORE TAXES	(6,816 )	(8,592 )	(17,952 )	(18,316 )
PROVISION FOR TAXES	(42 )	(4 )	(51 )	(73 )
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	\$(6,858)	\$(8,596)	\$(18,003)	\$(18,389)
NET LOSS PER SHARE APPLICABLE TO COMMON STOCKHOLDERS — Basic and diluted	\$(0.15 )	\$(0.19 )	\$(0.40 )	\$(0.41 )
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	45,088,074	44,396,656	45,046,952	44,372,283

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2016 AND 2015

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)			
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	\$(6,858)	\$(8,596)	\$(18,003)	\$(18,389)
OTHER COMPREHENSIVE (LOSS) INCOME				
Foreign currency translation adjustments	(70 )	70	49	(288 )
TOTAL OTHER COMPREHENSIVE (LOSS) INCOME	(70 )	70	49	(288 )
COMPREHENSIVE LOSS	\$(6,928)	\$(8,526)	\$(17,954)	\$(18,677)

See Notes to Consolidated Financial Statements.



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ALIMERA SCIENCES, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE SIX MONTHS ENDED JUNE 30, 2016 AND 2015

	Six Months Ended June 30,	
	2016	2015
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(18,003)	\$(18,389)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,385	1,211
Inventory reserve	50	—
Unrealized foreign currency transaction gain	(20 )	(29 )
Loss on early extinguishment of debt	2,564	—
Amortization of debt discount	517	349
Stock-based compensation expense	2,619	2,309
Change in fair value of derivative warrant liability	(2,343 )	(4,722 )
Changes in assets and liabilities:		
Accounts receivable	(3,456 )	(6,831 )
Prepaid expenses and other current assets	(652 )	9
Inventory	301	(16 )
Accounts payable	264	(1,206 )
Accrued expenses and other current liabilities	2,604	(450 )
Other non-current liabilities	(26 )	111
Net cash used in operating activities	(14,196 )	(27,654 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(116 )	(337 )
Net cash used in investing activities	(116 )	(337 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	88	138
Proceeds from sale of common stock	287	42
Payment of issuance cost of common stock	(52 )	—
Payment of Series B Convertible Preferred Stock offering costs	—	(327 )
Payment of debt costs	(357 )	—
Payment of capital lease obligations	(124 )	(150 )
Net cash used in financing activities	(158 )	(297 )
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS	22	(273 )
NET DECREASE IN CASH AND CASH EQUIVALENTS	(14,448 )	(28,561 )
CASH AND CASH EQUIVALENTS — Beginning of period	31,075	76,697
CASH AND CASH EQUIVALENTS — End of period	\$16,627	\$48,136
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for interest	\$2,006	\$1,934
Cash paid for income taxes	\$263	\$—
Supplemental schedule of non-cash investing and financing activities:		
Property and equipment acquired under capital leases	\$56	\$941
Proceeds receivable from sale of common stock	\$172	\$—
Common stock issuance costs accrued but unpaid	\$32	\$—
Note payable end of term payment accrued but unpaid	\$1,400	\$—

There were no dividend payments made during the six months ended June 30, 2016 and 2015.

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 market opportunity. The Company's only commercial product is ILUVIEN<sup>®</sup>, 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 in 800 patients treated with ILUVIEN per the labeled indication. The Company launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015.

In addition, the Company has entered into various agreements under which distributors will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in numerous countries in the Middle East, Canada, Italy, Australia and New Zealand.

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, 2015 and related notes included in the Company's Annual Report on Form 10-K, which was filed with the SEC on March 15, 2016. The financial results for any interim period are not necessarily indicative of the expected financial results for the full year.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accounting policies followed for quarterly financial reporting are the same as those disclosed in the Notes to Financial Statements included in the Company's Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2015.

Allowance for Doubtful Accounts on Accounts Receivable

Allowance for doubtful accounts on accounts receivable were \$42,000 and \$118,000 as of June 30, 2016 and December 31, 2015, respectively.

Research and Development Expenses

Research and development expenses were \$1,464,000 and \$1,595,000 for the three months ended June 30, 2016 and 2015, respectively. Research and development expenses were \$2,871,000 and \$2,901,000 for the six months ended June 30, 2016 and 2015, 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 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 currently in the process of evaluating the potential impact of adopting this guidance on its financial statements.

In July 2015, FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. This update requires entities to measure inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. This ASU is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those years. The Company is currently in the process of evaluating the impact of the adoption on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). This standard requires all leases with durations greater than twelve months to be recognized on the balance sheet and is effective for interim and annual reporting periods beginning after December 15, 2018, although early adoption is permitted. The Company is currently in the process of evaluating the impact of the adoption on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718). This standard makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation and the financial statement presentation of excess tax benefits or deficiencies. ASU

2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, although early adoption is permitted. The Company is currently in the process of evaluating the impact of the adoption on its financial statements.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**4. FACTORS AFFECTING OPERATIONS**

To date, the Company has incurred negative cash flow from operations and has accumulated a deficit of \$361,903,000 from inception through June 30, 2016. As of June 30, 2016, the Company had approximately \$16,627,000 in cash and cash equivalents.

As of June 30, 2016, the Company did not meet the liquidity threshold covenant under the Company's loan and security agreement with Hercules Capital, Inc. (Hercules) (see Note 9 Loan Agreements). While this violation was waived by Hercules, the Company's current financial forecast for the remainder of 2016 projects that the Company must obtain alternative or additional financing or it is probable that the Company will not be in compliance with its covenants in the future. While these financial covenant requirements may be waived in the future, there can be no certainty that this will be the case. The Company is currently pursuing alternative or additional debt financing and has an at-the-market offering in place under which it can sell up to approximately \$33,784,000 of its common stock as of June 30, 2016. In an event of default, all amounts may become due under our loan agreement with Hercules and there would be substantial doubt about our ability to continue as a going concern.

Further, due to the limited revenue generated by ILUVIEN to date, even if the Company is able to refinance its loan and security agreement with Hercules and maintain compliance with its debt covenants, it will need to raise additional capital to fund the continued commercialization of ILUVIEN. If the Company is unable to raise additional financing, the Company will need to adjust its commercial plans so that it can continue to operate with its existing cash resources. The actual amount of funds that the Company will need will be determined by many factors, some of which are beyond its control and the Company may need funds sooner than currently anticipated.

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.

