

ALIMERA SCIENCES INC  
Form 10-Q  
November 04, 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 September 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 November 3, 2016 there were 64,862,904 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), the United States (U.S.) and other regions of the world where we sell ILUVIEN;
- our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility;
- dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality;
- uncertainty as to the pricing and reimbursement guidelines for ILUVIEN or any future products or product candidates, including ILUVIEN in new markets;
- our ability to successfully commercialize ILUVIEN following regulatory approval in additional markets;
- delay in or failure to obtain regulatory approval of ILUVIEN in additional countries or any future products or product candidates;
- the extent of government regulations; and
- our need to raise additional financing.

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

We encourage you to read the discussion and analysis of our financial condition and our unaudited interim financial statements contained in this report. We also encourage you to read Item 1A of Part II of this Quarterly Report on Form 10-Q entitled “Risk Factors” and Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 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

	September 30, 2016	December 31, 2015
	(In thousands, except share and per share data)	
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 33,853	\$ 31,075
Restricted cash	38	37
Accounts receivable, net	13,397	9,799
Prepaid expenses and other current assets	3,402	2,696
Inventory, net (Note 5)	913	1,552
Total current assets	51,603	45,159
<b>NON-CURRENT ASSETS:</b>		
Property and equipment, net	2,054	2,553
Intangible asset, net (Note 6)	21,093	22,549
Deferred tax asset, net	230	223
<b>TOTAL ASSETS</b>	<b>\$ 74,980</b>	<b>\$ 70,484</b>
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 3,449	\$ 4,002
Accrued expenses (Note 7)	4,169	3,911
Note payable, net of discount (Note 9)	—	31,786
Capital lease obligations	235	234
Total current liabilities	7,853	39,933
<b>NON-CURRENT LIABILITIES:</b>		
Derivative warrant liability	1,060	2,815
Note payable, net of discount — less current portion (Note 9)	33,425	—
Capital lease obligations — less current portion	401	582
Other non-current liabilities	2,209	834
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$.01 par value — 10,000,000 shares authorized at September 30, 2016 and December 31, 2015:		
Series A Convertible Preferred Stock, 1,300,000 authorized and 600,000 issued and outstanding at September 30, 2016 and December 31, 2015; liquidation preference of 19,227 \$24,000 at September 30, 2016 and December 31, 2015		19,227
Series B Convertible Preferred Stock, 8,417 authorized and 8,416.251 issued and outstanding at September 30, 2016 and December 31, 2015; liquidation preference of 49,568 \$50,750 at September 30, 2016 and December 31, 2015		49,568
Common stock, \$.01 par value — 100,000,000 shares authorized, 64,710,724 shares issued and outstanding at September 30, 2016 and 45,005,833 shares issued and outstanding at December 31, 2015	647	450
Additional paid-in capital	329,467	299,376
Common stock warrants	3,338	2,747
Accumulated deficit	(371,146	) (343,900
Accumulated other comprehensive loss	(1,069	) (1,148
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>30,032</b>	<b>26,320</b>

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 74,980	\$ 70,484
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See Notes to Consolidated Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands, except share and per share data)			
NET REVENUE	\$8,298	\$ 6,901	\$23,656	\$ 16,615
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(486 )	(634 )	(1,420 )	(1,293 )
GROSS PROFIT	7,812	6,267	22,236	15,322
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	3,261	4,078	9,486	11,222
GENERAL AND ADMINISTRATIVE EXPENSES	3,645	3,031	11,079	10,471
SALES AND MARKETING EXPENSES	7,452	6,949	22,071	21,003
DEPRECIATION AND AMORTIZATION	697	653	2,082	1,864
OPERATING EXPENSES	15,055	14,711	44,718	44,560
NET LOSS FROM OPERATIONS	(7,243 )	(8,444 )	(22,482 )	(29,238 )
INTEREST EXPENSE, NET AND OTHER	(1,330 )	(1,317 )	(3,842 )	(3,590 )
UNREALIZED FOREIGN CURRENCY LOSS, NET	(51 )	(63 )	(31 )	(34 )
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	(588 )	8,363	1,755	13,085
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	—	(2,564 )	—
NET LOSS BEFORE TAXES	(9,212 )	(1,461 )	(27,164 )	(19,777 )
PROVISION FOR TAXES	(33 )	(82 )	(84 )	(155 )
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	\$(9,245)	\$(1,543)	\$(27,248)	\$(19,932)
NET LOSS PER SHARE APPLICABLE TO COMMON STOCKHOLDERS — Basic and diluted	\$(0.16 )	\$(0.03 )	\$(0.56 )	\$(0.45 )
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	55,103,534	44,436,224	48,759,381	44,393,831

See Notes to Consolidated Financial Statements.



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ALIMERA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)			
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	\$(9,245)	\$(1,543)	\$(27,248)	\$(19,932)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	30	40	79	(248 )
TOTAL OTHER COMPREHENSIVE INCOME (LOSS)	30	40	79	(248 )
COMPREHENSIVE LOSS	\$(9,215)	\$(1,503)	\$(27,169)	\$(20,180)

See Notes to Consolidated Financial Statements.

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

	Nine Months Ended September 30, 2016      2015 (In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(27,248)	\$(19,932)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,082	1,864
Inventory reserve	39	—
Unrealized foreign currency transaction loss	31	34
Loss on early extinguishment of debt	2,564	—
Amortization of debt discount	795	524
Stock-based compensation expense	3,753	3,702
Change in fair value of derivative warrant liability	(1,755 )	(13,085 )
Changes in assets and liabilities:		
Accounts receivable	(3,564 )	(8,455 )
Prepaid expenses and other current assets	(514 )	627
Inventory	612	(88 )
Accounts payable	(2,101 )	(1,447 )
Accrued expenses and other current liabilities	1,256	(828 )
Other non-current liabilities	1,354	612
Net cash used in operating activities	(22,696 )	(36,472 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(122 )	(370 )
Net cash used in investing activities	(122 )	(370 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	157	278
Proceeds from sale of common stock	27,547	42
Payment of issuance cost of common stock	(1,227 )	—
Payment of Series B Convertible Preferred Stock offering costs	—	(327 )
Payment of debt costs	(715 )	—
Payment of capital lease obligations	(178 )	(207 )
Net cash provided by (used in) financing activities	25,584	(214 )
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS	12	(301 )
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,778	(37,357 )
CASH AND CASH EQUIVALENTS — Beginning of period	31,075	76,697
CASH AND CASH EQUIVALENTS — End of period	\$33,853	\$39,340
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for interest	\$2,977	\$2,904
Cash paid for income taxes	\$299	\$9
Supplemental schedule of non-cash investing and financing activities:		
Property and equipment acquired under capital leases	\$76	\$997
Common stock issuance costs accrued but unpaid	\$114	\$—
Note payable end of term payment accrued but unpaid	\$1,400	\$—
There were no dividend payments made during the nine months ended September 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. Alimera Sciences, Inc. 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. Through September 30, 2016, over 430 patients have been enrolled.

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. In the third quarter of 2016, the Company's Middle East distributor initiated named patient sales of ILUVIEN in the Middle East.

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 \$26,000 and \$118,000 as of September 30, 2016 and December 31, 2015, respectively.

