ALIMERA SCIENCES INC
Form 10-Q
June 07, 2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2010

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	**20-0028718**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
6120 Windward Parkway, Suite 290 Alpharetta, GA	**30005**
(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 o No þ

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 o No o

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 þ	Smaller reporting company o
		(Do not check if a 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 o No þ

As of June 1, 2010, there were 31,052,069 shares of the registrant s common stock issued and outstanding.

ALIMERA SCIENCES, INC.

QUARTERLY REPORT ON FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1 *Financial Statements*

ALIMERA SCIENCES, INC.

BALANCE SHEETS

	March 31, 2010 (Unaudited)	December 31 2009
	(In thousands except share and per share data)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,178	$ 4,858
Prepaid expenses and other current assets	751	634
Deferred offering costs	1,093	815
Total current assets	16,022	6,307
PROPERTY AND EQUIPMENT at cost less accumulated depreciation	229	254
TOTAL ASSETS	$ 16,251	$ 6,561
CURRENT LIABILITIES:		
Accounts payable	$ 1,940	$ 1,215
Accrued expenses	2,258	3,314
Accrued interest	901	543
Outsourced services payable	1,440	1,157
Note payable (Note 6)	6,000	4,500
Capital lease obligations	5	6
Total current liabilities	12,544	10,735
LONG-TERM LIABILITIES:		
Note payable less current portion (Note 6)	9,000	10,500
Fair value of preferred stock conversion feature	36,907	36,701
Other long-term liabilities	524	708
PREFERRED STOCK:		
Series A preferred stock, $.01 par value 6,624,866 shares authorized and 6.624,844 shares issued, and outstanding at March 31, 2010 and December 31, 2009; liquidation preference of $37,546 and $37,019 at March 31, 2010 and December 31, 2009	37,026	36,467
Series B preferred stock, $.01 par value 7,147,912 shares authorized and 7,147,894 shares issued, and outstanding at March 31, 2010 and December 31, 2009; liquidation preference of $41,686 and $41,057 at March 31, 2010 and	41,271	40,617

December 31, 2009		
Series C preferred stock, $.01 par value 5,807,131 shares authorized and 5,807,112 shares issued and outstanding at March 31, 2010 and December 31, 2009; liquidation preference of $34,873 and $34,281 at March 31, 2010 and December 31, 2009	34,092	33,452
Series C-1 preferred stock, $.01 par value 2,903,565 shares authorized and 2,903,545 shares issued and outstanding at March 31, 2010 and 967,845 shares issued and outstanding at December 31, 2009; liquidation preference of $15,419 and $5,140 at March 31, 2010 and December 31, 2009	11,382	2,853
STOCKHOLDERS DEFICIT:		
Common stock, $.01 par value 29,411,764 shares authorized and 1,637,359 shares issued and outstanding at March 31, 2010 and 29,411,764 shares authorized and 1,598,571 shares issued and outstanding at December 31, 2009	56	54
Additional paid-in capital	5,090	4,836
Series C-1 preferred stock warrants		1,472
Common stock warrants	57	57
Accumulated deficit	(171,698)	(171,891)
TOTAL STOCKHOLDERS DEFICIT	(166,495)	(165,472)
TOTAL LIABILITIES AND STOCKHOLDERS DEFICIT	$ 16,251	$ 6,561

See Notes to Financial Statements.

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ALIMERA SCIENCES, INC.

STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2010	2009
	(Unaudited)	
	(In thousands except share and per share data)	
RESEARCH AND DEVELOPMENT EXPENSES	$ 3,065	$ 4,528
GENERAL AND ADMINISTRATIVE EXPENSES	904	771
MARKETING EXPENSES	247	191
OPERATING EXPENSES	4,216	5,490
INTEREST INCOME	2	23
INTEREST EXPENSE	(474)	(474)
DECREASE (INCREASE) IN FAIR VALUE OF PREFERRED STOCK CONVERSION FEATURE	3,265	(4,237)
LOSS FROM CONTINUING OPERATIONS	(1,423)	(10,178)
INCOME FROM DISCONTINUED OPERATIONS (NOTE 4)	4,000	
NET INCOME (LOSS)	2,577	(10,178)
PREFERRED STOCK ACCRETION	(359)	(107)
PREFERRED STOCK DIVIDENDS	(2,025)	(1,747)
NET INCOME (LOSS) APPLICABLE TO COMMON STOCKHOLDERS	$ 193	$ (12,032)
NET INCOME (LOSS) PER SHARE APPLICABLE TO COMMON STOCKHOLDERS Basic and diluted	$ 0.12	$ (8.07)
WEIGHTED AVERAGE SHARES OUTSTANDING Basic and diluted	1,619,011	1,490,138

See Notes to Financial Statements.

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ALIMERA SCIENCES, INC.

STATEMENTS OF CASH FLOWS

	Three Months Ended March 31,	
	2010	2009
	(Unaudited)	
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 2,577	$ (10,178)
Income from discontinued operations (Note 4)	(4,000)	
Depreciation and amortization	48	494
Change in fair value of preferred stock conversion feature	(3,265)	4,237
Stock compensation expense and other	108	104
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(118)	251
Accounts payable	962	489
Accrued expenses and other current liabilities	(767)	899
Other long-term liabilities	(184)	174
Net cash used in operating activities of continuing operations	(4,639)	(3,530)
Net cash used in operating activities	(4,639)	(3,530)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(23)	
Net cash used in investing activities of continuing operations	(23)	
Net cash provided by investing activities of discontinued operations (Note 4)	4,000	
Net cash provided by investing activities	3,977	
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of Series C-1 preferred warrants	9,998	
Proceeds from exercise of common warrants	148	
Deferred offering costs	(163)	
Payments on capital lease obligations	(1)	(3)
Net cash provided by (used in) financing activities	9,982	(3)
NET INCREASE (DECREASE) IN CASH	9,320	(3,533)
CASH Beginning of period	4,858	17,875
CASH End of period	$ 14,178	$ 14,342

	Three Months Ended March 31,	
	2010	**2009**
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$ 300	$ 300

There were no income tax or dividend payments made for the three months ended March 31, 2010 and 2009.

See Notes to Financial Statements.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS

1. Description of Business

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

During the year ended December 31, 2006, management and the board of directors approved a plan to discontinue the operations of its non-prescription business (see Note 4). As a result of the completion of the disposal of its non-prescription business in July 2007, the Company no longer has active products and will not have active products until the Company receives U.S. Food and Drug Administration (FDA) approval and launches its initial prescription product (see Note 5).

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 most advanced product candidate is Iluvien, which is being developed for the treatment of diabetic macular edema (DME). DME is a disease of the retina which affects individuals with diabetes and can lead to severe vision loss and blindness. The Company has completed enrollment of its two Phase 3 pivotal clinical trials (collectively referred to as the Company s FAME Study) for Iluvien involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of Iluvien in the treatment of DME.

On April 21, 2010, the Company s Registration Statement on Form S-1 (as amended) was declared effective by the Securities and Exchange Commission (SEC) for the Company s initial public offering (IPO), pursuant to which the Company sold 6,550,000 shares of its common stock at a public offering price of $11.00 per share. The Company received net proceeds of approximately $68,395,000 from this transaction, after underwriting discounts and commissions.

2. Basis of Presentation

The Company has prepared the accompanying unaudited interim financial statements and notes thereto in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and the instructions to Form 10-Q and Article 10-01 of Regulations S-X of the Securities and Exchange Commission. 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 financial statements reflect all adjustments, which include normal recurring adjustments, necessary to present fairly the Company s interim financial information.

