

GEO GROUP INC
Form CT ORDER
June 16, 2015

estimates of taxable income in the jurisdictions in which we operate and the period over which deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact our financial position and results of operations. Our deferred tax assets primarily consist of net operating loss (NOL) carry-forwards. At March 31, 2013, we had federal NOL carry-forwards of approximately \$149.8 million and state NOL carry-forwards of approximately \$133.2 million, respectively, that are available to reduce future income otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2023 and 2032 and the state NOL carry-forwards will expire at various dates between 2020 and 2032. We periodically evaluate our NOL carry-forwards and whether certain changes in ownership have occurred that would limit our ability to utilize a portion of our NOL carry-forwards. If it is determined that significant ownership changes have occurred since these NOLs were generated, we may be subject to annual limitations on the use of these NOLs under Internal Revenue Code (IRC) Section 382 (or comparable provisions of state law). The issuance of the Series A Convertible Preferred Stock on October 2, 2012 constituted such a change in ownership. We are currently performing a formal analysis of our NOLs in connection with IRC Section 382 as a result of this change in ownership to determine the extent of the limitation of our NOL carry-forwards.

In the event that we were to determine that we are able to realize any of our net deferred tax assets in the future, an adjustment to the valuation allowance would increase net income in the period such determination was made. We believe that the most significant uncertainty that will impact the determination of our valuation allowance will be our estimation of the extent and timing of future net income, if any.

We considered our income tax positions for uncertainty in accordance with ASC 740. We believe our income tax filing positions and deductions are more likely than not of being sustained on audit and do not anticipate any adjustments that will result in a material change to our financial position; therefore, we have not recorded ASC 740 liabilities. We recognize accrued interest and penalties related to unrecognized tax benefits as interest expense and income tax expense, respectively, in our statements of operations. Our tax years since 2003 remain subject to examination in Georgia, Tennessee, and on the federal level. We do not anticipate any material changes to our uncertain tax positions within the next 12 months.

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Results of Operations

The following selected unaudited financial and operating data are derived from our financial statements and should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements.

	Three Months Ended		
	March 31,		
	2013	2012	
	(In thousands)		
Research and Development Expenses	\$ 2,023	\$ 1,581	
General and Administrative Expenses	2,670	1,434	
Sales and Marketing Expenses	3,563	1,113	
Operating Expenses	8,256	4,128	
Interest and Other Income	1	1	
Interest Expense	(135) (234)
Change in Fair Value of Derivative Warrant Liability	(5,594) —	
Net Loss	\$ (13,984) \$ (4,361)

Three months ended March 31, 2013 compared to the three months ended March 31, 2012

Research and development expenses. Research and development expenses increased by approximately \$400,000, or 25%, to approximately \$2.0 million for the three months ended March 31, 2013 compared to approximately \$1.6 million for the three months ended March 31, 2012. The increase was primarily attributable to increases of approximately \$260,000 in costs associated with contracting medical science liaisons to engage with retina specialists in the study of ILUVIEN in preparation for commercial launch of ILUVIEN in the EU and \$100,000 in costs associated with completing the establishment of manufacturing capabilities with our third party manufacturer for the ILUVIEN applicator.

General and administrative expenses. General and administrative expenses increased by approximately \$1.3 million or 93%, to approximately \$2.7 million for the three months ended March 31, 2013 compared to approximately \$1.4 million for the three months ended March 31, 2012. The increase was primarily attributable to increases of approximately \$480,000 in professional fees associated with the establishment of our infrastructure and tax planning for our expansion in Europe, and the registration of common stock underlying our Series A Convertible Preferred Stock issued in October 2012, \$180,000 associated with the hiring of a new managing director of Europe and executive director of finance in the first quarter of 2013 to support the EU launch of ILUVIEN, \$150,000 in stock compensation expense associated with executive and director stock options granted in the fourth quarter of 2012 and the first quarter of 2013 and \$140,000 associated with the hiring of a logistics manager in the third quarter of 2012 and the initial set up of our third party logistics provider in the first quarter of 2013.