Research and Development Expenses

Research and development expenses were \$1,567,000 and \$940,000 for the three months ended September 30, 2016 and 2015, respectively. Research and development expenses were \$4,438,000 and \$1,958,000 for the nine months ended September 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 continuing to evaluate the new guidance and plans to provide additional information about its expected financial impact at a future date.

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 does not expect the potential impact of adopting this guidance to have a material impact 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 does not expect the impact of the adoption to have a material effect 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 does not expect the impact of the adoption to have a material effect 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 \$371,146,000 from inception through September 30, 2016. As of September 30, 2016, the Company had approximately \$33,853,000 in cash and cash equivalents.

Subsequent to September 30, 2016, the Company entered into the Fourth Loan Amendment (as defined below) with Hercules Capital, Inc. (Hercules) in order to modify certain terms of the Term Loan Agreement (as defined below) and obtain additional loan amounts (see Note 9 Loan Agreements). If there is an event of default, all amounts may become due under the Term Loan Agreement and there would be substantial doubt about the Company's ability to continue as a going concern.

Further, due to the limited revenue generated by ILUVIEN to date, the Company may need to raise additional capital to fund the continued commercialization of ILUVIEN. If the Company were unable to raise additional financing, the Company would need to adjust its commercial plans so that it could continue to operate with its existing cash resources. The actual amount of funds that the Company would need would be determined by many factors, some of which may be beyond its control.

The accompanying Interim Financial Statements have been prepared assuming the Company will continue as a going concern. However, 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:

	September 30, 2016	December 31, 2015
	(In thousands)	
Component parts (1)	\$172	\$131
Work-in-process (2)	214	333
Finished goods	566	1,525
Total inventory	952	1,989
Inventory reserve	(39 )	(437 )
Inventory — net	\$913	\$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 is \$25,000,000, which is being amortized over approximately 13 years from the acquisition date. The amortization expense related to the intangible asset was \$489,000 for both the three months ended September 30, 2016 and 2015. The amortization expense related to the intangible asset was \$1,457,000 and \$1,451,000 for the nine months ended September 30, 2016 and 2015, respectively. The net book value of the intangible asset was \$21,093,000 and \$22,549,000 as of September 30, 2016 and December 31, 2015, respectively.

The estimated future amortization expense as of September 30, 2016 for the remainder of 2016, the next four years and thereafter is as follows (in thousands):

Years Ending December 31

2016	\$489
2017	1,940
2018	1,940
2019	1,940
2020	1,940
Thereafter	12,844
Total	\$21,093

## 7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	September	December
	30,	31,
	2016	2015
	(In thousands)	
Accrued compensation expenses	\$1,561	\$ 804
Accrued clinical investigator expenses	1,092	732
Accrued rebate and other revenue reserves	724	452
Accrued End of Term Payment (Note 9)	—	1,050
Other accrued expenses	792	873
Total accrued expenses	\$4,169	\$ 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 pSivida Agreement). The pSivida Agreement 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 the pSivida Agreement 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 Company's net profits of ILUVIEN, determined on a cash basis, in each country where the Company sells ILUVIEN directly or through its distributors or sub-distributors and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined by the pSivida Agreement. In connection with this arrangement, the Company is entitled to recover 20% of commercialization costs of ILUVIEN incurred prior to product profitability out of pSivida's share of net profits, as defined in the pSivida Agreement. As of September 30, 2016 and December 31, 2015, the Company was owed approximately \$25,239,000 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 using the alternative dispute resolution mechanism under the pSivida Agreement. 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 nine months ended September 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 \$25,239,000 to \$20,931,000 at September 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 nine months ended September 30, 2016 would be immaterial.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 9. LOAN AGREEMENTS

## Hercules Loan Agreement

## 2014 Loan Agreement

In April 2014, Alimera Sciences Limited (Limited), a subsidiary of the Company, entered into a loan and security agreement (2014 Loan Agreement) with Hercules Capital, Inc. (Hercules) providing for a term loan of up to \$35,000,000 (2014 Term Loan), which Limited and Hercules amended in November 2015 (the First Loan Amendment), March 2016 (the Second Loan Amendment), May 2016 (the Third Loan Amendment) and October 2016 (the Fourth Loan Amendment and, collectively with the 2014 Loan Agreement, the First Loan Amendment, the Second Loan Amendment and the Third Loan Amendment, 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 accrued 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 September 30, 2016.

## First Loan Amendment

In November 2015, Limited and Hercules amended the 2014 Loan Agreement to extend the interest only payments through May 2017. In connection with the First 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 (End of Term Payment).

Limited and the Company, on a consolidated basis with the Company's other subsidiaries (the Consolidated Group), 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 First Loan Amendment, Limited agreed to covenants regarding certain revenue thresholds and a liquidity threshold.

## Second Loan Amendment

In January 2016, the revenue threshold covenant was not met by the Consolidated Group and as a result, in March 2016, Limited and Hercules entered into the Second Loan Amendment, which further amended certain terms of the 2014 Loan Agreement. In conjunction with the Second Loan Amendment, Hercules waived this covenant violation. The Second Loan Amendment adjusted the revenue covenant to a rolling three-month calculation, first measured for the three months ended May 31, 2016. In addition, the Second Loan Amendment increased the liquidity covenant. Upon execution of the Second 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 was payable on the date that the 2014 Term Loan was to be paid in full.

The Company concluded that the Second Loan Amendment resulted in a substantial modification of the terms of debt when considered with the First Loan Amendment in accordance with the guidance in ASC 470-50, Debt. As a result, the Company accounted for the Second 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 nine months ended September 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 Second Loan Amendment, the incremental fair value of the warrant as a result of modifying the terms of the warrant and the debt issuance costs of \$360,000 paid to Hercules for the Second Loan Amendment.

## Third Loan Amendment and July 2016 Waiver

In May 2016, Limited and Hercules entered into the Third Loan Amendment to expand the definition of liquidity to allow for the inclusion of cash of up to \$2,000,000 in bank accounts outside of the U.S. and the United Kingdom. In July 2016, Limited obtained a waiver of the requirements of the liquidity covenant (the Waiver) because the Consolidated Group was not in compliance with the liquidity covenant as of June 30, 2016. The Waiver cured the default of the liquidity covenant then existing under the Term Loan Agreement and decreased the liquidity requirement. In addition, the

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 incurred a weekly ticking fee equal to 0.05% multiplied by the outstanding principal amount through the closing of the Company's public offering in August 2016 (see Note 12 Common Stock), totaling \$65,000. Further, Limited paid Hercules a fee of \$350,000 associated with the Waiver.