**5. INVENTORY**

Inventory consisted of the following:

	June 30, 2016	December 31, 2015
	(In thousands)	
Component parts (1)	\$ 132	\$ 131
Work-in-process (2)	650	333
Finished goods	485	1,525
Total inventory	1,267	1,989
Inventory reserve	(57 )	(437 )
Inventory — net	\$ 1,210	\$ 1,552

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

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

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 6. INTANGIBLE ASSET

As a result of the U.S. Food and Drug Administration's (FDA) approval of the New Drug Application (NDA) 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 License Agreements). 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 \$484,000 and \$483,000 for the three months ended June 30, 2016 and 2015, respectively. The amortization expense related to the intangible asset was \$967,000 and \$962,000 for the six months ended June 30, 2016 and 2015, respectively. The net book value of the intangible asset was \$21,582,000 and \$22,549,000 as of June 30, 2016 and December 31, 2015, respectively. The estimated future amortization expense as of June 30, 2016 for the remaining periods in the next five years and thereafter is as follows (in thousands):

Years Ending December 31

2016	\$978
2017	1,940
2018	1,940
2019	1,940
2020	1,940
Thereafter	12,844
Total	\$21,582

## 7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	June 30, 2016	December 31, 2015
	(In thousands)	
Accrued compensation expenses	\$1,338	\$ 804
Accrued clinical investigator expenses	1,214	732
Accrued rebate and other revenue reserves	616	452
Accrued End of Term Payment (Note 9)	1,400	1,050
Other accrued expenses	915	873
Total accrued expenses	\$5,483	\$ 3,911

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

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.

The Company must share 20% of the net profits of ILUVIEN, determined on a cash basis in each country and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined by the agreement with pSivida. In connection with this arrangement, the Company is entitled to recover 20% of commercialization costs of ILUVIEN, as defined in the agreement, incurred prior to product profitability out of pSivida's share of net profits. As of June 30, 2016 and December 31, 2015, the Company was owed approximately \$23,831,000 and \$21,565,000, respectively, in commercialization costs. Due to the uncertainty of future net profits, the Company has fully reserved these amounts in the accompanying Interim Financial Statements.

In the second quarter of 2016, pSivida disputed portions of the Company's claimed commercialization costs for the year ended December 31, 2014. As part of this dispute, pSivida notified the Company that it disagreed with \$1,290,000 of the \$12,956,000 in commercialization costs receivable that the Company had reported as of December 31, 2014 and claimed incremental profit sharing payments of \$136,000 for the year ended December 31, 2014. The Company is disputing pSivida's assertions through the alternative dispute resolution mechanism under the agreement with pSivida. If pSivida's assertions were to prevail in the alternative dispute resolution mechanism and their assertions were then applied to the commercialization cost calculations for the year ended December 31, 2015 and the six months ended June 30, 2016, then the Company believes the commercialization costs receivable from pSivida would be reduced from \$21,565,000 to \$18,504,000 at December 31, 2015 and from \$23,831,000 to \$19,951,000 at June 30, 2016. If pSivida's assertions were to prevail in the alternative dispute resolution mechanism, the impact on the statements of operations for the year ended December 31, 2015 and the six months ended June 30, 2016 would be immaterial.

9. LOAN AGREEMENTS

2014 Loan Agreement, 2015 Loan Amendment and 2016 Loan Amendment

In April 2014, Alimera Sciences Limited (Limited), a subsidiary of the Company, entered into a loan and security agreement (2014 Loan Agreement) with Hercules providing for a term loan of up to \$35,000,000 (2014 Term Loan) which Limited and Hercules amended in November 2015 (the 2015 Loan Amendment and, together with the 2014 Loan Agreement and the 2016 Loan Amendment (as defined below), the Term Loan Agreement). Under the 2014 Loan 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 a 2013 term loan with Silicon Valley Bank. 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 Loan Agreement 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. The interest rate on the Term Loan Agreement was 11.15% as of June 30, 2016.

In connection with the initial advance under the 2014 Loan Agreement, 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

fees in connection with the second advance. If Limited repays the 2014 Term Loan prior to maturity, it will pay Hercules a prepayment penalty of 1.25% of the total principal amount repaid.

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 11 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 2015 Loan 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 (End of Term Payment).

Limited and the Company, on a consolidated basis with the Company's other subsidiaries, 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 Term Loan Agreement and an increase to the applicable interest rate and would permit Hercules to exercise remedies with respect to the collateral under the Term Loan Agreement. In connection with the 2015 Loan Amendment, Limited agreed to covenants regarding certain revenue thresholds and a liquidity threshold of \$20,000,000 for the Company of which at least \$10,000,000 had to be in cash.

In January 2016, the revenue threshold covenant was not met by the Company. As a result, in March 2016, Limited entered into an additional loan amendment with Hercules, which further amended certain terms of the Term Loan Agreement (the 2016 Loan Amendment). In conjunction with the 2016 Loan Amendment, Hercules waived the covenant violation.

The 2016 Loan Amendment amended the revenue covenant to a rolling three-month calculation to first be measured for the three months ended May 31, 2016. In addition, the 2016 Loan Amendment increased the liquidity covenant, requiring the Company to keep at least \$25,000,000 in liquid assets, with a minimum of \$17,500,000 in cash.

However, in any month in which the Company has \$25,000,000 in cash, the revenue requirement will be waived.

Upon execution of the 2016 Loan Amendment, Limited paid Hercules an amendment fee of \$350,000 and agreed to increase the End of Term Payment to \$1,400,000 from \$1,050,000, which is payable on the date that the 2014 Term Loan is paid in full.

The Company concluded the 2016 Loan Amendment resulted in a substantial modification of the terms of debt when considered with the 2015 Loan Amendment in accordance with the guidance in ASC 470-50, Debt. As a result, the Company accounted for the 2016 Loan Amendment as an extinguishment and recognized a loss on early extinguishment of debt of approximately \$2,564,000 within the consolidated statement of operations for the six months ended June 30, 2016. The loss on early extinguishment consisted primarily of the unamortized debt discount associated with the warrant and debt issuance costs incurred prior to the 2016 Loan Amendment, the incremental fair value of the warrant as a result of the modifying the terms of the warrant and the debt issuance costs of \$360,000 paid to Hercules for the 2016 Loan Amendment.

In July 2016, the Company obtained a waiver of the requirements of the liquidity covenant (the Waiver) because the Company was not in compliance with the liquidity covenant as of June 30, 2016. The Waiver cured the default of the liquidity covenant currently existing under the Term Loan Agreement and modified the liquidity requirement so that Limited and the Company must keep at least \$20,000,000 in liquid assets, consisting of cash and accounts receivable from customers in the U.S. with a minimum of \$12,500,000 in cash. In addition, the Waiver modified the three-month revenue covenant so that it was not measured at July 31, 2016 and reduced the three-month revenue target to be measured at August 31, 2016. Following execution of the Waiver, Limited will pay to Hercules a weekly ticking fee equal to 0.05% multiplied by the outstanding principal amount. The weekly ticking fee will no longer be payable if the Company raises \$15,000,000 in equity following the date of the Waiver. Further, Limited agreed that it will pay Hercules a fee of \$350,000, which amount will be paid no later than September 1, 2016.