The accompanying unaudited interim financial statements and related notes should be read in conjunction with the Company s audited financial statements for the year ended December 31, 2009 and related notes included in the Company s Registration Statement on Form S-1 (as amended). The financial results for any interim period are not necessarily indicative of the expected financial results for the full year.

On April 21, 2010, the Company effected a 1-for-3.4 reverse split of the Company s common and preferred stock. All share and per share amounts in the accompanying financial statements and notes have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

3. Recent Accounting Pronouncements

In January 2010, the FASB issued amendments to the existing fair value measurements and disclosures guidance which requires new disclosures and clarifies existing disclosure requirements. The purpose of these amendments is to provide a greater level of disaggregated information as well as more disclosure around valuation techniques and inputs to fair value measurements. The guidance was effective commencing with the

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Company s 2010 fiscal year. The adoption of this guidance did not have a material impact on the Company s financial statements.

4. Discontinued Operations

In October 2006, management and the board of directors of the Company approved a plan to discontinue the operations of its non-prescription ophthalmic pharmaceutical business (the OTC Business). The plan included the sale of the assets of the Company s OTC Business and also the termination of its sales and marketing personnel. The Company previously determined that the discontinued OTC Business comprised operations and cash flows that could be clearly distinguished, operationally and for financial reporting purposes, from the rest of the Company. Accordingly, the results of operations for the discontinued OTC Business have been presented as discontinued operations. During the three months ended March 31, 2010 the Company received a $4,000,000 option payment from the acquirer of the assets of the OTC Business to provide it with an additional two years to develop one of the acquired products. There were no revenues or expenses from discontinued operations during the three months ended March 31, 2009. The following table presents basic and diluted earnings per share from discontinued operations for the three months ended March 31, 2010 (in thousands except share and per share data):

Net income from discontinued operations	$ 4,000
Net income from discontinued operations per share Basic and diluted	$ 2.47
Weighted-average shares outstanding Basic and diluted	1,619,011

5. Factors Affecting Operations

To date the Company has incurred recurring losses, negative cash flow from operations, and has accumulated a deficit of $171,698,000 from the Company s inception through March 31, 2010. The Company does not expect to generate revenues from its product, Iluvien, until 2011, if at all, and therefore will have no cash flow from operations until that time. On a pro forma as adjusted basis to give effect to its IPO, as of March 31, 2010 the Company had approximately $65,400,000 in cash and cash equivalents, which management believes is sufficient to fund its operations through the projected commercialization of Iluvien and the expected generation of revenue in 2011. The commercialization of Iluvien is dependent upon approval by the FDA, however, and management cannot be sure that Iluvien will be approved by the FDA or that, if approved, future sales of Iluvien will generate enough revenue to fund the Company s operations beyond its commercialization. If Iluvien is not approved, or if approved, does not generate sufficient revenue, the Company may adjust its commercial plans so that it can continue to operate with its existing cash resources or seek to raise additional financing.

6. pSivida Agreement

In March 2008, in conjunction with the amendment and restatement of the Company s collaboration agreement with pSivida US, Inc. (pSivida), the licensor of the Iluvien technology, the Company issued to pSivida a note payable of $15,000,000. The note payable accrued interest at 8% per annum, payable quarterly. The principal was payable upon the earliest of a liquidity event as defined in the agreement, the occurrence of an event of default under the Company s agreement with pSivida or September 30, 2012. If the note was not paid in full by March 31, 2010, the interest rate was to increase to 20% per annum effective April 1, 2010, and the Company was required to begin making principal payments of $500,000 per month. The effective interest rate on the note payable was 12.64%. As of March 31, 2010

and December 31, 2009, the Company had accrued and unpaid interest payable to pSivida of $524,000 and $708,000, respectively, which is classified as other long-term liabilities, and $901,000 and $543,000, respectively, which is included in accrued interest in the accompanying balances.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

On April 27, 2010 the Company paid pSivida $15,225,000 in principal and interest to satisfy the note payable.

Upon commercialization, the Company must share 20% of net profits, as defined by the agreement, with pSivida. In connection with this arrangement the Company is entitled to recover 20% of commercialization costs, as defined in the amendment, incurred prior to product profitability out of pSivida s share of net profits. As of March 31, 2010 and December 31, 2009 the Company was owed $1,072,000 and $958,000, respectively, in commercialization costs. Due to the uncertainty of FDA approval, the Company has fully reserved these amounts in the accompanying financial statements.

7. Earnings (Loss) Per Share (EPS)

Basic EPS is calculated in accordance with Accounting Standards Codification 260 (ASC 260), 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, convertible preferred stock and accrued but unpaid convertible preferred stock dividends. In periods where a net loss from continuing operations is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive. Total securities that could potentially dilute basic EPS in the future were not included in the computation of diluted EPS because to do so would have been anti-dilutive were as follows:

	Three Months Ended March 31, 2010 unaudited	Three Months Ended March 31, 2009 unaudited
Series A preferred stock and convertible accrued dividends	7,005,145	7,005,145
Series B preferred stock	7,147,894	7,147,894
Series C preferred stock	5,807,112	5,807,112
Series C-1 preferred stock	2,752,990	
Common stock warrants	150,703	29,931
Stock options	1,792,764	1,019,146
Total	24,656,608	21,009,228

8. Preferred Stock

Prior to the Company s IPO, the Company had four series of preferred stock. Significant terms of all series of the preferred stock were as follows:

Dividends were cumulative and accrued on a daily basis at the rate of 8% per annum beginning on the date of issuance and based on the original issue price, as adjusted for any stock dividend, stock split, combination, or other event involving the preferred stock. Dividends accrued, whether or not declared, annually and were due

and payable when and if declared by the Board of Directors, upon a liquidating event, as defined, upon redemption of the preferred stock, as defined, or on the date that the preferred stock was otherwise acquired by the Company. Accumulated, accrued, and unpaid dividends were $25,961,000 and $23,934,000 at March 31, 2010 and December 31, 2009, respectively.

Upon any liquidation, dissolution, or winding up of the Company, the preferred stockholders were entitled to a liquidation preference payment equal to (i) the sum of the liquidation value plus all accumulated, accrued, and unpaid dividends and (ii) the pro rata share of any remaining amounts such holder would have been entitled to receive had such holder s shares been converted into common stock

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

immediately prior to the liquidation, dissolution, or winding up. The liquidation value plus accumulated, accrued, and unpaid dividends were $129,524,000 and $117,497,000 at March 31, 2010 and December 31, 2009, respectively.

At any time subsequent to March 17, 2013, the holders of a majority of the preferred stock could have required the Company to redeem all or any portion of the preferred stock. If the preferred stock was redeemed, the redemption would have occurred in equal installments over a three-year period. The price paid by the Company to redeem the shares would have been the greater of (i) the original issue price, plus all accumulated, accrued, and unpaid dividends, and (ii) the fair market value of the preferred stock being redeemed at the time of the redemption.

Because the preferred stock provided the holders the right to require the Company to redeem such shares for cash after March 17, 2013 at the greater of (i) the original issue price plus any accrued but unpaid dividends and (ii) the fair market value of the preferred stock being redeemed, the embedded conversion feature required separate accounting. Consequently, the conversion feature had to be bifurcated from the preferred stock and accounted for separately at each issuance date. The carrying value of the embedded derivative was adjusted to fair value at the end of each reporting period and the change in fair value was recognized in the statement of operations.

At each reporting date, the Company adjusted the carrying value of the embedded derivatives to estimated fair value and recognized the change in such estimated value in its statement of operations. The estimated fair value of the derivatives at March 31, 2010 and December 2009 were $36,907,000 and $36,701,000, respectively. The Company recognized a gain of $3,265,000 associated with the change in fair value for the three months ended March 31, 2010 and a loss of $4,237,000 associated with the change in fair value for the three months ended March 31, 2009.