Fourth Loan Amendment

In October 2016, Limited entered into the Fourth Loan Amendment with Hercules, which further amended certain terms of the Term Loan Agreement. Pursuant to the terms of the Fourth Loan Amendment, Hercules agreed to provide up to an additional \$10,000,000 to Limited with (i) the first \$5,000,000 available at Limited's option through June 30, 2017 subject to (A) the Consolidated Group's achievement of \$12,000,000 in trailing three month net product revenue and (B) no event of default having occurred since October 20, 2016 (the Effective Date) and (ii) the second \$5,000,000 available at Limited's option through December 31, 2017 subject to (A) the Consolidated Group's achievement of \$15,000,000 in trailing three month net product revenue, (B) no event of default having occurred since the Effective Date and (C) the prior \$5,000,000 having been advanced to Limited (the Additional Advances and, together with the 2014 Term Loan, the Term Loan). The Fourth Loan Amendment provides for interest only payments through November 30, 2018 (the Interest-Only Period). Pursuant to the Fourth Loan Amendment, interest on the Term Loan accrues at a floating per annum rate equal the greater of (i) 11.0% and (ii) the sum of (A) 11.0% plus (B) the prime rate as reported in The Wall Street Journal, or if not reported, the prime rate most recently reported in The Wall Street Journal, minus 3.5%. In addition to the interest described above, the principal balance of the Term Loan will bear "payment-in kind" interest at the rate of 1.0% (PIK Interest), which PIK Interest will be added to the outstanding principal balance of the Term Loan so as to increase the outstanding principal balance of the Term Loan on each payment date for the Term Loan and which amount will be payable when the aggregate outstanding principal amount of the Term Loan is payable. The Term Loan will be due and payable to Hercules in 24 equal monthly payments of principal and interest following the Interest-Only Period beginning on December 1, 2018 and matures in full on November 1, 2020.

Limited paid Hercules a facility charge of \$337,500 and reimbursed Hercules for legal and diligence fees incurred in connection with the Fourth Loan Amendment. If Limited prepays the Term Loan, it will pay Hercules a prepayment penalty (i) if such amounts are prepaid in any of the first 12 months following the Effective Date, equal to 3.0% of the principal amount of the Term Loan being repaid, (ii) if such amounts are prepaid after 12 months but prior to 24 months following the Effective Date, equal to 2.0% of the principal amount of the Term Loan being repaid, and (iii) if such amounts are prepaid at any time thereafter, equal to 1.0% of the principal amount of the Term Loan being repaid. The Consolidated Group also agreed to customary affirmative and negative covenants, including, without limitation, covenants relating to minimum liquidity, minimum trailing six-month net revenue and adjusted EBITDA, 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, as amended by the Fourth Loan Amendment 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, as amended by the Fourth Loan Amendment. In the event that the Company maintains \$35,000,000 in liquidity, including cash and eligible accounts receivable, at the end of the month and has not been and is not in breach of the amended debt facility, the six-month trailing revenue covenant is effectively waived for such month.

General Discussion of the Term Loan Agreement

Pursuant to 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. The Company and certain of the Company's other subsidiaries 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.

2014 Warrant

In connection with Limited entering into the 2014 Loan Agreement, the Company issued a warrant to Hercules to purchase up to 285,016 shares of the Company's common stock at an exercise price of \$6.14 per share (the 2014 Warrant). Sixty percent of the 2014 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The Company agreed to amend the 2014 Warrant in connection with the First Loan Amendment to increase the number of shares issuable upon exercise to 660,377 and decrease the exercise price to \$2.65 per share. Upon entering into the Second Loan Amendment, the Company agreed to further amend the 2014 Warrant 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 July 2016 Waiver, the Company agreed to further amend the 2014 Warrant to increase the number of shares issuable upon exercise to 1,258,993 and decrease the exercise price to \$1.39 per share.

2016 Warrant

In connection with Limited entering into the Fourth Loan Amendment, the Company agreed to issue a new warrant to Hercules (the 2016 Warrant) to purchase up to the number of shares of the Company's common stock equal to \$500,000 divided by the lowest volume-weighted average sale price for a share of the Company's common stock reported over any ten consecutive trading days during the period commencing on and including September 23, 2016 and ending on the earlier to occur of (i) December 30, 2016 (inclusive of such date), and (ii) the second trading day immediately preceding the date of closing of a merger event (as defined in the 2016 Warrant).

Fair Value of Debt

The weighted average interest rates of the Company's notes payable approximate the rate at which the Company could obtain alternative financing; therefore, the carrying amount of the notes approximated their fair value at September 30, 2016 and December 31, 2015.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 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		Nine Months Ended	
	September 30,		September 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	1,336,947	362,970	1,336,947	362,970
Stock options	11,231,644	9,094,716	11,231,644	9,094,716
Total	34,518,677	31,407,772	34,518,677	31,407,772

## 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 Conversion Price upon the occurrence of the later to occur of both (i) the Company receives and publicly announces the approval by the FDA of the Company's NDA for ILUVIEN and (ii) the date on which the Company consummates an equity financing transaction pursuant to which the Company sells to one or more third party investors either (a) shares of common stock or (b) other equity securities that are convertible into shares of common stock and that have rights, preference or privileges, senior to or on a parity with, the Series A Convertible Preferred Stock, in each case having an as-converted per share of common stock price of not less than \$10.00 and that results in total gross proceeds to the Company of at least \$30,000,000. The rights and preferences of Series A Convertible Preferred Stock also place limitations on the Company's ability to declare or pay any dividend or distribution on any shares of capital stock.

Each unit sold in the preferred stock financing included a warrant to purchase 0.30 shares of Series A Convertible Preferred Stock at an exercise price equal to \$44.00 per share. At the election of the holder of a warrant, the warrant may be exercised for the number of shares of common stock then issuable upon conversion of the Series A Convertible Preferred Stock that would otherwise be issued upon such exercise at the then-effective Conversion Price. These warrants are considered derivative instruments because the agreements provide for settlement in Series A Convertible Preferred Stock shares or common stock shares at the option of the holder, an adjustment to the warrant exercise price for common shares at some point in the future and contain anti-dilution provisions whereby the number

of shares for which the warrants are exercisable and/or the exercise price of the warrants are subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. Therefore, the warrants were recorded as a liability at issuance. The warrant anti-dilution provisions lapsed in September 2014. At September 30, 2016 and December 31, 2015, the fair market value of the warrants was estimated to be \$1,060,000 and \$2,815,000, respectively. During the three months ended September 30, 2016, the Company recorded a loss of \$588,000 and during the three months ended September 30, 2015, the Company recorded a gain of \$8,363,000, as a result of the change in fair value of the warrants. During the nine



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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

months ended September 30, 2016 and 2015, the Company recorded gains of \$1,755,000 and \$13,085,000, respectively, as a result of the change in fair value of the warrants.

In April 2014, 2,255,639 shares of common stock were issued pursuant to the conversion of 150,000 shares of Series A Convertible Preferred Stock held by an investor. In September 2014, 3,759,398 shares of common stock were issued pursuant to the conversion of 250,000 shares of Series A Convertible Preferred Stock held by another investor. As of September 30, 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.

**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 nine months ended September 30, 2016, the Company sold a total of 662,779 shares of its common stock at a weighted average purchase price of \$1.83 per share, resulting in gross proceeds of \$1,211,000, prior to the payment of approximately \$62,000 of underwriter discounts and commissions and related issuance costs.

In addition, in August, 2016, pursuant to an underwriting agreement with Cowen, as representative of the several underwriters named therein, the Company closed a public offering in which it sold 18,900,000 shares of its common stock at a price to the public of \$1.40 per share. The offering resulted in gross proceeds of \$26,460,000, prior to the payment of approximately \$1,309,000 of underwriter discounts and commissions and related issuance costs.