The Company's current financial forecast for 2016 projects that the Company must obtain alternative or additional financing or it is probable that the Company will not be able to comply with its financial covenants in the future. While Hercules may waive compliance with financial covenants in the future, there can be no certainty that this

will be the case. The Company is currently pursuing alternatives with various lenders and investors and has an at-the-market offering in place under which it can sell up to approximately \$33,784,000 of its common stock as of June 30, 2016. However, the ability of the Company to comply with any of its financial covenants cannot be assured. If the Company does not maintain compliance with any of its financial covenants, Hercules could demand immediate repayment in full of the \$35,000,000 under the 2014 Term Loan and make the End of Term Payment. As a result, the 2014 Term Loan and the End of Term Payment have been classified as current liabilities in the accompanying consolidated balance sheets at June 30, 2016 and December 31, 2015.

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

are guarantors of the obligations of Limited to Hercules under the Term Loan Agreement pursuant to separate guaranty agreements between Hercules and each of Limited and such subsidiaries (Guaranties). Pursuant to the Guaranties, the Company and these subsidiaries granted Hercules a first priority security interest in substantially all of their respective assets excluding intellectual property. The Term Loan Agreement also places limitations on the Company's ability to declare or pay any dividend or distribution on any shares of capital stock.

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 warrant was 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 2015 Loan Amendment to increase the number of shares issuable upon exercise to 660,377 and decrease the exercise price to \$2.65 per share. In connection with the 2016 Loan Amendment, the Company agreed to further amend the warrant agreement to increase the number of shares issuable upon exercise to 862,069 and decrease the exercise price to \$2.03 per share. In connection with the Waiver, the Company agreed to further amend the warrant agreement again to increase the number of shares issuable upon exercise to 1,258,993 and decrease the exercise price to \$1.39 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 June 30, 2016 and December 31, 2015.

**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		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
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	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	940,023	362,970	940,023	362,970
Stock options	10,648,702	9,292,947	10,648,702	9,292,947
Total	33,538,811	31,606,003	33,538,811	31,606,003

**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

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 June 30, 2016 and December 31, 2015, the fair market value of the warrants was estimated to be \$472,000 and \$2,815,000, respectively. During the three months ended June 30, 2016 and 2015, the Company recorded gains of \$824,000 and \$2,216,000, respectively, as a result of the change in fair value of the warrants. During the six months ended June 30, 2016 and 2015, the Company recorded gains of \$2,343,000 and \$4,722,000, 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 June 30, 2016, 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.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 12. COMMON STOCK

In September 2014, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen) to offer shares of its common stock from time to time through Cowen up to an aggregate offering price of \$35,000,000. During the three months and six months ended June 30, 2016, the Company sold a total of 278,965 shares of its common stock at a weighted average purchase price of \$1.40 per share. Proceeds from the offering, in the amount of \$381,000, prior to the payment of approximately \$32,000 of related issuance costs were used for general corporate and working capital purposes. Under the terms of the sales agreement, the Company can sell up to approximately \$33,784,000 of its common stock as of June 30, 2016.

During the three and six months ended June 30, 2016 and 2015, 41,413 and 10,993 shares of the Company's common stock were acquired through its employee stock purchase plan resulting in proceeds of \$78,000 and \$42,000, respectively.

## 13. STOCK INCENTIVE PLANS

## Stock Option Plans

During the three months ended June 30, 2016 and 2015, the Company recorded compensation expense related to stock options of approximately \$1,323,000 and \$1,198,000, respectively. During the six months ended June 30, 2016 and 2015, the Company recorded compensation expense related to stock options of approximately \$2,619,000 and \$2,268,000, respectively. As of June 30, 2016, the total unrecognized compensation cost related to non-vested stock options granted was \$9,881,000 and is expected to be recognized over a weighted average period of 2.63 years. The following table presents a summary of stock option activity for the three and six months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	Options	Options	Options	Options
	Weighted Average Exercise Price	Weighted Average Exercise Price	Weighted Average Exercise Price	Weighted Average Exercise Price
Options outstanding at beginning of period	10,626,673.32	9,180,668.46	9,475,890.43	7,681,256.03
Grants	192,5001.59	235,0004.91	1,420,5003.4	1,833,5004.2
Forfeitures	(120,642.81)	(116,245.19)	(198,460.10)	(149,385.29)
Exercises	(49,2281.80)	(6,476) 1.86	(49,2281.80)	(72,424) 1.90
Options outstanding at period end	10,648,702.0	9,292,947.49	10,648,702.0	9,292,947.49
Options exercisable at period end	6,739,491.28	5,227,981.19	6,739,491.28	5,227,981.19
Weighted average per share fair value of options granted during the period	\$1.19	\$3.69	\$1.77	\$4.22

The following table provides additional information related to outstanding stock options, exercisable stock options and stock options expected to vest as of June 30, 2016:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding	10,648,702	\$ 3.30	6.69 years	\$ —
Exercisable	6,739,491	3.28	5.51 years	—
Outstanding, vested and expected to vest	10,161,259	3.29	6.58 years	—

(In thousands)



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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table provides additional information related to outstanding stock options, exercisable stock options and stock options expected to vest as of December 31, 2015:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Term	Contractual	Aggregate Intrinsic Value
					(In thousands)
Outstanding	9,475,890	\$ 3.43	6.96 years		\$ 2,565
Exercisable	5,808,528	3.27	5.87 years		2,186
Outstanding, vested and expected to vest	9,016,217	3.41	6.86 years		2,541

## Employee Stock Purchase Plan

During the three months ended June 30, 2016 and 2015, the Company recorded compensation expense related to its employee stock purchase plan of approximately \$19,000 and \$29,000, respectively. During the six months ended June 30, 2016 and 2015, the Company recorded compensation expense related to its employee stock purchase plan of approximately \$52,000 and \$41,000, 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 June 30, 2016 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, 2015, the Company had federal NOL carry-forwards of approximately \$100,844,000 and state NOL carry-forwards of approximately \$84,301,000 available to reduce future income. The Company's federal NOL carry-forwards remain fully reserved as of June 30, 2016. If not utilized, the federal NOL carry-forwards will expire at various dates between 2029 and 2035 and the state NOL carry-forwards will expire at various dates between 2020 and 2035.

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, 2015, the Company had cumulative book losses in foreign subsidiaries of \$67,452,000. 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 June 30, 2016 and December 31, 2015.

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

	June 30, 2016			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents (1)	\$—	\$—	\$—	—\$—
Assets measured at fair value	\$—	\$—	\$—	—\$—
Liabilities:				
Derivative warrant liability (2)	\$—	\$472	\$—	—\$472
Liabilities measured at fair value	\$—	\$472	\$—	—\$472
	December 31, 2015			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash equivalents (1)	\$1,010	\$—	\$—	—\$1,010
Assets measured at fair value	\$1,010	\$—	\$—	—\$1,010
Liabilities:				
Derivative warrant liability (2)	\$—	\$2,815	\$—	—\$2,815
Liabilities measured at fair value	\$—	\$2,815	\$—	—\$2,815

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



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The Company uses the Black-Scholes option pricing model and assumptions that consider, among other variables, (2) 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.