Sales and Marketing expenses. Marketing expenses increased by approximately \$2.5 million or 227%, to approximately \$3.6 million for the three months ended March 31, 2013 compared to approximately \$1.1 million for the three months ended March 31, 2012. The increase was primarily attributable to increases of approximately \$1.2 million in costs associated with contracting with Quintiles Commercial for marketing, brand management, sales promotion and detailing, market access, pricing and reimbursement support, regulatory, and communications and/or other advisory services in the EU beginning in the fourth quarter of 2012, \$890,000 in advertising and promotion in preparation for the commercial launch of ILUVIEN in the EU, and \$210,000 associated with the hiring of new marketing and medical marketing directors of Europe in the fourth quarter of 2012 to support the EU launch of ILUVIEN.

Interest expense. Interest expense decreased by approximately \$90,000, or 39%, to approximately \$140,000 for the three months ended March 31, 2013 compared to approximately \$230,000 for the three months ended March 31, 2012. Interest expense for the three months ended March 31, 2013 and 2012 was incurred in connection with our Credit Facility with Silicon Valley Bank and MidCap Financial LLP. The decrease was primarily attributable to lower

principal balances with both Silicon Valley Bank and MidCap Financial LLP due to amortization payments which began in August 2011.

Change in fair value of derivative warrant liability. Change in fair value of derivative warrant liability resulted in non-cash expense of approximately \$5.6 million for the three months ended March 31, 2013. The increased loss was primarily due to an increase in the fair market value of our underlying common stock since December 31, 2012.

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Liquidity and Capital Resources

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of \$245.1 million from our inception through March 31, 2013. Prior to our IPO in April 2010, we funded our operations through the private placement of common stock, preferred stock, preferred stock warrants and convertible debt, as well as by the sale of certain assets of the non-prescription business in which we were previously engaged.

As of March 31, 2013, we had approximately \$39.3 million in cash and cash equivalents. We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and currently plan to launch ILUVIEN in France in late 2013. We believe that we have sufficient funds available to fund our operations for the commercialization of ILUVIEN in these EU countries. We do not expect to have positive cash flow from operations until 2014, if at all. The commercialization of ILUVIEN is dependent upon numerous factors and we cannot be sure that future sales of ILUVIEN will generate enough revenue to fund our operations beyond the initial commercialization. Due to the uncertainty around the market acceptance of ILUVIEN following its commercial launch, management cannot be certain that we will not need additional funds for its commercialization. If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

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

For the three months ended March 31, 2013, cash used in our operations of \$9.8 million was primarily due to our net loss of \$14.0 million decreased by a non-cash loss of \$5.6 million for a change in derivative warrant liability and by non-cash stock-based compensation and other expense of \$530,000. Further increasing our cash used in operations was a net decrease in accounts payable, accrued expenses and other current liabilities of \$1.1 million and an increase in prepaid expenses and other current assets of \$610,000. Accounts payable, accrued expenses and other current liabilities decreased primarily due to decreases of \$1.4 million paid to Quintiles Commercial for marketing, brand management, sales promotion and detailing, market access, pricing and reimbursement support, regulatory, medical science liaison and communications and/or other advisory services in the EU and \$250,000 paid to our third party reading center for additional analysis of photographs of the retina of patients of our FAME Study to be included in the response to the second CRL from the FDA. Prepaid expenses and other current assets increased primarily due to \$450,000 receivable from Quintiles Commercial for excess billings during first quarter of 2013 and \$140,000 in prepaid marketing expense for meetings and conventions.