During the nine months ended September 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.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 13. STOCK INCENTIVE PLANS

## Stock Option Plans

During the three months ended September 30, 2016 and 2015, the Company recorded compensation expense related to stock options of approximately \$1,116,000 and \$1,355,000, respectively. During the nine months ended September 30, 2016 and 2015, the Company recorded compensation expense related to stock options of approximately \$3,683,000 and \$3,623,000, respectively. As of September 30, 2016, the total unrecognized compensation cost related to non-vested stock options granted was \$9,448,000 and is expected to be recognized over a weighted average period of 2.57 years. The following table presents a summary of stock option activity for the three and nine months ended September 30, 2016 and 2015:

	Three Months Ended September		Nine Months Ended September	
	30, 2016	2015	30, 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	10,648,703	9,292,947	9,475,890	7,681,256
Grants	749,250	69,000	2,169,750	1,902,500
Forfeitures	(114,837)	(200,266)	(313,297)	(349,643)
Exercises	(51,471)	(66,971)	(100,699)	(139,395)
Options outstanding at period end	11,231,644	9,094,764	11,231,644	9,094,764
Options exercisable at period end	7,116,652	5,510,064	7,116,652	5,510,064
Weighted average per share fair value of options granted during the period	\$1.17	\$3.37	\$1.56	\$4.19

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Term	Aggregate Intrinsic Value
				(In thousands)
Outstanding	11,231,644	\$ 3.18	6.69 years	\$ 71
Exercisable	7,116,615	3.26	5.46 years	70
Outstanding, vested and expected to vest	10,696,132	3.19	6.57 years	71

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	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

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Employee Stock Purchase Plan

During the three months ended September 30, 2016 and 2015, the Company recorded compensation expense related to its employee stock purchase plan of approximately \$18,000 and \$38,000, respectively. During the nine months ended September 30, 2016 and 2015, the Company recorded compensation expense related to its employee stock purchase plan of approximately \$69,000 and \$79,000, respectively.

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

14. INCOME TAXES

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

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

The Company's income tax expense and resulting effective tax rate are based upon the respective estimated annual effective tax rates applicable for the respective periods adjusted for the effects of items required to be treated as discrete to the period, including changes in tax laws, changes in estimated exposures for uncertain tax positions and other items. The Company's effective tax rate for the three months ended September 30, 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 U.S. net deferred tax assets. Due to uncertainties with respect to the realization of U.S. deferred tax assets due to the history of operating losses, a valuation allowance has been established against the entire U.S. 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 \$100,835,000 and state NOL carry-forwards of approximately \$78,762,000 available to reduce future income. The Company's federal NOL carry-forwards remain fully reserved as of September 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 August 2016 common stock issuance, have occurred that would limit its ability to utilize a portion of the Company's NOL carry-forwards. Currently, a full valuation allowance has been recorded against the NOL deferred tax asset.

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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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 15. FAIR VALUE

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

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

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

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

There have been no changes in the methodologies used at September 30, 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:

	September 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)	\$—	\$—	\$—	\$—
Liabilities measured at fair value	\$—	\$—	\$—	\$—
	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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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 September 30, 2016 and 2015, two customers within the U.S. segment accounted for 75% and 73%, respectively, of the Company's consolidated revenues as a result of our sales to two pharmaceutical distributors in the U.S. During the nine months ended September 30, 2016 and 2015, these two customers within the U.S. segment accounted for 74% and 68%, respectively, of the Company's consolidated revenues. These two customers within the U.S. segment accounted for approximately 89% and 88% of the Company's consolidated accounts receivable at September 30, 2016 and December 31, 2015, respectively.

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

	Three Months Ended September 30, 2016			Three Months Ended September 30, 2015		
	U.S.	International	Consolidated	U.S.	International	Consolidated
	(In thousands)					
NET REVENUE	\$6,184	\$ 2,114	\$ 8,298	\$5,032	\$ 1,869	\$ 6,901
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(374 )	(112 )	(486 )	(245 )	(389 )	(634 )
GROSS PROFIT	5,810	2,002	7,812	4,787	1,480	6,267
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	2,204	1,057	3,261	2,320	1,758	4,078
GENERAL AND ADMINISTRATIVE EXPENSES	2,232	1,413	3,645	1,712	1,319	3,031
SALES AND MARKETING EXPENSES	5,618	1,834	7,452	4,546	2,403	6,949
DEPRECIATION AND AMORTIZATION	674	23	697	639	14	653
OPERATING EXPENSES	10,728	4,327	15,055	9,217	5,494	14,711
NET LOSS FROM OPERATIONS	(4,918 )	(2,325 )	(7,243 )	(4,430 )	(4,014 )	(8,444 )
OTHER INCOME AND EXPENSES, NET			(1,969 )			6,983
NET LOSS BEFORE TAXES			\$ (9,212 )			\$ (1,461 )



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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 nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30, 2016			Nine Months Ended September 30, 2015		
	U.S.	International	Consolidated	U.S.	International	Consolidated
	(In thousands)					
NET REVENUE	\$17,511	\$ 6,145	\$ 23,656	\$11,279	\$ 5,336	\$ 16,615
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(964 )	(456 )	(1,420 )	(573 )	(720 )	(1,293 )
GROSS PROFIT	16,547	5,689	22,236	10,706	4,616	15,322
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	6,024	3,462	9,486	5,176	6,046	11,222
GENERAL AND ADMINISTRATIVE EXPENSES	6,569	4,510	11,079	6,080	4,391	10,471
SALES AND MARKETING EXPENSES	16,573	5,498	22,071	14,274	6,729	21,003
DEPRECIATION AND AMORTIZATION	2,015	67	2,082	1,819	45	1,864
OPERATING EXPENSES	31,181	13,537	44,718	27,349	17,211	44,560
NET LOSS FROM OPERATIONS	(14,634 )	(7,848 )	(22,482 )	(16,643 )	(12,595 )	(29,238 )
OTHER INCOME AND EXPENSES, NET			(4,682 )			9,461
NET LOSS BEFORE TAXES			\$ (27,164 )			\$ (19,777 )

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ALIMERA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

17. SUBSEQUENT EVENT

In October 2016, Limited and Hercules entered into the Fourth Loan Amendment (see Note 9 Loan Agreements). In connection with the Fourth Loan Amendment, the Company agreed to issue to Hercules the 2016 Warrant (see 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 September 30, 2016, over 430 patients have been enrolled.

Through September 30, 2016, over 430 patients have been enrolled.

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. In the third quarter of 2016 our Middle East distributor initiated named patient sales of ILUVIEN in the Middle East.

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of September 30, 2016, we have accumulated a deficit of \$371.1 million. We expect to continue to incur losses as we:

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

As of September 30, 2016, we had approximately \$33.9 million in cash and cash equivalents.

As a result of the limited revenue generated by ILUVIEN to date, our negative cash flow from operations and accumulated deficit raise substantial doubt about our ability to continue as a going concern. Our Interim Financial Statements do not include any adjustments that might result from the outcome of this uncertainty. We believe that we have sufficient funds to allow us to become cash flow positive in the countries in which we sell ILUVIEN. However, it is possible that we may determine that we may need to raise additional funds in the future in order to support our business in these countries, to expand ILUVIEN into new geographies, to allow us to expand the indication of ILUVIEN or other business development activities. We cannot be sure that 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.