## 16. SEGMENT INFORMATION

During the three months ended June 30, 2016 and 2015, two customers within the U.S. segment accounted for 75% and 65%, respectively, of the Company's consolidated revenues as a result of our sales to two pharmaceutical distributors in the U.S. During the six months ended June 30, 2016 and 2015, these two customers within the U.S. segment accounted for 74% and 64%, respectively, of the Company's consolidated revenues. These two customers within the U.S. segment accounted for approximately 88% of the Company's consolidated accounts receivable at June 30, 2016 and December 31, 2015.

The following table presents a summary of the Company's reporting segments for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30, 2016			Three Months Ended June 30, 2015		
	U.S.	International	Consolidated	U.S.	International	Consolidated
	(In thousands)					
NET REVENUE	\$7,208	\$ 2,349	\$ 9,557	\$3,804	\$ 1,972	\$ 5,776
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(368 )	(188 )	(556 )	(190 )	(186 )	(376 )
GROSS PROFIT	6,840	2,161	9,001	3,614	1,786	5,400
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	2,181	1,024	3,205	1,478	2,337	3,815
GENERAL AND ADMINISTRATIVE EXPENSES	2,323	1,716	4,039	2,179	1,642	3,821
SALES AND MARKETING EXPENSES	5,403	2,107	7,510	4,848	2,077	6,925
DEPRECIATION AND AMORTIZATION	673	23	696	621	18	639
OPERATING EXPENSES	10,580	4,870	15,450	9,126	6,074	15,200
NET LOSS FROM OPERATIONS	(3,740 )	(2,709 )	(6,449 )	(5,512 )	(4,288 )	(9,800 )
OTHER INCOME AND EXPENSES, NET			(367 )			1,208
NET LOSS BEFORE TAXES			\$ (6,816 )			\$ (8,592 )

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table presents a summary of the Company's reporting segments for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30, 2016			Six Months Ended June 30, 2015		
	U.S.	International	Consolidated	U.S.	International	Consolidated
	(In thousands)					
NET REVENUE	\$11,327	\$ 4,031	\$ 15,358	\$6,247	\$ 3,467	\$ 9,714
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(590 )	(344 )	(934 )	(328 )	(331 )	(659 )
GROSS PROFIT	10,737	3,687	14,424	5,919	3,136	9,055
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	3,820	2,405	6,225	2,856	4,288	7,144
GENERAL AND ADMINISTRATIVE EXPENSES	4,337	3,097	7,434	4,368	3,072	7,440
SALES AND MARKETING EXPENSES	10,955	3,664	14,619	9,728	4,326	14,054
DEPRECIATION AND AMORTIZATION	1,341	44	1,385	1,180	31	1,211
OPERATING EXPENSES	20,453	9,210	29,663	18,132	11,717	29,849
NET LOSS FROM OPERATIONS	(9,716 )	(5,523 )	(15,239 )	(12,213)	(8,581 )	(20,794 )
OTHER INCOME AND EXPENSES, NET			(2,713 )			2,478
NET LOSS BEFORE TAXES			\$ (17,952 )			\$ (18,316 )

## 17. SUBSEQUENT EVENT

As disclosed in Note 9 Loan Agreements, the Company obtained the Waiver under its Term Loan Agreement with Hercules in July 2016. The specific terms of the Waiver are described in detail within Note 9 Loan Agreements.

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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<sup>®</sup>, 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 in 800 patients of ILUVIEN per the labeled indication. Through June 30, 2016, we have enrolled over 380 patients.

Through June 30, 2016, we have enrolled over 380 patients.

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

In addition, we have entered into various agreements under which distributors will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in numerous countries in the Middle East, Canada, Italy, Australia and New Zealand.

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of June 30, 2016, we have accumulated a deficit of \$361.9 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 June 30, 2016, we had approximately \$16.6 million in cash and cash equivalents.

As of June 30, 2016, we did not meet the liquidity threshold under the financial covenants in our Term Loan Agreement (as defined below) with Hercules Capital, Inc. (Hercules). While this violation was subsequently waived by Hercules, our current financial forecast for 2016 projects that we must obtain additional or alternative financing or it is probable that we will not be able to comply with the financial covenants under the Term Loan Agreement. We are currently pursuing alternative or additional debt financing and have an at-the-market offering in place under which we may sell up to approximately \$33.8 million of our common stock. In an event of default, all amounts may become due under the Term Loan Agreement and there would be substantial doubt about our ability to continue as a going concern.

Further, due to the limited revenue generated by ILUVIEN to date, even if we are able to refinance the Term Loan Agreement and maintain compliance with its financial covenants, we will need to raise additional capital to fund the continued commercialization of ILUVIEN. If we are unable to raise 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 a permeable membrane cap on one end and an impermeable silicone cap on the other end 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.

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

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 June 30, 2016 and December 31, 2015, pSivida owed us \$23.8 million and \$21.6 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.

In the second quarter of 2016, pSivida disputed portions of our claimed commercialization costs for the year ended December 31, 2014. As part of this dispute, pSivida notified us that it disagreed with \$1.3 million of the \$13.0 million in commercialization costs receivable that we had reported as of December 31, 2014 and claimed incremental profit sharing payments of \$136,000 for the year ended December 31, 2014. We are disputing pSivida's assertions through the alternative dispute resolution mechanism under the agreement with pSivida. If pSivida's assertions were to prevail in the alternative dispute resolution mechanism and their assertions were then applied to the commercialization cost calculations for the year ended December 31, 2015 and the six months ended June 30, 2016, then the commercialization costs receivable from pSivida would be reduced from \$21.6 million to \$18.5 million at December 31, 2015 and from \$23.8 million to \$20.0 million at June 30, 2016. If pSivida's assertions were to prevail in the alternative dispute resolution mechanism, the impact on the statements of operations for the year ended December 31, 2015 and the six months ended June 30, 2016 would be immaterial.

### Our Loan Agreements

#### 2014 Loan Agreement, 2015 Loan Amendment and 2016 Loan Amendment

In April 2014, Alimera Sciences Limited (Limited), our subsidiary, entered into a loan and security agreement (2014 Loan Agreement) with Hercules providing for a term loan of up to \$35.0 million (the 2014 Term Loan), which Limited and Hercules later amended in November 2015 (the 2015 Loan Amendment and, together with the 2014 Loan Agreement and the 2016 Loan Amendment (as defined below), the Term Loan Agreement). Under the 2014 Loan Agreement, Hercules made an 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 a 2013 term loan with Silicon Valley Bank. Hercules made an additional advance of \$25.0 million to Limited in September 2014 following the approval of ILUVIEN by the FDA to fund the pSivida Milestone Payment. The 2014 Loan Agreement provided for interest only payments through November 2015. The 2015 Loan Amendment extended the interest only payments through May 2017. 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. Beginning in June 2017, Limited will make 11 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 initial advance under the 2014 Loan Agreement, 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 prior to maturity, it will pay Hercules a prepayment penalty of 1.25% of the total principal amount repaid. In connection with the 2015 Loan Amendment, Limited paid

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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 (End of Term Payment).