On January 8, 2010 warrants to purchase shares of the Company s Series C-1 preferred stock were exercised resulting in $10,000,000 in cash proceeds and the issuance of 1,935,700 additional shares of Series C-1 preferred stock. The Company recorded a derivative liability of $3,471,000 upon the exercise of the warrants and the issuance of 1,935,700 shares of Series C-1 preferred stock in January 2010.

In connection with the IPO, all outstanding shares of the Company s preferred stock were converted into 22,863,696 shares of common stock in April 2010 and all preferred stock dividends were eliminated.

9. Stock Options

During the three months ended March 31, 2010 and 2009, the Company recorded compensation expense of approximately $108,000 and $104,000, respectively. As of March 31, 2010, the total unrecognized compensation cost related to non-vested stock options granted was $1,386,000 and is expected to be recognized over a weighted average period of 2.52 years. The Company did not grant any stock options and no stock options were forfeited or exercised during the three months ended March 31, 2010 and 2009.

The following table provides additional information related to outstanding stock options, fully vested stock options, and stock options expected to vest as of March 31, 2010:

	Weighted	Weighted

	Shares	Average Exercise Price	Average Contractual Term	Aggregate Intrinsic Value
		(In thousands)		
Outstanding	2,225,778	$ 2.14	7.00 years	$ 19,720
Exercisable	1,491,507	1.71	6.29 years	13,856
Expected to vest	660,844	3.00	8.44 years	5,287

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The following table provides additional information related to outstanding stock options, fully vested stock options, and stock options expected to vest as of December 31, 2009:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value (In thousands)
Outstanding	2,225,778	$ 2.14	7.28 years	$ 14,251
Exercisable	1,427,649	1.70	6.52 years	9,765
Expected to vest	718,320	2.92	8.63 years	4,037

10. Income Taxes

In accordance with Accounting Standards Codification 740 (ASC 740) 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. 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.

Income tax positions are considered for uncertainty in accordance with FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes an interpretation of ASC 740-10. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position; therefore, no ASC 740-10 liabilities have been recorded. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as interest expense and income tax expense, respectively, in the statements of operations.

Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of deferred tax assets due to the history of operating losses, a valuation allowance has been established against the entire net deferred tax asset balance. The valuation allowance is based on management s estimates of taxable income in the jurisdictions in which the Company operates and the period over which deferred tax assets will be recoverable. In the event that actual results differ from these estimates or the Company adjusts these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact the Company s financial position and results of operations.

At March 31, 2010 and December 31, 2009, the Company had federal net operating loss (NOL) carryforwards of approximately $80,601,000 and $79,494,000 and state NOL carryforwards of approximately $63,773,000 and $62,666,000, respectively, that are available to reduce future income unless otherwise taxable. If not utilized, the federal NOL carryforwards will expire at various dates between 2023 and 2029 and the state NOL carryforwards will expire at various dates between 2018 and 2029.

NOL carryforwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of the Company were to occur. The Company is

currently evaluating the impact of its IPO (see Note 1) on the Company s NOL carryforwards and whether certain changes in ownership have occurred that would limit the Company s ability to utilize a portion of its NOL carryforwards.

11. Fair Value Measurements

The Company adopted Accounting Standards Codification 820, effective January 1, 2008. 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.

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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.

The following fair value tables present information about the Company s assets and liabilities measured at fair value on a recurring basis:

	March 31, 2010			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash and cash equivalents				
Government-backed money market funds(1)	$ 13,781	$	$	$ 13,781
Assets measured at fair value	$ 13,781	$	$	$ 13,781
Liabilities:				
Beneficial conversion feature of preferred stock(2)	$	$	$ 36,907	$ 36,907
Liabilities measured at fair value	$	$	$ 36,907	$ 36,907

	December 31, 2009			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Cash and cash equivalents				

Government-backed money market funds(1)	$ 4,668	$	$	$ 4,668
Assets measured at fair value	$ 4,668	$	$	$ 4,668
Liabilities:				
Beneficial conversion feature of preferred stock(2)	$	$	$ 36,701	$ 36,701
Liabilities measured at fair value	$	$	$ 36,701	$ 36,701

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

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ALIMERA SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) The fair value of the beneficial conversion feature of preferred stock (see note 8) is established using a probability weighted expected return method (PWERM) and Black Scholes valuation model. Significant inputs to the valuation include:

probability of various scenarios occurring, including the potential for an initial public offering, sale of the Company or its assets, decision to remain a private company or liquidation of the Company;

at March 31, 2010, the fair value of common stock as determined by the IPO; at March 31, 2009, fair value of common stock as determined under each of the scenarios under the PWERM, adjusted for a lack of control and lack of marketability discount;

volatility estimated as an average of volatilities of publicly traded companies deemed similar to the Company in terms of product composition, stage of lifecycle, capitalization, and scope of operations;

exercise price and weighted-average expected life estimated based on the underlying and the expected remaining life of the underlying instrument;

risk-free interest rate estimated as the daily treasury yield for the period that most closely approximates the weighted-average expected life as the valuation date as published by the United States Department of Treasury.

The method described above may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. Furthermore, while the Company believes its valuation methods are appropriate, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different fair value measurement at the reporting date.

The following table presents the changes to the fair value of the beneficial conversion feature of preferred stock during the three months ended March 31, 2010 (in thousands):

Balance of beneficial conversion feature of preferred stock at December 31, 2009	$ 36,701
Issuance of Series C-1 preferred stock (See Note 8)	3,471
Change in fair value of beneficial conversion feature of preferred stock during the three months ended March 31, 2010	(3,265)
Balance of beneficial conversion feature of preferred stock at March 31, 2010	$ 36,907

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PART I. FINANCIAL INFORMATION

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

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Quarterly Report on Form 10-Q regarding our 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 anticipate, believe, estimate, expect, intend, may, plan, predict, project, likely, will, would, could and similar expressions are i forward-looking statements, although not all forward-looking statements contain these identifying words.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in Part II Item 1A Risk Factors of this Quarterly Report on Form 10-Q, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.

You should read this Quarterly Report on Form 10-Q in conjunction with the documents that we reference herein. Our forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

We are a biopharmaceutical 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 most advanced product candidate is Iluvien, which we are developing for the treatment of 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. We are currently conducting two Phase 3 pivotal clinical trials (collectively, our FAME Study) for Iluvien involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of Iluvien in the treatment of DME. In December 2009 we received the month 24 clinical readout from our FAME Study. Based upon our analysis of this data, we plan to file a New Drug Application (NDA) in the United States for the low dose of Iluvien in the second quarter of 2010, followed by registration filings in certain European countries and Canada. We intend to request Priority Review of our NDA from the U.S. Food and Drug Administration (FDA). If Priority Review is granted, we can expect a response to our NDA from the FDA in the fourth quarter of 2010. If our NDA is approved, we plan to commercialize Iluvien in the United States by marketing and selling Iluvien to retinal specialists as early as the first quarter of 2011. In addition to treating DME, Iluvien is being studied in three Phase 2 clinical trials for the treatment of the dry form of age-related macular degeneration (AMD), the wet form of AMD and retinal vein occlusion (RVO). We are also conducting testing on two classes of nicotinamide adenine dinucleotide phosphate (NADPH) oxidase inhibitors, for which we have acquired exclusive, worldwide licenses from Emory University, in the treatment of dry AMD. We plan to evaluate the use of NADPH oxidase inhibitors in the treatment of other eye diseases of the eye, including wet AMD and diabetic retinopathy. We intend to seek a collaboration partner for sales and marketing activities outside North America. We currently contract with development partners or outside firms for various operational aspects of our development activities, including the preparation of clinical supplies and have no plans to establish inhouse manufacturing capabilities.