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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 (the pSivida Agreement). The pSivida Agreement 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). The pSivida 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, the pSivida Agreement 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 pSivida Agreement provides that after commercialization of ILUVIEN, pSivida will be entitled to 20% of our net profits determined on a cash basis, in each country where we sell ILUVIEN directly or through our distributors or sub-distributors and 33% of any lump sum milestone payments received from a sub-licensee of ILUVIEN, as defined in the pSivida Agreement. In connection with this arrangement we are entitled to recover 20% of commercialization costs of ILUVIEN incurred prior to product profitability out of pSivida's share of net profits, as defined in the pSivida Agreement. As of September 30, 2016 and December 31, 2015, pSivida owed us \$25.2 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 pSivida Agreement. 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 nine months ended September 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 \$25.2 million to \$20.9 million at September 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 nine months ended September 30, 2016 would be immaterial.

### Our Loan Agreements

#### Hercules Loan Agreement

#### 2014 Loan Agreement

In April 2014, Alimera Sciences Limited (Limited), our subsidiary, entered into a loan and security agreement (2014 Loan Agreement) with Hercules Capital, Inc. (Hercules) providing for a term loan of up to \$35.0 million (2014 Term Loan), which Limited and Hercules amended in November 2015 (the First Loan Amendment), March 2016 (the Second Loan Amendment), May 2016 (the Third Loan Amendment) and October 2016 (the Fourth Loan Amendment) and, together with the 2014 Loan Agreement, the First Loan Amendment, the Second Loan Amendment and Third Loan Amendment, 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. Interest on the 2014 Term Loan accrued 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 September 30, 2016.

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### First Loan Amendment

In November 2015, Limited and Hercules amended the 2014 Loan Agreement to extend the interest only payments through May 2017. In connection with the First 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 (End of Term Payment).

We and Limited, on a consolidated basis with our other subsidiaries (the Consolidated Group), 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 First Loan Amendment, Limited agreed to covenants regarding certain revenue thresholds and a liquidity threshold.

### Second Loan Amendment

In January 2016, the revenue threshold covenant was not met by the Consolidated Group and as a result, in March 2016, Limited entered into the Second Loan Amendment, which further amended certain terms of the Term Loan Agreement. In conjunction with the Second Loan Amendment, Hercules waived this covenant violation.

The Second Loan Amendment adjusted the revenue covenant to a rolling three-month calculation, first measured for the three months ended May 31, 2016. In addition, the Second Loan Amendment increased the liquidity covenant. Upon execution of the Second 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 was payable on the date that the 2014 Term Loan was to be paid in full.

We concluded that the Second Loan Amendment resulted in a substantial modification of the terms of debt when considered with the First Loan Amendment in accordance with the guidance in ASC 470-50, Debt. As a result, we accounted for the Second Loan Amendment as an extinguishment and recognized a loss on early extinguishment of debt of approximately \$2.6 million within the consolidated statement of operations for the nine months ended September 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 Second Loan Amendment, the incremental fair value of the warrant as a result of modifying the terms of the warrant and the debt issuance costs of \$360,000 paid to Hercules for the Second Loan Amendment.

### Third Loan Amendment and July 2016 Waiver

In May 2016, Limited and Hercules entered into the Third Loan Amendment to expand the definition of liquidity to allow for the inclusion of cash of up to \$2.0 million in bank accounts outside of the U.S. and the United Kingdom.

In July 2016, Limited obtained a waiver of the requirements of the liquidity covenant (the Waiver) because the Consolidated Group was not in compliance with the liquidity covenant as of June 30, 2016. The Waiver cured the default of the liquidity covenant then existing under the Term Loan Agreement and decreased the liquidity requirement. 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 incurred a weekly ticking fee equal to 0.05% multiplied by the outstanding principal amount through the closing of our public offering in August 2016, totaling \$65,000. Further, Limited paid Hercules a fee of \$350,000 associated with the Waiver.

### Fourth Loan Amendment

In October 2016, Limited entered into the Fourth Loan Amendment to with Hercules, which further amended certain terms of the Amended Loan Agreement. Pursuant to the terms of the Fourth Loan Amendment, Hercules agreed to provide up to an additional \$10.0 million to Limited with (i) the first \$5.0 million available at Limited's option through June 30, 2017 subject to (A) the achievement of \$12.0 million in trailing three month net product revenue and (B) no event of default having occurred since October 20, 2016 (the Effective Date) and (ii) the second \$5.0 million available at Limited's option through December 31, 2017 subject to (A) the achievement of \$15.0 million in trailing three month net product revenue, (B) no event of default having occurred since the Effective Date and (C) the prior \$5.0 million having been advanced to Limited (the Additional Advances and, together with the 2014 Term Loan, the Term Loan). The Fourth Loan Amendment provides for interest only payments through November 30, 2018 (the Interest-Only

Period). Pursuant to the Fourth Loan Amendment, interest on the Term Loan accrues at a floating per annum rate equal the greater of (i) 11.0% and (ii) the sum of (A) 11.0% plus (B) the prime rate as reported in The Wall Street Journal, or if not reported, the prime rate most recently reported in The Wall Street Journal, minus 3.5%. In addition to the interest described above, the principal balance of the Term Loan will bear “payment-in kind” interest at the rate of 1.0% (PIK Interest), which PIK Interest will be added to the outstanding principal balance of the Term Loan so as to increase the outstanding principal balance of the Term Loan on each payment date for the Term Loan and which amount will be payable when the aggregate outstanding principal amount of the Term Loan is payable.

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The Term Loan will be due and payable to Hercules in 24 equal monthly payments of principal and interest following the Interest-Only Period beginning on December 1, 2018 and matures in full on November 1, 2020.

Limited paid to Hercules a facility charge of \$337,500 and reimbursed Hercules for legal and diligence fees incurred of approximately \$4,000 in connection with the Fourth Loan Amendment. If Limited prepays the Term Loan, it will pay Hercules a prepayment penalty (i) if such amounts are prepaid in any of the first 12 months following the Effective Date, equal to 3.0% of the principal amount of the Term Loan being repaid, (ii) if such amounts are prepaid after 12 months but prior to 24 months following the Effective Date, equal to 2.0% of the principal amount of the Term Loan being repaid, and (iii) if such amounts are prepaid at any time thereafter, equal to 1.0% of the principal amount of the Term Loan being repaid.

The Consolidated Group also agreed to customary affirmative and negative covenants, including, without limitation, covenants relating to minimum liquidity, minimum trailing six-month net revenue and adjusted EBITDA 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, as amended by the Fourth Loan Amendment. In the event that we maintain \$35.0 million in liquidity, including cash and eligible accounts receivable, at the end of the month and has not been and is not in breach of the amended debt facility, the six-month trailing revenue covenant is effectively waived for such month.

General Discussion of the Term Loan Agreement

Pursuant to 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 our subsidiaries 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, we and our 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 our ability to declare or pay any dividend or distribution on any shares of our capital stock.

2014 Warrant

In connection with Limited entering into the 2014 Loan Agreement, we issued a warrant to Hercules to purchase up to 285,016 shares of our common stock at an exercise price of \$6.14 per share (the 2014 Warrant). Sixty percent of the 2014 Warrant was exercisable at the closing in April 2014 and the remaining forty percent became exercisable upon the funding of the additional \$25.0 million to Limited in September 2014.