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.

In January 2016, we did not meet the revenue threshold covenant. As a result, in March 2016, Limited entered into a second amendment to the Term Loan Agreement with Hercules, which waived the covenant violation and amended certain terms of the Term Loan Agreement (the 2016 Loan Amendment).

The 2016 Loan Amendment amended the revenue covenant to a rolling three-month calculation to first be measured for the three months ending May 31, 2016 and increases the liquidity covenant. The amended liquidity covenant requires us to keep at least \$25.0 million in liquid assets, with a minimum of \$17.5 million in cash. Additionally, in any month in which we have \$25.0 million in cash, the revenue requirement will be waived. Upon execution of the 2016 Loan Amendment, Limited paid Hercules an amendment fee of \$350,000 and agreed to increase the End of Term Payment to \$1,400,000 from \$1,050,000, which is payable on the date that the 2014 Term Loan is paid in full. We concluded the 2016 Loan Amendment resulted in a substantial modification of the terms of debt when considered with the 2015 Loan Amendment in accordance with the guidance in ASC 470-50, Debt. As a result, we accounted for the 2016 Loan Amendment as an extinguishment and recognized a loss on early extinguishment of debt of \$2.6 million within the consolidated statement of operations for the six months ended June 30, 2016. The loss on early extinguishment consisted primarily of the unamortized debt discount associated with the warrant and debt issuance costs incurred prior to the 2016 Loan Amendment, the incremental fair value of the warrant as a result of the modifying the terms of the warrant and the debt issuance cost of \$360,000 paid to Hercules for the 2016 Loan Amendment.

In July 2016, we obtained a waiver of the requirements of the liquidity covenant (the Waiver) because we were not in compliance with our liquidity covenant as of June 30, 2016. The Waiver cured the default of the liquidity covenant and modified the liquidity covenant requirement so that we must keep at least \$20.0 million in liquid assets, consisting of cash and accounts receivable from customers in the U.S. with a minimum of \$12.5 million in cash. In addition, the Waiver modified the three-month revenue covenant so that it was not measured at July 31, 2016 and reduced the three-month revenue target to be measured at August 31, 2016. Following execution of the Waiver, Limited will pay to Hercules a weekly ticking fee equal to 0.05% multiplied by the outstanding principal amount. The weekly ticking fee will no longer be payable if we raise collectively \$15.0 million in equity following the date of the Waiver. In addition, Limited agreed that it will pay Hercules a fee of \$350,000, which amount will be paid no later than September 1, 2016.

Our current financial forecast for 2016 projects that we must obtain alternative or additional financing or it is probable that we will not be able to comply with our financial covenants in the future. While Hercules may waive compliance with financial covenants in the future, there can be no certainty that this will be the case and we will need to raise additional capital to fund the continued commercialization of ILUVIEN. We are currently pursuing alternatives with various lenders and have an at-the-market offering in place under which we can sell up to approximately \$33.8 million of our common stock, however, the avoidance of noncompliance with our financial covenants cannot be assured. If we do not maintain compliance with any of our financial covenants, Hercules could demand immediate repayment in full the \$35.0 million under the 2014 Term Loan and the End of Term Payment. As a result, the full amount of the 2014 Term Loan and make the End of Term Payment have been classified as current liabilities in the accompanying consolidated balance sheet at June 30, 2016 and December 31, 2015. Regardless of the noncompliance with financial covenants, we have made every scheduled payment required under the terms of the Term 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 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 warrant was 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

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price to \$2.65 per share. We agreed to further amend the warrant agreement in connection with the 2016 Loan Amendment to increase the number of shares issuable upon exercise to 862,069 and decrease the exercise price to \$2.03 per share. In connection with the Waiver, we agreed to amend the warrant again to increase the number of shares issuable upon exercise to 1,258,993 shares and decrease the exercise price to \$1.39 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 June 30, 2016 and December 31, 2015.

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## Financial Operations Overview

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
	(In thousands)			
NET REVENUE	\$9,557	\$5,776	\$15,358	\$9,714
GROSS PROFIT	9,001	5,400	14,424	9,055
OPERATING EXPENSES	15,450	15,200	29,663	29,849
NET LOSS FROM OPERATIONS	(6,449 )	(9,800 )	(15,239 )	(20,794 )
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	(6,858 )	(8,596 )	(18,003 )	(18,389 )

## Revenue

We began generating revenue from ILUVIEN in the second quarter of 2013. In addition to generating revenue from product sales, we intend 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. Additionally, margins will be lower in countries where we choose to partner with distributors who will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN. 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 \$3.8 million, or 66%, to approximately \$9.6 million for the three months ended June 30, 2016 and by approximately \$5.7 million, or 59%, to approximately \$15.4 million for the six months ended June 30, 2016. The increase was primarily as a result of higher U.S. sales and our U.S. launch of ILUVIEN in March 2015.

## Operating Expenses

Operating expenses increased by approximately \$300,000, or 2%, to approximately \$15.5 million for the three months ended June 30, 2016 primarily as a result of increases in sales and marketing expenses of \$600,000, general and administrative expenses of \$300,000 and depreciation and amortization expenses of \$100,000 offset by a decrease of \$600,000 in research, development and medical affairs expenses.

Operating expenses decreased by approximately \$100,000 to approximately \$29.7 million for the six months ended June 30, 2016 primarily as a result of decreases in research, development and medical affairs expenses of \$900,000 offset by an increases in sales and marketing expenses of \$500,000 and depreciation and amortization expenses of \$200,000.

## 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 may incur additional research, development and medical affairs expenses in the future as we expand the availability of ILUVIEN in additional geographies, 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;
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fees paid to consultants and contract research organizations 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;

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• 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.

**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 for 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 Germany and the United Kingdom in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015.

We have a European management team, local management teams and commercial personnel in France, Germany, Portugal and the United Kingdom totaling 32 persons at June 30, 2016, of which five are consultants. As of June 30, 2016, we had a U.S. field force of approximately 48 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 our Annual Report on Form 10-K. There have been no significant changes in our critical accounting policies.



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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 Interim 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 2016 or 2015.