For the three months ended March 31, 2012, cash used in our operations of \$5.4 million was primarily due to our net loss of \$4.4 million offset by non-cash stock-based compensation and other expense of \$350,000. Further increasing our cash used in operations was a net decrease in accounts payable, accrued expenses and other current liabilities of \$1.5 million and an increase in prepaid expenses and other current assets of \$50,000. Accounts payable, accrued expenses and other current liabilities decreased primarily due to decreases of \$540,000 for a termination payment to the administrator of our U.S. reimbursement and patient assistance programs, \$430,000 in amounts payable to our CROs, \$330,000 of 2011 employee bonus payments made in the first quarter of 2012, \$210,000 in severance payments associated with our fourth quarter reduction in force and \$150,000 in amounts payable to the investigators of our clinical studies, offset by an increase of \$170,000 in amounts payable to vendors performing pharmacoeconomic studies to evaluate the pricing of ILUVIEN in the EU.

For the three months ended March 31, 2013, net cash used by our investing activities was \$28,000, which was due to the purchases of property and equipment.

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For the three months ended March 31, 2012, net cash provided by our investing activities was \$500,000, which was due to the maturities of investments.

For the three months ended March 31, 2013, net cash used in our financing activities was \$460,000, which was primarily due to payments on principal on our notes payable to SVB and MidCap.

For the three months ended March 31, 2012, net cash used in our financing activities was \$570,000, which was primarily due to payments of principal on our notes payable to SVB and MidCap.

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Contractual Obligations and Commitments

In connection with our efforts to obtain the approval of ILUVIEN from the FDA, in February 2012, we engaged a consultant for services related to the continued pursuit of approval of ILUVIEN in the U.S. During the three month periods ended March 31, 2013 and 2012, we recorded charges of \$450,000 and \$375,000, respectively, pertaining to consulting fees related to our agreement with this consultant. We expect to record an additional \$825,000 in charges in connection with this agreement through December 31, 2013. In addition, we have agreed to pay the consultant \$2.0 million, if, and only if, the FDA approves our NDA for ILUVIEN.

In November 2012, we entered into an agreement with Quintiles Commercial Europe Limited. Under the agreement, Quintiles Commercial Europe Limited and its affiliates (collectively, Quintiles Commercial) will provide certain services to us in connection with the commercialization of ILUVIEN in certain countries in Europe under subsequent project orders. Such services may include marketing, brand management, sales promotion and detailing, market access, pricing and reimbursement support, regulatory, medical science liaison and communications and/or other advisory services. Currently, we have entered into six project orders with Quintiles Commercial for the provision of services in Germany, the United Kingdom and France. Under the existing project orders, we will incur approximately \$27.1 million in costs with Quintiles Commercial through 2015. During the three month period ended March 31, 2013 we recorded charges of \$1.7 million in connection with this agreement. At March 31, 2013, \$1.1 million is included in outsourced services payable and \$1.7 million is included in prepaid expenses and other current assets.

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, 2012, filed with the SEC on March 28, 2013.

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.

New 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 March 2013, the FASB issued Accounting Standard Update (ASU) No. 2013-05: Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity (ASU 2013-05), which applies to the release of the cumulative translation adjustment resulting from certain events occurring in foreign subsidiaries. ASU 2013-05 is effective for fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2012. The adoption of ASU 2013-05 did not have a material impact on our interim financial statements.

In February 2013, the FASB issued ASU No. 2013-02: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02), which adds new disclosure requirements for items reclassified out of accumulated other comprehensive income. ASU 2013-02 is effective for fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2012. The adoption of ASU 2013-02 did not have a material impact on our interim financial statements.

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ITEM 3. Qualitative and Quantitative Disclosures About Market Risk

Not applicable.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2013. 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 March 31, 2013, 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 March 31, 2013 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, 2012, filed with the SEC on March 28, 2013, 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 Form 10-Q. 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, 2012. However, the risks described in our Form 10-K are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

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
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.

* Filed herewith.

+ 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.

May 10, 2013

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

May 10, 2013

By: /s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
Chief Operating Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)

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