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We commenced operations in June 2003. Since our inception we have incurred significant losses. As of March 31, 2010, we have accumulated a deficit of $171.7 million. We expect to incur substantial losses through the projected commercialization of Iluvien through at least the first quarter of 2011 as we:

complete the clinical development and registration of Iluvien;

build our sales and marketing capabilities for the anticipated commercial launch of Iluvien as early as the first quarter of 2011;

add the necessary infrastructure to support our growth;

evaluate the use of Iluvien for the treatment of other diseases; and

advance the clinical development of other new product candidates either currently in our pipeline, or that we may license or acquire in the future.

To date we have funded our operations through the private placement of common stock, preferred stock 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, 2010, we had $14.2 million in cash and cash equivalents including the January 2010 receipt of $10.0 million in proceeds from the exercise of outstanding Series C-1 warrants, and a $4.0 million option payment from Bausch & Lomb Incorporated (Bausch & Lomb) upon the exercise by Bausch & Lomb of its option to extend the period during which it may continue to develop an allergy product acquired from us in 2006 by two years.

On April 21, 2010, our Registration Statement on Form S-1 (as amended) was declared effective by the Securities and Exchange Commission (SEC) for our initial public offering (IPO), pursuant to which we sold 6,550,000 shares of our common stock at a public offering price of $11.00 per share. We received net proceeds of approximately $68.4 million from this transaction, after deducting underwriting discounts and commissions. To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of $171.7 million from our inception through March 31, 2010. We do not expect to generate revenues from our product, Iluvien, until 2011, if at all, and therefore we will have no cash flow from operations until that time. On a pro forma as adjusted basis to give effect to our IPO, as of March 31, 2010 we had approximately $65.4 million in cash and cash equivalents, which we believe is sufficient to fund our operations through the projected commercialization of Iluvien and the expected generation of revenue in 2011. The commercialization of Iluvien is dependent upon approval by the FDA, however, and we cannot be sure that Iluvien will be approved by the FDA or that, if approved, future sales of Iluvien will generate enough revenue to fund our operations beyond its commercialization. If Iluvien is not approved, or if approved, 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.

Our Agreement with pSivida US, Inc.

In February 2005, we entered into an agreement with pSivida US, Inc. (pSivida) for the use of fluocinolone acetonide (FA) in pSivida s proprietary delivery device. pSivida is a global drug delivery company committed to the biomedical sector and the development of drug delivery products. Our agreement with pSivida provides us with a worldwide exclusive license to develop and sell Iluvien, which consists of a tiny polyimide tube with membrane caps that is filled with FA in a polyvinyl alcohol matrix, for delivery to the back of the eye for the treatment and prevention of eye diseases in humans (other than uveitis). This agreement also provided us with a worldwide non-exclusive license to develop and sell 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 develop and sell pSivida s proprietary delivery device for indications for diseases outside of the eye or for the treatment of uveitis. Further, our agreement with pSivida permits pSivida to grant to any other party the right to use its intellectual property (i) to treat DME through an incision smaller than that required for a 25-gauge needle, unless using a corticosteroid delivered to the back of the eye, (ii) to deliver any compound outside the back of the eye unless it is to treat DME through an incision required for a 25-gauge or

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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.

We made initial license fee payments totaling $750,000 to pSivida in 2004 and additional license fee payments of $750,000 in 2005 upon the initiation of our FAME Study. Under the February 2005 agreement, we and pSivida agreed to collaborate on the development of Iluvien for DME, and share financial responsibility for the development expenses equally. Per the terms of the agreement, we each reported our monthly expenditures on a cash basis, and the party expending the lesser amount of cash during the period was required to make a cash payment to the party expending the greater amount to balance the cash expenditures. We retained primary responsibility for the development of the product, and therefore, were generally the party owed a balancing payment. Between February 2006 and December 2006, pSivida failed to make payments to us for its share of development costs totaling $2.0 million. For each payment not made, pSivida incurred a penalty of 50% of the missed payment and interest began accruing at the rate of 20% per annum on the missed payment and the penalty amount. In accordance with the terms of the agreement, pSivida was able to remain in compliance with the terms of the February 2005 agreement as long as the total amount of development payments past due did not exceed $2.0 million, and pSivida began making payments again in December 2006 in order to maintain compliance with the agreement. For financial reporting purposes we fully reserved the $2.0 million in past due development payments and all penalties and interest due with respect to such past due payment, due to the uncertainty of future collection.

The February 2005 agreement provided that after commercialization of Iluvien, profits, as defined in our agreement, would be shared equally. In March 2008, we and pSivida amended and restated the agreement to provide us with 80% of the net profits and pSivida with 20% of the net profits.

Total consideration to pSivida in connection with the execution of the March 2008 agreement was $33.8 million, which consisted of a payment of $12.0 million, the issuance of a $15.0 million note payable, and the forgiveness of $6.8 million in outstanding receivables. The $15.0 million promissory note accrued interest at 8% per annum, payable quarterly and was payable in full to pSivida upon the earliest of a liquidity event as defined in the agreement, the occurrence of an event of default under our agreement with pSivida, or September 30, 2012. If the note was not paid in full by March 31, 2010, the interest rate was to increase to 20% effective as of April 1, 2010, and we were required to begin making principal payments of $500,000 per month.

On April 27, 2010, we paid pSivida approximately $15.2 million in principal and interest to satisfy the note payable.

We will owe pSivida an additional milestone payment of $25.0 million upon FDA approval of Iluvien.

Our Discontinued Non-Prescription Business

At the inception of our company, we were focused primarily on the development and commercialization of non-prescription over-the-counter ophthalmic products. In October 2006, due to the progress and resource requirements related to the development of Iluvien, we decided to discontinue our non-prescription business. As a result, we received proceeds of $10.0 million from the sale of our allergy products in December 2006 and $6.7 million from the sale of our dry eye product in July 2007, both to Bausch & Lomb. If one of the allergy products receives FDA approval, we are entitled to an additional $8.0 million payment from Bausch & Lomb under the sales agreement. In January 2010 we received a $4.0 million option payment from Bausch & Lomb upon the exercise by Bausch & Lomb of its option to extend the period during which it may continue to develop an allergy product acquired from us in 2006 by two years. However, there can be no assurance that Bausch & Lomb will continue the development of this allergy product, that it will receive FDA approval or that we will receive the $8.0 million payment. As a result of the discontinuance of our non-prescription business, all revenues and expenses associated with our over-the-counter portfolio are included in the income (loss) from discontinued operations in the accompanying statements of

operations.

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Financial Operations Overview

Revenue

To date we have only generated revenue from our dry eye non-prescription product. From the launch of that product in September 2004 to its sale in July 2007, we generated $4.4 million in net revenues. We do not expect to generate any significant additional revenue unless or until we obtain regulatory approval of, and commercialize, our product candidates or in-license additional products that generate revenue. In addition to generating revenue from product sales, we intend to seek to generate revenue from other sources such as upfront fees, milestone payments in connection with collaborative or strategic relationships, and royalties resulting from the licensing of our product candidates and other intellectual property. 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, as well as revenue we may receive upon the sale of our products to the extent any are successfully commercialized.