## U.S. Segment

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)			
NET REVENUE	\$7,208	\$3,804	\$11,327	\$6,247
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(368 )	(190 )	(590 )	(328 )
GROSS PROFIT	6,840	3,614	10,737	5,919
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	2,181	1,478	3,820	2,856
GENERAL AND ADMINISTRATIVE EXPENSES	2,323	2,179	4,337	4,368
SALES AND MARKETING EXPENSES	5,403	4,848	10,955	9,728
DEPRECIATION AND AMORTIZATION	673	621	1,341	1,180
OPERATING EXPENSES	10,580	9,126	20,453	18,132
NET LOSS FROM OPERATIONS	\$(3,740)	\$(5,512)	\$(9,716)	\$(12,213)

Three months ended June 30, 2016 compared to the three months ended June 30, 2015

Net Revenue. Net revenue increased by approximately \$3.4 million, or 89%, to approximately \$7.2 million for the three months ended June 30, 2016 compared to approximately \$3.8 million for the three months ended June 30, 2015. The increase was primarily attributable to an increase in sales volume as ILUVIEN gains market acceptance in the U.S.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately \$180,000, or 95%, to approximately \$370,000 for the three months ended June 30, 2016 compared to approximately \$190,000 for the three months ended June 30, 2015, as a result of an increase in sales volume.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately \$700,000, or 47%, to approximately \$2.2 million for the three months ended June 30, 2016 compared to approximately \$1.5 million for the three months ended June 30, 2015. The increase was primarily attributable to an increase of \$760,000 in allocated costs associated with global research and development. These costs are allocated based upon our future expected revenues from our segments. There was an additional increase of \$200,000 in costs for medical science liaisons hired for the launch of ILUVIEN in the first half of 2015. The increase was offset by a decrease of approximately \$220,000 related to scientific study costs.

General and administrative expenses. General and administrative expenses increased by approximately \$100,000, or 5%, to approximately \$2.3 million for the three months ended June 30, 2016 compared to approximately \$2.2 million for the three months ended June 30, 2015. The increase was primarily attributable to an increase in professional and legal fees.

Sales and marketing expenses. Sales and marketing expenses increased by approximately \$600,000, or 13%, to approximately \$5.4 million for the three months ended June 30, 2016 compared to approximately \$4.8 million for the

three months ended June 30, 2015. The increase was primarily attributable to an increase of \$570,000 in commissions for the commercial team.

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Depreciation and amortization. Depreciation and amortization increased by approximately \$50,000, or 8%, to approximately \$670,000 for the three months ended June 30, 2015 compared to approximately \$620,000 for the three months ended June 30, 2015.

Six months ended June 30, 2016 compared to the six months ended June 30, 2015

Net Revenue. Net revenue increased by approximately \$5.1 million, or 82%, to approximately \$11.3 million for the six months ended June 30, 2016 compared to approximately \$6.2 million for the six months ended June 30, 2015. The increase was primarily attributable to an increase in sales volume as ILUVIEN gains market acceptance in the U.S.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately \$260,000, or 79%, to approximately \$590,000 for the six months ended June 30, 2016 compared to approximately \$330,000 for the six months ended June 30, 2015, as a result of an increase in sales volume.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately \$900,000, or 31%, to approximately \$3.8 million for the six months ended June 30, 2016 compared to approximately \$2.9 million for the six months ended June 30, 2015. The increase was primarily attributable to an increase of \$1.4 million in allocated costs associated with global research and development. These costs are allocated based upon our future expected revenues from our segments. There was an additional increase of \$210,000 for medical science liaison costs. The increase was offset by decreases of approximately \$310,000 related to state research and development tax credits, \$280,000 for scientific study costs and \$190,000 for U.S. compliance costs.

General and administrative expenses. General and administrative expenses decreased by approximately \$100,000, or 2%, to approximately \$4.3 million for the six months ended June 30, 2016 compared to approximately \$4.4 million for the six months ended June 30, 2015. The decrease was primarily attributable to a decrease in professional and legal fees.

Sales and marketing expenses. Sales and marketing expenses increased by approximately \$1.3 million, or 13%, to approximately \$11.0 million for the six months ended June 30, 2016 compared to approximately \$9.7 million for the six months ended June 30, 2015. The increase was primarily attributable to an increase of \$1.7 million in costs for the commercial team hired for the launch of ILUVIEN in the U.S. in the first quarter of 2015 offset by a decrease of \$440,000 in marketing and market access costs associated with the initial launch of ILUVIEN in the U.S. in the first quarter of 2015.

Depreciation and amortization. Depreciation and amortization increased by approximately \$100,000, or 8%, to approximately \$1.3 million for the six months ended June 30, 2016 compared to approximately \$1.2 million for the six months ended June 30, 2015. The increase was primarily attributable to depreciation expense associated with capital leases entered into beginning in late March 2015 for automobiles for the U.S. commercial team.

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## International Segment

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)			
NET REVENUE	\$2,349	\$1,972	\$4,031	\$3,467
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(188 )	(186 )	(344 )	(331 )
GROSS PROFIT	2,161	1,786	3,687	3,136
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	1,024	2,337	2,405	4,288
GENERAL AND ADMINISTRATIVE EXPENSES	1,716	1,642	3,097	3,072
SALES AND MARKETING EXPENSES	2,107	2,077	3,664	4,326
DEPRECIATION AND AMORTIZATION	23	18	44	31
OPERATING EXPENSES	4,870	6,074	9,210	11,717
NET LOSS FROM OPERATIONS	\$(2,709)	\$(4,288)	\$(5,523)	\$(8,581)

Three months ended June 30, 2016 compared to the three months ended June 30, 2015

Net Revenue. Net revenue increased by approximately \$300,000, or 15%, to approximately \$2.3 million for the three months ended June 30, 2016 compared to approximately \$2.0 million for the three months ended June 30, 2015. The increase was primarily attributable to a net increase of \$450,000 from higher sales volumes in Portugal and Germany offset by a decrease in sales volume in the United Kingdom. Revenue was further reduced by the change in the value of the British pound sterling and the Euro which reduced reported revenue by \$70,000 in the three months ended June 30, 2016 compared to the three months ended June 30, 2015.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization was approximately \$190,000 for the three months ended June 30, 2016 and 2015. There was an increase in cost of goods sold as a result of an increase in sales volume offset by a reduction to charges for expiring inventory of approximately \$60,000 recorded in the second quarter of 2015.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately \$1.3 million, or 57%, to approximately \$1.0 million for the three months ended June 30, 2016 compared to approximately \$2.3 million for the three months ended June 30, 2015. The decrease was primarily attributable to a reduction of allocated costs associated with global research and development. These costs are allocated based upon our future expected revenues from our segments.

General and administrative expenses. General and administrative expenses increased by approximately \$100,000, or 6%, to approximately \$1.7 million for the three months ended June 30, 2016 compared to \$1.6 million for the three months ended June 30, 2015. There was an increase in personnel costs of \$120,000 primarily related to training costs. Sales and marketing expenses. Sales and marketing expenses were \$2.1 million for the three months ended June 30, 2016 and 2015. There was an increase in personnel costs of \$360,000 offset by a decrease of approximately \$360,000 in costs for market research, consultants and market access.