We agreed to amend the 2014 Warrant in connection with the First Loan Amendment to increase the number of shares issuable upon exercise to 660,377 and decrease the exercise price to \$2.65 per share. Upon entering into the Second Loan Amendment, we agreed to further amend the 2014 Warrant 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 further amend the 2014 Warrant to increase the number of shares issuable upon exercise to 1,258,993 and decrease the exercise price to \$1.39 per share.

2016 Warrant

In connection with Limited entering into the Fourth Loan Amendment, we agreed to issue a new warrant to Hercules (the 2016 Warrant) to purchase up to the amount of shares of our common stock equal to \$500,000 divided by the lowest volume-weighted average sale price for a share of our common stock reported over any ten consecutive trading days during the period commencing on and including September 23, 2016 and ending on the earlier to occur of (i) December 30, 2016 (inclusive of such date), and (ii) the second trading day immediately preceding the date of closing of a Merger Event (as defined in the 2016 Warrant).

Fair Value of Debt

The weighted average interest rates of our notes payable approximate the rate at which we could obtain alternative financing; therefore, the carrying amount of the notes approximated their fair value at September 30, 2016 and December 31, 2015.





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## Financial Operations Overview

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
	2016	2015	2016	2015
	(In thousands)			
NET REVENUE	\$8,298	\$6,901	\$23,656	\$16,615
GROSS PROFIT	7,812	6,267	22,236	15,322
OPERATING EXPENSES	15,055	14,711	44,718	44,560
NET LOSS FROM OPERATIONS	(7,243 )	(8,444 )	(22,482 )	(29,238 )
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	(9,245 )	(1,543 )	(27,248 )	(19,932 )

## Revenue

We began generating revenue from ILUVIEN in the second quarter of 2013. In addition to generating revenue from product sales, we may seek to generate revenue from other sources such as upfront fees, milestone payments in connection with collaborative or strategic relationships and royalties resulting from the licensing of ILUVIEN or any future product candidates and other intellectual property. We expect the revenue we generate in countries where we are commercialized will continue to fluctuate from quarter to quarter based on seasonality and the timing of orders from our customers. Specifically, in the U.S., our revenue could fluctuate quarter over quarter, based on our distributors' ordering patterns which may not correspond directly with their customers' ordering patterns. 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 \$1.4 million, or 20%, to approximately \$8.3 million for the three months ended September 30, 2016 compared to approximately \$6.9 million for the three months ended September 30, 2015 and by approximately \$7.1 million, or 43%, to approximately \$23.7 million for the nine months ended September 30, 2016 compared to approximately \$16.6 million for the nine months ended September 30, 2015. The increases in both the three and nine months ended September 30, 2016 were primarily a result of increased U.S. sales.

## Operating Expenses

Operating expenses increased by approximately \$400,000, or 3%, to approximately \$15.1 million for the three months ended September 30, 2016 compared to approximately \$14.7 million for the three months ended September 30, 2015 primarily as a result of increases in sales and marketing expenses of \$500,000 and general and administrative expenses of \$610,000, offset by a decrease of \$820,000 in research, development and medical affairs expenses.

Operating expenses increased by approximately \$100,000, or less than 1%, to approximately \$44.7 million for the nine months ended September 30, 2016 compared to approximately \$44.6 million for the nine months ended September 30, 2015 primarily as a result of increases in sales and marketing expenses of \$1.1 million and general and administrative expenses of \$610,000, offset by a decrease of \$1.7 million in research, development and medical affairs expenses.

## 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 scientific advisory boards and symposia development for physician education;  
costs related to compliance with FDA, EU 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;  
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 for the foreseeable future will be incurred in support of educating physicians on the clinical benefits of ILUVIEN.

**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.

In Europe we have commercial personnel in France, Germany, Portugal and the United Kingdom consisting of approximately 28 persons as of September 30, 2016, of which five are consultants. As of September 30, 2016, we had a U.S. field force of approximately 47 persons, including sales personnel, reimbursement specialists and payor relations directors.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our unaudited interim condensed consolidated financial statements and notes (Interim Financial Statements) which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these Interim Financial Statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. We discuss our critical accounting policies in the Management's Discussion and Analysis section of 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)			
NET REVENUE	\$6,184	\$5,032	\$17,511	\$11,279
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(374 )	(245 )	(964 )	(573 )
GROSS PROFIT	5,810	4,787	16,547	10,706
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	2,204	2,320	6,024	5,176
GENERAL AND ADMINISTRATIVE EXPENSES	2,232	1,712	6,569	6,080
SALES AND MARKETING EXPENSES	5,618	4,546	16,573	14,274
DEPRECIATION AND AMORTIZATION	674	639	2,015	1,819
OPERATING EXPENSES	10,728	9,217	31,181	27,349
NET LOSS FROM OPERATIONS	\$(4,918)	\$(4,430)	\$(14,634)	\$(16,643)

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

Net Revenue. Net revenue increased by approximately \$1.2 million, or 24%, to approximately \$6.2 million for the three months ended September 30, 2016 compared to approximately \$5.0 million for the three months ended September 30, 2015. The increase was primarily attributable to an increase in sales volume as ILUVIEN continued to gain 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 \$120,000, or 48%, to approximately \$370,000 for the three months ended September 30, 2016 compared to approximately \$250,000 for the three months ended September 30, 2015 as a result of our increase in sales volume and minor increases in supplier costs.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately \$100,000, or 4%, to approximately \$2.2 million for the three months ended September 30, 2016 compared to approximately \$2.3 million for the three months ended September 30, 2015. The decrease was primarily attributable to decreases of \$680,000 in costs incurred with third parties related to potential product enhancements incurred in the third quarter of 2015 and \$290,000 for costs associated with maintaining the registration of ILUVIEN in the U.S., offset by an increase of \$730,000 in allocated costs associated with global research and development.

General and administrative expenses. General and administrative expenses increased by approximately \$500,000, or 29%, to approximately \$2.2 million for the three months ended September 30, 2016 compared to approximately \$1.7 million for the three months ended September 30, 2015. The increase was primarily attributable to an increase of \$360,000 for certain professional fees associated with pursuing alternative debt options.

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Sales and marketing expenses. Sales and marketing expenses increased by approximately \$1.1 million, or 24%, to approximately \$5.6 million for the three months ended September 30, 2016 compared to approximately \$4.5 million for the three months ended September 30, 2015. The increase was primarily attributable to an increase of \$940,000 in marketing costs including professional fees for the promotion of ILUVIEN, medical communications and an increased presence at certain regional and national meetings.

Depreciation and amortization. Depreciation and amortization increased by approximately \$30,000, or 5%, to approximately \$670,000 for the three months ended September 30, 2015 compared to approximately \$640,000 for the three months ended September 30, 2015.

Nine months ended September 30, 2016 compared to the nine months ended September 30, 2015

Net Revenue. Net revenue increased by approximately \$6.2 million, or 55%, to approximately \$17.5 million for the nine months ended September 30, 2016 compared to approximately \$11.3 million for the nine months ended September 30, 2015. The increase was primarily attributable to an increase in sales volume as ILUVIEN continued to gain 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 \$390,000, or 68%, to approximately \$960,000 for the nine months ended September 30, 2016 compared to approximately \$570,000 for the nine months ended September 30, 2015 as a result of our increase in sales volume and minor increases in supplier costs.