Research and Development Expenses

Substantially all of our research and development expenses incurred to date related to our continuing operations have been related to the development of Iluvien. We anticipate that we will incur expenses of approximately $11.6 million and $1.8 million during 2010 and 2011, respectively, to complete the clinical development and registration of Iluvien for DME. Upon the approval of Iluvien by the FDA, we will owe an additional milestone payment of $25.0 million to pSivida. We anticipate that we will incur additional research and development expenses in the future as we evaluate and possibly pursue the development of Iluvien for additional indications, or develop additional product candidates. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel;
- 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 our product candidates;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- costs related to upfront and milestone payments under in-licensing agreements;
- costs related to compliance with FDA regulatory requirements;
- consulting fees paid to third-parties involved in research and development 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 and development expenses in the future will be incurred in support of our current and future technical, preclinical and clinical development programs. These expenditures are subject to numerous uncertainties in terms of both their timing and total cost to completion. We expect to continue to develop stable formulations of our product candidates, test such formulations in preclinical studies for toxicology, safety and efficacy and to conduct clinical trials for each product candidate. We anticipate funding clinical trials for Iluvien ourselves, but we may engage collaboration partners at certain stages of clinical development. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain product candidates or programs in order to focus our resources on more promising product candidates or programs. Completion of clinical trials by us or our future collaborators may take several years or more, the length of time generally varying with the type, complexity, novelty and intended use

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of a product candidate. The costs of clinical trials may vary significantly over the life of a project owing to but not limited to the following:

- the number of sites included in the trials;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the duration of patient follow-up;
- the phase of development the product candidate is in; and
- the efficacy and safety profile of the product candidate.

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

None of our product candidates has received FDA or foreign regulatory marketing approval. In order to grant marketing approval, a health authority such as the FDA or foreign regulatory agencies must conclude that clinical and preclinical data establish the safety and efficacy of our product candidates with an appropriate benefit to risk profile relevant to a particular indication, and that the product can be manufactured under current Good Manufacturing Practice (cGMP) in a reproducible manner to deliver the product s intended performance in terms of its stability, quality, purity and potency. Until our submission is reviewed by a health authority, there is no way to predict the outcome of their review. Even if the clinical studies meet their predetermined primary endpoints, and a registration dossier is accepted for filing, a health authority could still determine that an appropriate benefit to risk relationship does not exist for the indication that we are seeking. We cannot forecast with any degree of certainty which of our product candidates will be subject to future collaborations or how such arrangements would affect our development plan or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will receive cash inflows from the commercialization and sale of an approved product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and administrative functions, including finance, accounting 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 anticipate incurring a significant increase in general and administrative expenses, as we operate as a

public company following our IPO. These increases will include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants, lawyers and accountants. We also expect to incur significant costs to comply with the corporate governance, internal control and similar requirements applicable to public companies.

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Marketing Expenses

Marketing expenses consist primarily of compensation for employees responsible for assessing the commercial opportunity of and developing market awareness and launch plans for our product candidates. Other costs include professional fees associated with developing brands for our product candidates and maintaining public relations. We expect significant increases in our marketing and selling expenses as we hire additional personnel and establish our sales and marketing capabilities in anticipation of the commercialization of our product candidates. We intend to capitalize on our management s past experience and expertise with eye-care products by marketing and selling Iluvien to the approximately 1,600 retinal specialists practicing in the approximately 900 retina centers across the United States and Canada. We intend to seek a commercialization partner for sales and marketing activities outside North America.

Our plan is to develop our own specialized domestic sales and marketing infrastructure, comprised of approximately 40 people, to market Iluvien and other ophthalmic products that we acquire or develop in the future. We will begin recruiting sales representatives and regional managers with extensive ophthalmic-based sales experience in 2010 in advance of an expected commercial launch of Iluvien as early as the first quarter of 2011. We expect that our domestic sales force will be able to access and form relationships with retinal specialists in the approximately 900 retina centers prior to the commercial launch of Iluvien.

Interest Income

Interest income consists primarily of interest earned on our cash and cash equivalents.

Interest Expense

Beginning in March 2008, we began recognizing interest on our $15.0 million note payable to pSivida at an effective interest rate of 12.64% per annum (this note accrued interest at the rate of 8% per annum from inception through March 31, 2010 and at the rate of 20% per annum effective as of April 1, 2010). Accrued interest in excess of amounts payable currently at the stated rate are included in accrued expenses and in other long-term liabilities in the accompanying balance sheets. Interest expense also includes interest on our capital leases. On April 27, 2010, we paid pSivida approximately $15.2 million in principal and interest to satisfy the note payable.

Change in Fair Value of Preferred Stock Conversion Feature

Prior to being converted into common stock in connection with our IPO, our preferred stock contained certain conversion features which were considered embedded derivatives. We accounted for such embedded derivative financial instruments in accordance with Accounting Standards Codification 815. We recorded derivative financial instruments as assets or liabilities in our balance sheet measured at their fair value. We recorded the changes in fair value of such instruments as non-cash gains or losses in the statement of operations.

Preferred Stock Accretion

Our preferred stock was recorded at issuance at the proceeds received net of any issuance discounts, issuance costs and the fair value of the conversion features at issuance. The difference between the amount recorded at issuance and the original issue price is accreted on a straight-line basis over a period extending from the date of issuance to the date at which the preferred stock becomes redeemable at the option of the holder.

Preferred Stock Dividends

Our preferred stock accrued dividends at 8% per annum which were recorded as an increase in the carrying amount of the respective preferred stock. At the time our preferred stock was converted into common stock in connection with our IPO, $1.5 million of dividends accrued on our Series A preferred stock prior to

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November 17, 2005 were converted into 380,301 shares of our common stock. All other preferred stock dividends were eliminated upon conversion of the underlying preferred stock in April 2010.

Basic and Diluted Net Loss Applicable to Common Stockholders per Common Share

We calculated net loss per share in accordance with Accounting Standards Codification 260 (ASC 260). We have determined that the Series A, Series B, Series C and Series C-1 preferred stock represent participating securities in accordance with ASC 260. However, since we operate at a loss, and losses are not allocated to the preferred stock, the two class method does not affect our calculation of earnings per share. We had a net loss from continuing operations for all periods presented; accordingly, the inclusion of common stock options and warrants would be antidilutive. Dilutive common stock equivalents would include the dilutive effect of convertible securities, common stock options, warrants for convertible securities and warrants for common stock equivalents. Potentially dilutive weighted average common stock equivalents totaled approximately 24,656,608 and 21,009,228 for the three months ended March 31, 2010 and 2009, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods of net loss from continuing operations because of their anti-dilutive effect. Therefore, for the three months ended March 31, 2010 and 2009, respectively, the weighted average shares used to calculate both basic and diluted loss per share are the same.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these 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. While our significant accounting policies are more fully described in Note 1 to our financial statements included within this prospectus, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Clinical Trial Prepaid and Accrued Expenses

We record prepaid assets and accrued liabilities related to clinical trials associated with contract research organizations, clinical trial investigators and other vendors based upon amounts paid and the estimated amount of work completed on each clinical trial. The financial terms of agreements vary from vendor to vendor and may result in uneven payment flows. As such, if we have advanced funds exceeding our estimate of the work completed, we record a prepaid asset. If our estimate of the work completed exceeds the amount paid, an accrued liability is recorded. All such costs are charged to research and development expenses based on these estimates. Our estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and discussions with our contract research organization and review of contractual terms. However, if we have incomplete or inaccurate information, we may underestimate or overestimate activity levels associated with various clinical trials at a given point in time. In this event, we could record significant research and development expenses in future periods when the actual level of activities becomes known. To date, we have not experienced material changes in these estimates. Additionally, we do not expect material adjustments to research and development expenses to result from changes in the nature and level of clinical trial activity and related expenses that are currently subject to estimation. In the future, as we expand our clinical trial activities, we expect to have increased levels of

research and development costs that will be subject to estimation.

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Research and Development Costs

Research and development expenditures are expensed as incurred, pursuant to Accounting Standards Codification 730. Costs to license technology to be used in our research and development that have not reached technological feasibility, defined as FDA approval for our current product candidates, and have no alternative future use are expensed when incurred. Payments to licensors that relate to the achievement of preapproval development milestones are recorded as research and development expense when incurred.