Six months ended June 30, 2016 compared to the six months ended June 30, 2015

Net Revenue. Net revenue increased by approximately \$500,000, or 14%, to approximately \$4.0 million for the six months ended June 30, 2016 compared to approximately \$3.5 million for the six months ended June 30, 2015. The increase was primarily attributable to a net increase of \$700,000 from higher sales volumes in Portugal and Germany offset by decreases in sales volume in the United Kingdom. Revenue was further reduced by the change in the value of the British pound sterling and the Euro which reduced reported revenue by \$140,000 in the six months ended June 30, 2016 compared to the three months ended June 30, 2015.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by approximately \$10,000, or 3%, to approximately \$340,000 for the six months ended June 30, 2016 compared to



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approximately \$330,000 for the six months ended June 30, 2015. The increase was primarily attributable to higher sales volume offset by a reduction to charges for expiring inventory of approximately \$60,000 recorded in the second quarter of 2015.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately \$1.9 million, or 44%, to approximately \$2.4 million for the six months ended June 30, 2016 compared to approximately \$4.3 million for the six months ended June 30, 2015. The decrease was primarily attributable to a reduction of allocated costs associated with global research and development. These costs are allocated based upon our future expected revenues from our segments.

General and administrative expenses. General and administrative expenses were approximately \$3.1 million for the six months ended June 30, 2016 and 2015.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately \$600,000, or 14%, to approximately \$3.7 million for the six months ended June 30, 2016 compared to approximately \$4.3 million for the six months ended June 30, 2015. The decrease was primarily attributable to decreases of approximately \$580,000 in costs for market research, consultants and market access.

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## Consolidated other income and expense

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 Interim Financial Statements.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
NET LOSS FROM OPERATIONS	\$(6,449)	\$(9,800)	\$(15,239)	\$(20,794)
INTEREST EXPENSE, NET AND OTHER	(1,177 )	(1,151 )	(2,512 )	(2,273 )
UNREALIZED FOREIGN CURRENCY (LOSS) GAIN, NET	(14 )	143	20	29
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	824	2,216	2,343	4,722
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	—	(2,564 )	—
NET LOSS BEFORE TAXES	(6,816 )	(8,592 )	(17,952 )	(18,316 )
PROVISION FOR TAXES	(42 )	(4 )	(51 )	(73 )
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	\$(6,858)	\$(8,596)	\$(18,003)	\$(18,389)

## Interest expense, net and other.

Interest expense, net and other was approximately \$1.2 million for the three months ended June 30, 2016 and 2015. Interest expense, net and other increased by approximately \$200,000, or 9%, to approximately \$2.5 million for the six months ended June 30, 2016 compared to approximately \$2.3 million for the six months ended June 30, 2015. The increase was primarily attributable to an increase in the underlying prime interest rate on our Term Loan Agreement.

## Unrealized foreign currency (loss) gain, net.

We recorded a non-cash unrealized foreign currency loss of approximately \$14,000 for the three months ended June 30, 2016 compared to a gain of approximately \$140,000 for the three months ended June 30, 2015. We recorded a non-cash unrealized foreign currency gain of approximately \$20,000 and \$30,000 for the six months ended June 30, 2016 and 2015, respectively.

## 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 \$820,000 and \$2.2 million for the three months ended June 30, 2016 and 2015, 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 June 30, 2016 and 2015.

A decrease in the fair value of our derivative warrant liability resulted in a non-cash gains of approximately \$2.3 million and \$4.7 million for the six months ended June 30, 2016 and 2015, respectively. The change in fair value was primarily attributable to decreases in the fair market value of our underlying common stock during both the six-month periods ended June 30, 2016 and 2015.

## Loss on early extinguishment of debt.

We recorded a loss on early extinguishment of debt of approximately \$2.6 million for the six months ended June 30, 2016, as a result of the 2016 Loan Amendment to our Term Loan Agreement.

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Liquidity and Capital Resources

To date, we have incurred negative cash flow from operations and have accumulated a deficit of \$361.9 million from our inception through June 30, 2016.

As of June 30, 2016, we had approximately \$16.6 million in cash and cash equivalents. We launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015.

The Term Loan Agreement requires that we maintain at least \$25.0 million in liquid assets, with a minimum of \$17.5 million in cash. Additionally, in any month in which we have \$25.0 million in cash, the revenue requirement will be waived.

In July 2016, we obtained a waiver of the requirements of the liquidity covenant as we were not in compliance with our liquidity covenant as of June 30, 2016. The Waiver cured the default of the liquidity covenant and modified the liquidity covenant requirement so that Limited and the Company must keep at least \$20.0 million in liquid assets, consisting of cash and accounts receivable from customers in the U.S. with a minimum of \$12.5 million in cash. In addition, the Waiver modified the three-month revenue covenant so that it was not measured at July 31, 2016 and reduced the three-month revenue target to be measured at August 31, 2016.

Our current financial forecasts for 2016 project that we must obtain alternative or additional financing otherwise it is probable that we will not be able to comply with our financial covenants in the future. We are currently pursuing alternative or additional debt financing and have an at-the-market offering in place under which we may sell up to approximately \$33.8 million of our common stock. If an event of default occurs under our Term Loan Agreement, Hercules may demand repayment of the 2014 Term Loan.

Further, due to the limited revenue generated by ILUVIEN to date, even if we are able to refinance the 2014 Term Loan and maintain compliance with its financial covenants, we will need to raise additional capital to fund the continued commercialization of ILUVIEN. If we are unable to raise 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.

We cannot be sure that alternative or additional financing 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 six months ended June 30, 2016, cash used by our operations of \$14.2 million was primarily due to our net loss of \$18.0 million increased by a non-cash gain of \$2.3 million for the change in our derivative warrant liability and offset by non-cash items including a \$2.6 million loss on early debt extinguishment for the amendment to our Term Loan Agreement, \$2.6 million of stock-based compensation expense, \$1.4 million for depreciation and amortization and \$520,000 for non-cash interest expense associated with our debt discount. Further decreasing cash used in operations were an increase in accounts payable, accrued expenses and other current liabilities of approximately \$2.9 million and a decrease in inventory of approximately \$300,000. These were offset by increases in accounts receivable of approximately \$3.5 million and in prepaid and other current assets of approximately \$650,000.

For the six months ended June 30, 2015, cash used by our operations of \$27.7 million was primarily due to our net loss of \$18.4 million, a \$6.8 million increase in accounts receivable and a \$1.7 million decrease in accounts payable, accrued expenses and other current liabilities offset 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 \$500,000 in amounts payable to Quintiles Commercial offset by increases of \$900,000 in payroll and related costs including bonuses. Non-cash items included a gain of \$4.7 million for the change in our derivative warrant liability



offset by \$2.3 million of stock-based compensation expense, \$1.2 million for depreciation and amortization and \$350,000 for non-cash interest expense associated with deferred financing costs and our debt discount.

For the six months ended June 30, 2016, net cash used in our investing activities was approximately \$120,000, which was due to the purchase of property and equipment, primarily the purchase of accounts payable software and leasehold improvements.

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For the six months ended June 30, 2015, net cash used in our investing activities was approximately \$340,000, which was due to the purchase of property and equipment, primarily the purchase of drug safety management software.

For the six months ended June 30, 2016, net cash used in our financing activities was approximately \$160,000 due to the payment of debt issuance costs of approximately \$350,000 associated with the second amendment of our Hercules Term Loan Agreement and approximately \$120,000 in payments on capital leases, offset by cash provided by proceeds from the issuance of common stock of \$290,000.