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by approximately \$800,000, or 15%, to approximately \$6.0 million for the nine months ended September 30, 2016 compared to approximately \$5.2 million for the nine months ended September 30, 2015. The increase was primarily attributable to an increase of \$2.1 million in allocated costs associated with global research and development. These costs are allocated based upon our future expected revenues from our segments. These costs were offset by a decrease of \$1.0 million in costs with third parties related to potential product enhancements incurred during 2015.

General and administrative expenses. General and administrative expenses increased by approximately \$500,000, or 8%, to approximately \$6.6 million for the nine months ended September 30, 2016 compared to approximately \$6.1 million for the nine months ended September 30, 2015. The increase was primarily attributable to an increase of \$360,000 for certain professional fees associated with pursuing alternative debt options.

Sales and marketing expenses. Sales and marketing expenses increased by approximately \$2.3 million, or 16%, to approximately \$16.6 million for the nine months ended September 30, 2016 compared to approximately \$14.3 million for the nine months ended September 30, 2015. The increase was primarily attributable to an increase of \$990,000 in costs for the commercial team hired for the launch of ILUVIEN in the U.S. in the first quarter of 2015, an increase of \$590,000 for commissions paid to our U.S. sales force due to increased sales, and an increase of \$450,000 in marketing costs including professional fees for the promotion of ILUVIEN, medical communications and an increased presence at certain regional and national meetings.

Depreciation and amortization. Depreciation and amortization increased by approximately \$200,000, or 11%, to approximately \$2.0 million for the nine months ended September 30, 2016 compared to approximately \$1.8 million for the nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)			
NET REVENUE	\$2,114	\$1,869	\$6,145	\$5,336
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(112 )	(389 )	(456 )	(720 )
GROSS PROFIT	2,002	1,480	5,689	4,616
RESEARCH, DEVELOPMENT AND MEDICAL AFFAIRS EXPENSES	1,057	1,758	3,462	6,046
GENERAL AND ADMINISTRATIVE EXPENSES	1,413	1,319	4,510	4,391
SALES AND MARKETING EXPENSES	1,834	2,403	5,498	6,729
DEPRECIATION AND AMORTIZATION	23	14	67	45
OPERATING EXPENSES	4,327	5,494	13,537	17,211
NET LOSS FROM OPERATIONS	\$(2,325)	\$(4,014)	\$(7,848)	\$(12,595)

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

Net Revenue. Net revenue increased by approximately \$200,000, or 11%, to approximately \$2.1 million for the three months ended September 30, 2016 compared to approximately \$1.9 million for the three months ended September 30, 2015. The increase was primarily attributable to 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 \$80,000 for the three months ended September 30, 2016 compared to the three months ended September 30, 2015.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization decreased by approximately \$280,000, or 72%, to approximately \$110,000 for the three months ended September 30, 2016 compared to approximately \$390,000 for the three months ended September 30, 2015. The decrease was primarily attributable to a decrease of \$260,000 in charges for expiring inventory recorded in the third quarter of 2015, offset by the increase in sales volume and minor increases in supplier costs.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately \$700,000, or 39%, to approximately \$1.1 million for the three months ended September 30, 2016 compared to approximately \$1.8 million for the three months ended September 30, 2015. The decrease was primarily attributable to a reduction of \$730,000 in allocated research and development expenses associated with global research and development in the third quarter of 2016 as compared to 2015, as these costs are allocated based upon our future expected revenues from our segments. There was also a decrease of \$110,000 in consulting costs as we hired an in-house head of drug safety in the second quarter of 2016.

General and administrative expenses. General and administrative expenses increased by approximately \$100,000, or 8%, to approximately \$1.4 million for the three months ended September 30, 2016 compared to \$1.3 million for the three months ended September 30, 2015.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately \$600,000, or 25%, to approximately \$1.8 million for the three months ended September 30, 2016 compared to approximately \$2.4 million for the three months ended September 30, 2015. The decrease was primarily attributable to a decrease of \$570,000 in marketing costs including reductions of \$170,000 in medical communications, \$160,000 in public relation costs and \$110,000 in trade show costs.

Nine months ended September 30, 2016 compared to the nine months ended September 30, 2015

Net Revenue. Net revenue increased by approximately \$800,000, or 15%, to approximately \$6.1 million for the nine months ended September 30, 2016 compared to approximately \$5.3 million for the nine months ended September 30, 2015. The increase was primarily attributable to 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

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reduced reported revenue by \$170,000 for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization decreased by approximately \$260,000, or 36%, to approximately \$460,000 for the nine months ended September 30, 2016 compared to approximately \$720,000 for the nine months ended September 30, 2015. The decrease was primarily attributable to a decrease of \$320,000 in charges for expiring inventory recorded in the second and third quarters of 2015, offset by increased sales volume and minor increases in supplier costs.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by approximately \$2.5 million, or 42%, to approximately \$3.5 million for the nine months ended September 30, 2016 compared to approximately \$6.0 million for the nine months ended September 30, 2015. The decrease was primarily attributable to a reduction of \$2.1 million in allocated research and development expenses associated with global research and development in 2016 as compared to 2015, as 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 2%, to approximately \$4.5 million for the nine months ended September 30, 2016 compared to approximately \$4.4 million for the nine months ended September 30, 2015.

Sales and marketing expenses. Sales and marketing expenses decreased by approximately \$1.2 million, or 18%, to approximately \$5.5 million for the nine months ended September 30, 2016 compared to approximately \$6.7 million for the nine months ended September 30, 2015. The decrease was primarily attributable to a decrease of \$1.4 million in marketing costs including reductions of \$800,000 in trade show costs, \$280,000 in medical communications and \$190,000 in market research costs.

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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 September 30, 2016		Nine Months Ended September 30, 2015	
	2016	2015	2016	2015
NET LOSS FROM OPERATIONS	\$(7,243)	\$(8,444)	\$(22,482)	\$(29,238)
INTEREST EXPENSE, NET AND OTHER	(1,330 )	(1,317 )	(3,842 )	(3,590 )
UNREALIZED FOREIGN CURRENCY LOSS, NET	(51 )	(63 )	(31 )	(34 )
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	(588 )	8,363	1,755	13,085
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	—	(2,564 )	—
NET LOSS BEFORE TAXES	(9,212 )	(1,461 )	(27,164 )	(19,777 )
PROVISION FOR TAXES	(33 )	(82 )	(84 )	(155 )
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	\$(9,245)	\$(1,543)	\$(27,248)	\$(19,932)

Interest expense, net and other.

Interest expense, net and other was approximately \$1.3 million for the three months ended September 30, 2016 and 2015.

Interest expense, net and other increased by approximately \$200,000, or 6%, to approximately \$3.8 million for the nine months ended September 30, 2016 compared to approximately \$3.6 million for the nine months ended September 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, net.

We recorded a non-cash unrealized foreign currency loss of approximately \$50,000 for the three months ended September 30, 2016 compared to a loss of approximately \$60,000 for the three months ended September 30, 2015. We recorded a non-cash unrealized foreign currency gain of approximately \$30,000 for each of the nine months ended September 30, 2016 and 2015, respectively.

Change in fair value of derivative warrant liability.