Income Taxes

We recognize deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of its assets and liabilities in accordance with Accounting Standards Codification 740 (ASC 740). We evaluate the positive and negative evidence bearing upon the realizability of our deferred tax assets on an annual basis. Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of our deferred tax assets due to our history of operating losses, a valuation allowance has been established against our deferred tax asset balances to reduce the net carrying value to an amount that is more likely than not to be realized. As a result we have fully reserved against the deferred tax asset balances. The valuation allowances are based on our 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, 2010 we had federal NOL carry-forwards of approximately $80.6 million and state NOL carry-forwards of approximately $63.8 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 2029 and the state NOL carry-forwards will expire at various dates between 2018 and 2029. 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 Section 382 (or comparable provisions of state law). We are currently evaluating the impact of our IPO on our NOL carryforwards and whether certain changes in ownership have occurred that would limit our ability to utilize a portion of our NOL carryforwards.

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.

Results of Operations

Research and Development Expenses

Research and development expenses decreased by approximately $1.4 million, or 31%, to $3.1 million for the three months ended March 31, 2010, compared to $4.5 million for the three months ended March 31, 2009. The decrease was primarily attributable to decreases of $1.1 million in technology transfer costs associated with establishing manufacturing capabilities with a third-party manufacturer for Iluvien and $287,000 for manufacture of registration batches incurred in the three months ended March 31, 2009, while no such costs were incurred during the three months ended March 31, 2010.

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General and Administrative Expenses

General and administrative expenses increased by approximately $133,000, or 17%, to $904,000 for the three months ended March 31, 2010, compared to $771,000 for the three months ended March 31, 2009. The increase was primarily due to incremental professional service fees incurred in the assessment of strategic financing options during the three months ended March 31, 2010.

Marketing Expenses

Marketing expenses increased by approximately $55,000, or 29%, to $247,000 for the three months ended March 31, 2010, compared to $191,000 for the three months ended March 31, 2009. The increase was primarily attributable to an increased presence at meetings and conventions during the three months ended March 31, 2010 to disseminate data from the FAME study that was not available during the three months ended March 31, 2009.

Interest Income

Interest income decreased by approximately $21,000 to approximately $2,000 for the three months ended March 31, 2010, compared to approximately $23,000 for the three months ended March 31, 2009. The decrease in interest income was primarily attributable to a decrease in the rates of return on our money market accounts from approximately 0.14% for the three months ended March 31, 2009 to 0.01% for the three months ended March 31, 2010.

Interest expense

Interest expense was approximately $474,000 for the three months ended March 31, 2010 and 2009. Our interest expense is associated with our $15.0 million note to pSivida issued in March 2008.

Increase in fair value of preferred stock conversion feature

For the three months ended March 31, 2010, we recognized a gain of approximately $3.3 million related to the decrease in the fair value of the conversion feature of our preferred stock. The change in fair value is primarily attributable to change in the estimated fair value of our common stock.

For the three months ended March 31, 2009 we recognized expense of approximately $4.2 million related to the increase in the fair value of the conversion feature of our preferred stock. The change in fair value is primarily attributable to change in the estimated fair value of our common stock.

Income (loss) from discontinued operations

We recognized income from discontinued operations of $4.0 million for an option payment we received from Bausch & Lomb upon the exercise by Bausch & Lomb of its option to extend the period during which it may continue to develop an allergy product acquired from us in 2006 by two years during the three months ended March 31, 2010. We did not have any income (loss) from discontinued operations for the three months ended March 31, 2009 due to the sale of our dry eye product to Bausch & Lomb in July 2007.

Liquidity and Capital Resources

To date we have incurred recurring losses, negative cash flow from operations, and have accumulated a deficit of $171.7 million from our inception through March 31, 2010. Prior to our IPO, we funded our operations through the

private placement of common stock, preferred stock 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, 2010, we had $14.2 million in cash and cash equivalents. On April 21, 2010, our Registration Statement on Form S-1 (as amended) was declared effective by the SEC for our IPO, pursuant to which we sold 6,550,000 shares of our common stock at a public offering price of $11.00 per share. We received net proceeds of approximately $68.4 million from this transaction, after deducting underwriting

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discounts and commissions. On a pro forma as adjusted basis to give effect to our IPO, as of March 31, 2010 we had approximately $65.4 million in cash and cash equivalents, which we believe is sufficient to fund our operations through the projected commercialization of Iluvien and the expected generation of revenue in 2011. The commercialization of Iluvien is dependent upon approval by the FDA, however, and we cannot be sure that Iluvien will be approved by the FDA or that, if approved, future sales of Iluvien will generate enough revenue to fund our operations beyond its commercialization. If Iluvien is not approved, or if approved, 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, we may seek to fund our operations through the sale of equity securities, strategic collaboration agreements and debt financing. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result and the terms of any new equity securities may have a preference over our common stock. If we attempt to raise additional funds through strategic collaboration agreements and debt financing, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize our product candidates or operate as a business.

For the three months ended March 31, 2010, cash used in our continuing operations of $4.6 million was primarily due to our net loss of $1.4 million increased by a non-cash gain of $3.3 million related to the change in fair value of our preferred stock conversion feature and offset by a non-cash charge of $110,000 in stock compensation and other expense. Further increasing our cash used in continuing operations were an increase in prepaid expenses and other current assets of $120,000 and a decrease in other long-term liabilities of $180,000. These uses of cash were offset by an increase in accounts payable and accrued expenses and other current liabilities of $200,000. Prepaid expenses and other current assets increased primarily due to $220,000 of advances to third-party manufacturers of Iluvien. The decrease in other long-term liabilities is due to a portion of the interest accrued on our promissory note to pSivida moving to a current liability. The increase in accounts payable and accrued and other current liabilities is primarily attributable to increases of $400,000 of clinical trial expenses, $360,000 of accrued short-term interest on the pSivida note payable, and $170,000 of professional services fees accrued for the preparation of our new drug application for Iluvien, offset by a decrease of $1.5 million of clinical trial site accruals for payments to our investigators.

For the three months ended March 31, 2009, cash used in our continuing operations of $3.5 million was primarily due to our net loss of $10.3 million offset by non-cash charges of $4.3 million related to the change in fair value of our preferred stock conversion feature, $490,000 in depreciation and amortization expense associated primarily with equipment used for the manufacture of Iluvien registration batches and $100,000 in stock compensation and other expense. Further offsetting our cash used in continuing operations were increases in accounts payable and accrued liabilities and other current liabilities of $1.4 million and other long-term liabilities of $170,000, and a decrease in prepaid expenses and other current assets of $250,000. Accounts payable and accrued liabilities and other current liabilities increased due to increases of $570,000 payable to our third-party manufacturers, $380,000 payable to our CROs and $380,000 in clinical trial expenses. The increase in other long-term liabilities is due to interest being accrued on our promissory note to pSivida. Prepaid expenses and other current assets decreased primarily due to the expensing of $70,000 of prepaid clinical trial site payments and the expensing of $150,000 of prepaid third-party manufacturing deposits and payments.

For the three months ended March 31, 2010, cash provided by our investing activities of $4.0 million was provided by our discontinued operations when we received $4.0 million from Bausch & Lomb upon the exercise by Bausch & Lomb of its option to extend the period during which it may continue to develop an allergy product acquired from us in 2006 by two years. For the three months ended March 31, 2009, there were no cash flows from our investing

activities.

