ALIMERA SCIENCES INC
Form 10-Q
November 14, 2014
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q
(Mark One)

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

For the quarterly period ended September 30, 2014
or

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x
As of November 12, 2014 there were 44,296,136 shares of the registrant's Common Stock issued and outstanding.

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

	September 30, 2014	December 31, 2013
	(In thousands, except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$61,424	$12,628
Accounts receivable, net	1,097	500
Prepaid expenses and other current assets	2,245	3,474
Inventory, net (Note 5)	1,654	1,786
Deferred financing costs	878	250
Total current assets	67,298	18,638
PROPERTY AND EQUIPMENT, net	1,042	982
INTANGIBLE ASSET, net (Note 6)	24,951	—
TOTAL ASSETS	$93,291	$19,620
CURRENT LIABILITIES:		
Accounts payable	$2,855	$1,735
Accrued expenses (Note 7)	1,572	934
Accrued milestone payments	27,000	—
Outsourced services payable	549	603
Note payable (Note 9)	—	1,667
Capital lease obligations	10	10
Total current liabilities	31,986	4,949
NON-CURRENT LIABILITIES:		
Derivative warrant liability	19,133	16,381
Note payable, net of discount — less current portion (Note 9)	33,938	3,194
Other non-current liabilities	11	21
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock, $.01 par value — 10,000,000 shares authorized at September 30, 2014 and December 31, 2013:		
Series A convertible preferred stock, 1,300,000 authorized and 600,000 issued and outstanding at September 30, 2014 and 1,000,000 issued and outstanding at December 31, 2013; liquidation preference of $24,000 at September 30, 2014 and $40,000 at December 31, 2013	19,227	32,045
Common stock, $.01 par value — 100,000,000 shares authorized, 44,272,208 shares issued and outstanding at September 30, 2014 and 31,610,991 shares issued and outstanding at December 31, 2013	443	316
Additional paid-in capital	291,716	240,135
Common stock warrants	1,497	412
Accumulated deficit	(303,997)	(277,345)
Accumulated other comprehensive loss	(663)	(488)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	8,223	(4,925)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$93,291	$19,620

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, 2014 AND 2013

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands, except share and per share data)			
NET REVENUE	$2,408	$758	$6,682	$937
COST OF GOODS SOLD, EXCLUDING DEPRECIATION AND AMORTIZATION	(372)	(57)	(1,312)	(68)
GROSS MARGIN	2,036	701	5,370	869
RESEARCH AND DEVELOPMENT EXPENSES	3,941	1,780	8,376	5,983
GENERAL AND ADMINISTRATIVE EXPENSES	2,958	2,071	8,643	7,151
SALES AND MARKETING EXPENSES	3,680	4,524	10,227	12,985
DEPRECIATION AND AMORTIZATION	82	42	151	101
OPERATING EXPENSES	10,661	8,417	27,397	26,220
INTEREST EXPENSE, NET AND OTHER	(408)	(134)	(862)	(397)
UNREALIZED FOREIGN CURRENCY (LOSS) GAIN, NET	(255)	508	(457)	552
CHANGE IN FAIR VALUE OF DERIVATIVE WARRANT LIABILITY	2,324	6,229	(2,752)	(6,107)
LOSS ON EARLY EXTINGUISHMENT OF DEBT	—	—	(440)	(153)
NET LOSS BEFORE TAXES	(6,964)	(1,113)	(26,538)	(31,456)
PROVISION FOR TAXES	(45)	—	(114)	—
NET LOSS	$(7,009)	$(1,113)	$(26,652)	$(31,456)
ACCRETION OF PREFERRED STOCK BENEFICIAL CONVERSION FEATURE	—	—	—	(4,950)
NET LOSS APPLICABLE TO COMMON STOCKHOLDERS	$(7,009)	$(1,113)	$(26,652)	$(36,406)
NET LOSS PER SHARE APPLICABLE TO COMMON STOCKHOLDERS — Basic and diluted	$(0.17)	$(0.04)	$(0.68)	$(1.15)
WEIGHTED AVERAGE SHARES OUTSTANDING — Basic and diluted	41,062,814	31,591,289	39,083,187	31,570,739

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, 2014 AND 2013

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands)			
NET LOSS	$(7,009)	$(1,113)	$(26,652)	$(31,456)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	(197)	(270)	(175)	(225)
TOTAL OTHER COMPREHENSIVE INCOME (LOSS)	(197)	(270)	(175)	(225)
COMPREHENSIVE LOSS	$(7,206)	$(1,383)	$(26,827)	$(31,681)

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, 2014 AND 2013

	Nine Months Ended September 30,	
	2014	2013
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(26,652)	$(31,456)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss from early extinguishment of debt	440	153
Depreciation and amortization	151	101
Unrealized foreign currency transaction loss (gain)	457	(552)
Amortization of deferred financing costs and debt discount	261	118
Stock-based compensation expense	2,833	1,597
Change in fair value of derivative warrant liability	2,752	6,107
Changes in assets and liabilities:		
Accounts receivable	(679)	(451)
Prepaid expenses and other current assets	1,307	(1,130)
Inventory	(9)	(2,227)
Accounts payable	1,341	717
Accrued expenses and other current liabilities	2,649	(866)
Other long-term liabilities	(2)	(204)
Net cash used in operating activities	(15,151)	(28,093)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(163)	(386)
Net cash used in investing activities	(163)	(386)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	709	59
Proceeds from sale of common stock	37,543	33
Payment of issuance cost of common stock	(2,389)	—
Payment of principal on notes payable	(4,861)	(3,030)
Payment of debt extinguishment costs	(246)	—
Proceeds from issuance of notes payable	35,000	5,000
Payment of debt costs	(1,016)	(292)
Payment of capital lease obligations	(7)	(9)
Net cash provided by financing activities	64,733	1,761
EFFECT OF EXCHANGE RATES ON CASH AND CASH EQUIVALENTS	(623)	258
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	48,796	(26,460)
CASH AND CASH EQUIVALENTS — Beginning of period	12,628	49,564
CASH AND CASH EQUIVALENTS — End of period	$61,424	$23,104
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$502	$511
Supplemental schedule of non-cash investing and financing activities:		
Property and equipment under capital leases	$—	$33
Intangible assets in accrued milestone payments	$25,000	$—

There were no income tax or dividend payments made during the nine months ended September 30, 2014 and 2013.