An increase in the fair value of our derivative warrant liability resulted in a non-cash loss of approximately \$590,000 for the three months ended September 30, 2016. A decrease in the fair value of our derivative warrant liability resulted in a non-cash gain of approximately \$8.4 million for the three months ended September 30, 2015. The changes in fair value were primarily attributable to changes in the fair market value of our underlying common stock during both the three-month periods ended September 30, 2016 and 2015.

A decrease in the fair value of our derivative warrant liability resulted in a non-cash gains of approximately \$1.8 million and \$13.1 million for the nine months ended September 30, 2016 and 2015, respectively. The changes in fair value were primarily attributable to decreases in the fair market value of our underlying common stock during both the nine-month periods ended September 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 nine months ended September 30, 2016, as a result of the Third 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 \$371.1 million from our inception through September 30, 2016.

As of September 30, 2016, we had approximately \$33.9 million in cash and cash equivalents.

In October 2016, Limited entered into the Fourth Loan Amendment. Under the Fourth Loan Amendment, Hercules agreed to provide up to an additional \$10.0 million to Limited with (i) the first \$5.0 million available at Limited's option through June 30, 2017 subject to (A) the achievement of \$12.0 million in trailing three month net product revenue and (B) no event of default having occurred since the Effective Date and (ii) the second \$5.0 million available at Limited's option through December 31, 2017 subject to (A) the achievement of \$15.0 million in trailing three month net product revenue, (B) no event of default having occurred since the Effective Date and (C) the prior \$5.0 million having been advanced to Limited.

The Term Loan Agreement requires that we maintain at least \$25.0 million in liquid assets, with a minimum of \$12.5 million in cash. Additionally, in any month in which we have \$35.0 million in liquidity, including cash and eligible accounts receivable, the revenue requirement will be waived.

As a result of the limited revenue generated by ILUVIEN to date, our negative cash flow from operations and accumulated deficit raise substantial doubt about our ability to continue as a going concern. Our Interim Financial Statements do not include any adjustments that might result from the outcome of this uncertainty. We believe that we have sufficient funds to allow us to become cash flow positive in the countries in which we sell ILUVIEN. However, it is possible that we may determine that we need to raise additional funds in order to support our business in these countries, to expand ILUVIEN into new geographies, to allow us to expand the indication of ILUVIEN or other business development activities.

We cannot be sure that additional financing would be available when needed or that, if available, the additional financing would be obtained on terms favorable to us or our stockholders. If we were to 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 were to attempt to raise additional funds through strategic collaboration agreements and debt financing, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize ILUVIEN or any future products or product candidates or operate our business.

For the nine months ended September 30, 2016, cash used by our operations of \$22.7 million was primarily due to our net loss of \$27.2 million, increased by a non-cash gain of \$1.8 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, \$3.8 million of stock-based compensation expense, \$2.1 million for depreciation and amortization and \$800,000 for non-cash interest expense associated with our debt discount. Cash used in operations was also decreased by a decrease in inventory of approximately \$600,000 and an increase in accounts payable, accrued expenses and other current liabilities and other non-current liabilities of approximately \$510,000. Cash used by operations were offset by increases in accounts receivable of approximately \$3.6 million and in prepaid and other current assets of approximately \$510,000.

For the nine months ended September 30, 2015, cash used by our operations of \$36.5 million was primarily due to our net loss of \$19.9 million, \$8.5 million increase in accounts receivable and \$2.3 million decrease in accounts payable, accrued expenses and other current liabilities, offset by a decrease in prepaid expenses and other current assets of \$630,000, an increase in other non-current liabilities of \$610,000 and by the impact of non-cash items on our net operating loss. Accounts receivable increased primarily due to the U.S. launch of ILUVIEN during the first quarter of 2015. Accounts payable and accrued expenses and other current liabilities decreased primarily due to the milestone payment of \$2.0 million to a consultant that was engaged to assist with the pursuit of approval of ILUVIEN in the U.S. and a decrease of \$1.2 million in amounts payable to Quintiles Commercial offset by increases of \$1.5 million in accrued payroll and related costs including bonuses. Prepaid expenses and other current assets decreased by approximately \$700,000 associated with the termination of the Quintiles Commercial project orders. Other non-current liabilities increased primarily due to receipt of \$500,000 upon the execution of a distribution agreement,

which is deferred over the service period. Non-cash items included a gain of \$13.1 million for the change in our derivative warrant liability offset by \$3.7 million of stock-based compensation expense, \$1.9 million for depreciation and amortization and \$520,000 for non-cash interest expense associated with deferred financing costs and our debt discount.

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

For the nine months ended September 30, 2016, net cash provided by our financing activities was approximately \$25.6 million. In August 2016, we closed an underwritten public offering pursuant to which we sold and issued 18,900,000 shares of our common stock at a price to the public of \$1.40 per share, resulting in gross proceeds of \$26,460,000. Offsetting this increase were payments of approximately \$1.2 million in payments of the issuance costs of common stock, \$720,000 associated with the amendments of our Term Loan Agreement and \$180,000 in payments on capital leases.

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

**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 does not expect the potential impact of adopting this guidance to have a material impact 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 does not expect the potential impact of adopting this guidance to have a material impact on our financial statements.

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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.

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 does not expect the potential impact of adopting this guidance to have a material impact 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 \$270,000 increase in interest expense for the three months ended September 30, 2016 and nine months ended September 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 nine months ended September 30, 2016 and 2015, we did not recognize any charges for write-offs of accounts receivable. As of September 30, 2016 and December 31, 2015, two U.S. distributors accounted for 89% and 88%, respectively, 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 September 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 September 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 September 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."

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).
4.15	Third Amendment to Warrant Agreement dated July 21, 2016 by and among the Registrant and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc.
4.16	Warrant Agreement dated October 20, 2016 by and among the Registrant and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc.
10.44	Waiver by Hercules Capital, Inc. of Certain Defaults under Loan and Security Agreement dated July 21, 2016.
10.45	Fourth Amendment to Loan and Security Agreement dated October 20, 2016 by and among Alimera Sciences Limited, Hercules Capital Funding Trust and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc.
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	XBRL Instance Document.
101.SCH+	XBRL Taxonomy Extension Schema Document.
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	XBRL Taxonomy Extension Label Link Document.

101.PRE+ XBRL Taxonomy Extension Presentation Linkbase Document.

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

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

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Signatures

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

ALIMERA SCIENCES, INC.

November 4, 2016 By: /s/ C. Daniel Myers

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

November 4, 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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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).
4.15	Third Amendment to Warrant Agreement dated July 21, 2016 by and among the Registrant and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc.
4.16	Warrant Agreement dated October 20, 2016 by and among the Registrant and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc.
10.44	Waiver by Hercules Capital, Inc. of Certain Defaults under Loan and Security Agreement dated July 21, 2016.
10.45	Fourth Amendment to Loan and Security Agreement dated October 20, 2016 by and among Alimera Sciences Limited, Hercules Capital Funding Trust and Hercules Capital, Inc. f/k/a Hercules Technology Growth Capital, Inc.
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	XBRL Instance Document.
101.SCH+	XBRL Taxonomy Extension Schema Document.
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	XBRL Taxonomy Extension Label Link Document.

101.PRE+ XBRL Taxonomy Extension Presentation Linkbase Document.

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

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

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