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Net cash provided by our financing activities was $10.1 million for the three months ended March 31, 2010, and is primarily attributable to the net proceeds of $9.9 million received from the exercise of warrants to purchase shares of our Series C-1 preferred stock and proceeds of $150,000 from the exercise of warrants to purchase shares of our common stock. Cash flows from our financing activities for the three months ended March 31, 2009 was not material.

Contractual Obligations and Commitments

On April 27, 2010, we paid $15.2 million to pSivida to satisfy our $15.0 million note payable and all accrued interest. There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our final prospectus filed pursuant to Rule 424(b) under the Securities Act with the SEC on April 22, 2010.

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.

ITEM 3 ***Qualitative and Quantitative Disclosures about Market Risk***

We are exposed to market risk related to changes in interest rates. As of March 31, 2010, we had cash and cash equivalents of $14.2 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

We contract for the conduct of some of our clinical trials and other research and development activities with contract research organizations and investigational sites in the United States, Europe and India. We may be subject to exposure to fluctuations in foreign exchange rates in connection with these agreements. We do not hedge our foreign currency exposures. We have not used derivative financial instruments for speculation or trading purposes.

ITEM 4 ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic reports filed with the SEC is recorded, processed and summarized and reported within the time periods

specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the

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disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and no evaluation of controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Our management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Under the supervision and with the participation of the our management, including the Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2010. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 2010, the end of the period covered by this Quarterly Report on Form 10-Q, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

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 first quarter of 2010 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 1A *Risk Factors*

Our business is subject to numerous risks. We caution you that the following important factors, among others, could cause our actual results to differ materially from those expressed in forward-looking statements made by us or on our behalf in filings with the SEC, press releases, communications with investors and oral statements. Any or all of our forward-looking statements in this Quarterly Report on Form 10-Q and in any other public statements we make may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in the discussion below will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may differ materially from those anticipated in forward-looking statements. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosure we make in our reports filed with the SEC.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our lead product candidate, Iluvien, which is still under development. If we are unable to commercialize Iluvien, or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our time and financial resources in the development of Iluvien, our only product candidate in clinical development. We anticipate that in the near term our ability to generate revenues will depend solely on the successful development and commercialization of Iluvien. Based on our analysis of the month 24 clinical readout from our Phase 3 pivotal clinical trials for the use of Iluvien in the treatment of diabetic macular edema, or DME (collectively, our FAME Study), we plan to file a New Drug Application (NDA) for the low dose of Iluvien in the United States in the second quarter of 2010, followed by registration filings in certain European countries and Canada. However, we may not complete our registration filings in our anticipated time frame. Even after we complete our NDA filing, the U.S. Food and Drug Administration (FDA) may not accept our submission, may request additional information from us, including data from additional clinical trials, and, ultimately, may not grant marketing approval for Iluvien. In addition, although we believe the month 24 clinical readout from our FAME Study demonstrates that Iluvien is effective in the treatment of DME, clinical data often is susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products.

If we are not successful in commercializing Iluvien, or are significantly delayed in doing so, our business will be materially harmed and we may need to curtail or cease operations. Our ability to successfully commercialize Iluvien will depend, among other things, on our ability to:

- successfully complete our clinical trials;
- produce, through a validated process, batches of Iluvien in quantities sufficiently large to permit successful commercialization;
- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- establish commercial manufacturing arrangements with third-party manufacturers;

launch commercial sales of Iluvien; and

secure acceptance of Iluvien in the medical community and with third-party payors.

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We face heavy government regulation, and approval of Iluvien and our other product candidates from the FDA and from similar entities in other countries is uncertain.

The research, testing, manufacturing and marketing of drug products are subject to extensive regulation by U.S. federal, state and local government authorities, including the FDA, and similar entities in other countries. To obtain regulatory approval of a product, we must demonstrate to the satisfaction of the regulatory agencies that, among other things, the product is safe and effective for its intended use. In addition, we must show that the manufacturing facilities used to produce the products are in compliance with current Good Manufacturing Practice (cGMP) regulations.

The process of obtaining regulatory approvals and clearances will require us to expend substantial time and capital. Despite the time and expense incurred, regulatory approval is never guaranteed. The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the drug candidate, the disease or condition for which the drug candidate is in development and the regulations applicable to that particular drug candidate. Regulatory agencies, including those in the United States, Canada, the European Union and other countries where drugs are regulated, can delay, limit or deny approval of a drug candidate for many reasons, including that:

a drug candidate may not be safe or effective;

regulatory agencies may interpret data from preclinical and clinical testing in different ways from those which we do;

they may not approve of our manufacturing process;

they may conclude that the drug candidate does not meet quality standards for stability, quality, purity and potency; and

they may change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the United States. For example, the FDA may object to the use of a sham injection in our control arm or may not approve of certain of our methods for analyzing our trial data, including how we evaluate the risk/benefit relationship. Further, we intend to market Iluvien, and may market other product candidates, outside the United States and specifically in the European Union and Canada. Regulatory agencies within these countries will require that we obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedures within these countries can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

We plan to submit an NDA in the United States for the low dose of Iluvien in the second quarter of 2010 with 24 months of clinical data from our FAME Study, followed by registration filings in certain European countries and Canada. Consistent with recommendations regarding the appropriate population for primary analysis as described in the FDA-adopted International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidance E9, Statistical Principals for Clinical Trials, we believe that the FDA will consider the most relevant population for determining safety and efficacy to be the full data set of all 956 patients

randomized into our FAME Study, with data imputation employed using last observation carried forward, for data missing because of patients who discontinued the trial or are unavailable for follow-up (the Full Analysis Set). The primary efficacy endpoint was met with statistical significance for both the low dose and the high dose of Iluvien in both trials using the Full Analysis Set and we intend to submit an analysis based on this data set for the low dose to the FDA. However, our FAME Study protocol did not include the Full Analysis Set and provides that the primary assessment of efficacy will be based on another data set that excludes from the Full Analysis Set three patients who were

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enrolled but never treated as well as data collected for patients subsequent to their use of treatments prohibited by our FAME Study protocol (the Modified ART Data Set). Statistical significance was not achieved for either the low dose or the high dose in one trial using the Modified ART Data Set. There is no assurance that the FDA will utilize the Full Analysis Set and not the Modified ART Data Set or another data set in determining whether Iluvien is safe and effective, which could result in the FDA not granting marketing approval for Iluvien.

Regulatory agencies require carcinogenicity studies in animals to identify tumorigenic potential in animals to assess the relevant risk in humans. Based on month 18 readouts from our open-label Phase 2 human pharmacokinetic clinical trial (PK Study), which indicate that there is negligible systemic absorption of fluocinolone acetonide (FA) in patients being treated with Iluvien, we expect to obtain a waiver from these regulatory agencies from the requirement to perform carcinogenicity studies. However, we may not be able to demonstrate negligible systemic absorption of FA in our PK Study beyond 18 months or may not obtain a waiver from regulatory agencies for the requirement to perform carcinogenicity studies in animals. If we are required to perform carcinogenicity studies in animals, the approval of Iluvien could be delayed by up to 36 months.

Any delay or failure by us to obtain regulatory approvals for our product candidates could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. We have not yet received regulatory approval to market any of our product candidates in any jurisdiction.

Iluvien utilizes FA, a corticosteroid that has demonstrated undesirable side effects in the eye; therefore, the success of Iluvien will be dependent upon the achievement of an appropriate relationship between the benefits of its efficacy and the risks of its side-effect profile.

The use of corticosteroids in the eye has been associated with undesirable side effects, including increased incidence of intraocular pressure (IOP), which may increase the risk of glaucoma, and cataract formation. We have received only the month 24 clinical readout from our FAME Study and the extent of Iluvien s long-term side effect profile is not yet known. Upon review of our NDA for the low dose of Iluvien in the treatment of DME, the FDA may conclude that our FAME Study did not demonstrate that Iluvien has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. Conversely, the FDA may conclude that Iluvien s side-effect profile does not demonstrate an acceptable risk/benefit relationship in line with Iluvien s demonstrated efficacy. In the event of such conclusions, we may not receive regulatory approval from the FDA or from similar regulatory agencies in other countries.