For the six months ended June 30, 2015, net cash used in our financing activities was approximately \$300,000 due to the payment of issuance costs of \$330,000 associated with the sale of our Series B Convertible Preferred Stock and approximately \$150,000 in payments on capital leases offset by cash received of \$140,000 from the proceeds from exercises of stock options.

### Contractual Obligations and Commitments

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, 2015, filed with the SEC on March 15, 2016.

### Off-Balance Sheet Arrangements

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

### Recent Accounting Pronouncements

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

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 provides a single, comprehensive revenue recognition model for all contracts with customers. The revenue guidance contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an 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 currently in the process of evaluating the potential impact of adopting this guidance on our financial statements.

In July 2015, FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. This update requires entities to measure inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. This ASU is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those years. Our management is currently in the process of evaluating the impact of the adoption on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). This standard requires all leases with durations greater than twelve months to be recognized on the balance sheet and is effective for interim and annual reporting periods beginning after December 15, 2018, although early adoption is permitted. Our management is currently in the process of evaluating the impact of the adoption on our financial statements.

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In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718). This standard makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation and the financial statement presentation of excess tax benefits or deficiencies. ASU 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, although early adoption is permitted. Our management is currently in the process of evaluating the impact of the adoption on our 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 \$180,000 increase in interest expense for the three months ended June 30, 2016 and six months ended June 30, 2016, 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 six months ended June 30, 2016 and 2015, we did not recognize any charges for write-offs of accounts receivable. As of June 30, 2016 and December 31, 2015, two U.S. distributors accounted for 88%, of our accounts receivable balances.

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 June 30, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the three months ended June 30, 2016 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, 2015, filed with the SEC on March 15, 2016, 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. Except as set forth below, there have been no material changes in our risk factors subsequent to the filing of our Form 10-K for the fiscal year ended December 31, 2015. The following information should be read in conjunction with the interim condensed consolidated financial statements and related notes in Part I, Item 1, "Interim Condensed Consolidated Financial Statements" and the discussion and analysis of our financial condition in Part I, Item 2, "Management's, Discussion and Analysis of Financial Condition and Results of Operations."

We will need alternative financing to replace our \$35.0 million debt facility or additional capital to maintain compliance with the financial covenants under this debt facility, which we may be unable to obtain.

At June 30, 2016, we had approximately \$16.6 million in cash and cash equivalents. We will need to raise alternative or additional financing to maintain compliance with our financial covenants under our loan and security agreement with Hercules Capital, Inc. (Hercules), which Alimera Sciences Limited (Limited), our subsidiary, entered into in April 2014, and amended in November 2015, March 2016, May 2016 and July 2016 (collectively, the Term Loan Agreement). Under the Term Loan Agreement, Limited obtained a term loan in an aggregate principal amount of \$35.0 million (the 2014 Term Loan). We are currently pursuing alternatives with various lenders and investors for alternative or additional financing and we have an at-the-market offering in place under which we could sell up to approximately \$33.8 million of our common stock. If we are unable to raise additional financing, or if the funds we raise are not sufficient then we will not be able to maintain compliance with our financial covenants.

In an event of default, Hercules may call the 2014 Term Loan, which could require us to pay back the entire amount owed and pay an early termination fee, or if they do not call the 2014 Term Loan, we may have to pay an increased rate of interest, pay additional monetary amounts in exchange for a waiver or modification of the 2014 Term Loan, or grant additional equity or warrant coverage and agree to further restrictions on our operations that could hinder us in the future. To secure the performance of our obligations under the Term Loan Agreement, Limited pledged all of its assets to the lender. Our or Limited's failure to comply with the covenants under the Term 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 the lender under the Term Loan Agreement (Guaranties). Pursuant to the Guaranties, we and these subsidiaries granted the lender a first priority security interest in substantially all of our respective assets. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline significantly and may cause us to raise funds on terms not favorable to us or our stockholders. 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, which could cause significant reputational damage and impact our ability to sell ILUVIEN.

For example, in January 2016 we did not meet the revenue requirement under the Term Loan Agreement and in June 2016 we did not meet the liquidity requirement under the Term Loan Agreement. While these violations were waived by Hercules, we were required to pay additional monies to Hercules as a condition to obtaining them. In conjunction with the first waiver, we paid an amendment fee of \$350,000 and agreed to increase the payment that will be made

when the 2014 Term Loan ends to \$1.4 million. In conjunction with the second waiver, we agreed to pay a fee of \$350,000 by September 1, 2016 and begin paying a weekly ticking fee of 0.05% multiplied by the outstanding principal amount of the 2014 Term Loan, in addition to our normal interest payments, until we raise \$15.0 million in equity. In addition, in connection with each of these waivers, we modified the warrant previously issued to Hercules, to increase the number of shares that may be purchased under the warrant and reduce the exercise price. Although Hercules waived each of these defaults, there can be no assurance that it will do so with respect to any future default.



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The results of the United Kingdom's referendum on withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

On June 23, 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the European Union (EU), commonly referred to as "Brexit." As a result of the referendum, it is expected that the British government will begin negotiating the terms of the UK's withdrawal from the EU. A withdrawal could, among other outcomes, disrupt the free movement of goods, services and people between the UK and the EU, undermine bilateral cooperation in key policy areas and significantly disrupt trade between the UK and the EU. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws and regulations to replace or replicate, including tax and pharmaceutical laws and regulations. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would affect us.

The announcement of Brexit caused significant volatility in global stock markets and currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we conduct business. The strengthening of the U.S. dollar relative to other currencies may adversely affect our operating results. The announcement of Brexit and the withdrawal of the UK from the EU have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity. Any of these effects of Brexit, among others, could adversely affect our business, financial condition, operating results and cash flows.

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

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

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ITEM 6. Exhibits

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Registrant, as amended on various dates (filed as Exhibit 3.2 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010 and incorporated herein by reference).
3.2	Amended and Restated Bylaws of the Registrant, as amended (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, as filed on November 5, 2015 and incorporated herein by reference).
3.3	Certificate of Designation of Series A Convertible Preferred Stock (filed as Exhibit 3.5 to the Registrant's Current Report on Form 8-K, as filed on October 2, 2012 and incorporated herein by reference).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (filed as Exhibit 3.6 to the Registrant's Current Report on Form 8-K, as filed on December 15, 2014 and incorporated herein by reference).
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	XBRL Instance Document.
101.SCH+	XBRL Taxonomy Extension Schema Document.
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	XBRL Taxonomy Extension Label Link Document.
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document.

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

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



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Signatures

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

ALIMERA SCIENCES, INC.

August 5, 2016 By: /s/ C. Daniel Myers

C. Daniel Myers  
Chief Executive Officer  
(Principal Executive Officer)

August 5, 2016 By: /s/ Richard S. Eiswirth, Jr.

Richard S. Eiswirth, Jr.  
President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

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incorporation language contained in such filing.

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