See Notes to Consolidated Financial Statements.

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ALIMERA SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS

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

The Company is presently focused on diseases affecting the back of the eye, or retina, because the Company's management believes these diseases are inadequately treated with current therapies and represent a significant market opportunity. The Company's only commercially approved product is ILUVIEN®, which has been developed to treat diabetic macular edema (DME). DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN has received marketing authorization in the United States (U.S.), United Kingdom, Austria, Portugal, France, Germany, Spain, Italy, Norway, Denmark, Sweden and Belgium, and has been recommended for marketing authorization in six additional European Union (EU) countries. 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 EU countries in which ILUVIEN has received marketing authorization, it is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. As part of the approval process in the EU, the Company has committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients.

In September 2013, the Company submitted an application to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, as the Reference Member State, for ten additional EU country approvals through the Mutual Recognition Procedure (MRP). In June 2014, the Company received a positive outcome from the Repeat-Use Procedure for ILUVIEN in these ten countries. In the second, third and fourth quarters of 2014, the Company received marketing authorizations resulting from the MRP in Norway, Denmark, Sweden and Belgium. The regulatory process in Ireland, the Netherlands, Luxembourg, Finland, Poland and the Czech Republic is in the national phase in which each country grants marketing authorization.

In September 2014, the Company received notification from the U.S. Food and Drug Administration (FDA) that the New Drug Application (NDA) for ILUVIEN was approved 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 IOP.

The Company launched ILUVIEN in the United Kingdom and Germany in the second quarter of 2013 and currently plans to launch ILUVIEN in Portugal in late 2014 and the U.S. in early 2015. The Company was able to launch in Germany without price restrictions, but continues to work with the statutory health insurance funds in Germany to streamline reimbursement for ILUVIEN.

In October 2013, the United Kingdom's National Institute for Health and Care Excellence (NICE) issued a positive Final Appraisal Determination recommending ILUVIEN funding, taking into consideration a simple patient access scheme (PAS) for the treatment of pseudophakic eyes (eyes with an artificial lens) in chronic DME patients considered insufficiently responsive to available therapies. The Company began receiving orders for ILUVIEN from several NHS facilities in January 2014 following the final technology appraisal guidance that was published in November 2013. Further, in February 2014, the Scottish Medicines Consortium, after completing its assessment and review of a similar simple PAS, announced that is has accepted ILUVIEN for restricted use within the NHS Scotland.

In July 2013, the Transparency Commission (Commission de la Transparence or CT) of the French National Health Authority (Haute Autorite de Sante) issued a favorable opinion for the reimbursement and hospital listing of ILUVIEN for the treatment of chronic DME considered insufficiently responsive to available therapies. In the opinion, ILUVIEN was deemed as providing a "moderate medical benefit" as defined by the Service Medical Rendu. The Company continues to negotiate with the French authorities, but has not yet reached an agreement on price. If the Company and the French authorities agree on a price for ILUVIEN, patients will be reimbursed for 100% of the cost of ILUVIEN under the Affection de Longue Duree, a specific program for severe chronic diseases such as diabetes. When comparing the clinical benefit of ILUVIEN to existing therapies, the CT rated the product at "level IV"

(Amelioration du Service Medical Rendu or ASMR) which will be used in considering the price and any reimbursement conditions for ILUVIEN in France.

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

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

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

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

Reclassifications

Within the Operating expenses section of the unaudited Consolidated Statements of Operations for the three and nine months ended September 30, 2013, we reclassified depreciation expense of $42,000 and $101,000, respectively, from General and administrative expenses to Depreciation and amortization to conform to the current year presentation.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accounting policies followed for quarterly financial reporting are the same as those disclosed in the Notes to Financial Statements included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2013.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (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 will be effective for the first interim period within annual reporting periods beginning after December 15, 2016 for public entities, with no early adoption permitted. The Company is still evaluating the potential impact of adopting this guidance on its financial statements.

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

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

2016. Early adoption is permitted. The Company is still evaluating the potential impact of adopting this guidance on its financial statements.

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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 $303,997,000 from the Company’s inception through September 30, 2014. As of September 30, 2014, the Company had approximately $61,424,000 in cash and cash equivalents.

The Company believes that it has sufficient funds available to fund its operations for the continued commercialization of ILUVIEN in Germany and the United Kingdom, and the projected launch of ILUVIEN in Portugal and the U.S. The Company will seek to raise additional financing to fund its working capital needs associated with the commercialization of ILUVIEN in the U.S. If the Company is unable to raise additional financing, then it may adjust its commercial plans so that it can continue to operate with its existing cash resources.

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

5. INVENTORY

Inventory consisted of the following:

	September 30, 2014	December 31, 2013
	(In thousands)	
Component parts (1)	$195	$266
Work-in-process (2)	1,217	