Even if we do receive regulatory approval for Iluvien, the FDA or other regulatory agencies may impose limitations on the indicated uses for which Iluvien may be marketed, subsequently withdraw approval or take other actions against us or Iluvien that would be adverse to our business.

Regulatory agencies generally approve products for particular indications. If any such regulatory agency approves Iluvien for a limited indication, the size of our potential market for Iluvien will be reduced. For example, our potential market for Iluvien would be reduced if the FDA limited the indications of use to patients diagnosed with only clinically significant DME as opposed to DME or restricted the use to patients exhibiting IOP below a certain level at the time of treatment. Product approvals, once granted, may be withdrawn if problems occur after initial marketing. If and when Iluvien does receive regulatory approval or clearance, the marketing, distribution and manufacture of Iluvien will be subject to regulation in the United States by the FDA and by similar entities in other countries. We will need to comply with facility registration and product listing requirements of the FDA and similar entities in other countries and adhere to the FDA s Quality System Regulations. Noncompliance with applicable FDA and similar entities requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of Iluvien, total or partial suspension of production, refusal of regulatory agencies to grant approvals, withdrawal of approvals by regulatory agencies or criminal prosecution. We would also need to maintain compliance with federal, state and foreign laws regarding sales incentives, referrals and other programs.

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Iluvien may not be granted Priority Review by the FDA and, even if Iluvien receives Priority Review, Iluvien may not receive approval within the six-month review/approval cycle.

We believe that Iluvien may be eligible for Priority Review under FDA procedures. We will request Priority Review for Iluvien at the time we submit our NDA. Although the FDA has granted Priority Review to other products that treat retinal disease (including Visudyne, Retisert, Macugen, Lucentis and Ozurdex), Iluvien may not receive similar consideration. However, even in the event that Iluvien is designated for Priority Review, such a designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving Priority Review from the FDA does not guarantee approval within the six-month review/approval cycle.

Our product candidates may never achieve market acceptance even if we obtain regulatory approvals.

Even if we receive regulatory approvals for the sale of our product candidates, the commercial success of these products will depend, among other things, on their acceptance by retinal specialists, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. The degree of market acceptance of any of our product candidates will depend on a number of factors, including the demonstration of its safety and efficacy, its cost-effectiveness, its potential advantages over other therapies, the reimbursement policies of government and third-party payors with respect to the product candidate, and the effectiveness of our marketing and distribution capabilities. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our product candidates are not accepted by retinal specialists, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable.

Our ability to pursue the development and commercialization of Iluvien depends upon the continuation of our license from pSivida US, Inc.

Our license rights to pSivida US, Inc. s (pSivida s) proprietary delivery device could revert to pSivida if we (i) fail twice to cure our 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 our agreement with pSivida within 30 days after notice of such breaches or such longer period (up to 90 days) as may be reasonably necessary if the breach cannot be cured within such 30-day period; (iii) file for protection under the bankruptcy laws, make an assignment for the benefit of creditors, appoint or suffer appointment of a receiver or trustee over our property, file a petition under any bankruptcy or insolvency act or have any such petition filed against us and such proceeding remains undismissed or unstayed for a period of more than 60 days; or (iv) notify pSivida in writing of our decision to abandon our license with respect to a certain product using pSivida s proprietary delivery device. If our agreement with pSivida were terminated, we would lose our rights to develop and commercialize Iluvien, which would materially and adversely affect our business, results of operations and future prospects.

We will rely on a single manufacturer for Iluvien, a single manufacturer for the Iluvien inserter and a single active pharmaceutical ingredient formulator for Iluvien s active pharmaceutical ingredient. Our business would be seriously harmed if these third-parties are not able to satisfy our demand and alternative sources are not available.

We do not have in-house manufacturing capability and will depend completely on a single third-party manufacturer for the manufacture of the Iluvien insert (Alliance Medical Products, Inc. (Alliance)), a single third-party manufacturer for the manufacture of the Iluvien inserter (Flextronics International, Ltd. or an affiliate of Flextronics International, Ltd. (Flextronics)) and a single third-party manufacturer for the manufacture of Iluvien s active pharmaceutical ingredient (FARMABIOS S.R.L./Byron Chemical Company Inc. (FARMABIOS)). Although we have finalized a long-term agreement for the manufacture of the Iluvien insert (with Alliance), we have not yet finalized

long-term agreements for the manufacture of the Iluvien inserter (with Flextronics) or for the manufacture of Iluvien s active pharmaceutical ingredient (with FARMABIOS), and if any of the third-party manufacturers are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators, enter into favorable agreements with them

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or get them approved by the FDA in a timely manner. Further, all of our manufacturers rely on additional third-parties for the manufacture of component parts. Any inability to acquire sufficient quantities of Iluvien, the Iluvien inserter or the active pharmaceutical ingredient in a timely manner from these third-parties could delay commercial production of, and impact our ability to fulfill demand for, Iluvien. Any inability to acquire information necessary to file for regulatory approval from such third-parties could also prevent us from obtaining regulatory approval for Iluvien in a timely manner. In addition, all our third-party manufacturers are subject to cGMP and comparable requirements of foreign regulatory bodies, and certain of our manufacturers utilize production facilities outside the U.S. that are subject to local regulations with respect to those operations, and we do not have control over compliance with these regulations by our manufacturer. If our manufacturer fails to maintain compliance, the production of Iluvien could be interrupted, resulting in delays and additional costs. In addition, if the facilities of our manufacturer do not pass a pre-approval plant inspection, the FDA will not grant market approval for Iluvien.

Materials necessary to manufacture Iluvien and our other product candidates may not be available on commercially reasonable terms, or at all, which may delay the development, regulatory approval and commercialization of our product candidates.

We will rely on our manufacturers to purchase materials from third-party suppliers necessary to produce Iluvien and our other product candidates for our clinical trials. Suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently have not finalized any agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, product testing and potential regulatory approval of Iluvien and our other product candidates could be delayed, significantly affecting our ability to develop Iluvien and our other product candidates. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for Iluvien and our other product candidates, the commercial launch of Iluvien and our other product candidates would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of Iluvien and our other product candidates. Moreover, although we have finalized an agreement for the commercial production of the Iluvien insert, we currently have not yet finalized any agreements for the commercial production of the active pharmaceutical ingredient in Iluvien or the Iluvien inserter.

The manufacture and packaging of pharmaceutical products such as Iluvien are subject to the requirements of the FDA and similar foreign regulatory entities. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be materially harmed.

The manufacture and packaging of pharmaceutical products such as Iluvien and our future product candidates are regulated by the FDA and similar foreign regulatory entities and must be conducted in accordance with the FDA s cGMP and comparable requirements of foreign regulatory entities. There are a limited number of manufacturers that operate under these cGMP regulations which are both capable of manufacturing Iluvien and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, will require prior FDA review and/or approval of the manufacturing process and procedures in accordance with the FDA s cGMP regulations. There are comparable foreign requirements. This review may be costly and time consuming and could delay or prevent the launch of a product. If we elect to manufacture products in our own facility or at the facility of another third-party, we would need to ensure

that the new facility and the manufacturing process are in substantial compliance with cGMP regulations. The new facility will also be subject to pre-approval inspection. In

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addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

Furthermore, in order to obtain approval of our products, including Iluvien, by the FDA and foreign regulatory agencies, we need to complete testing on both the active pharmaceutical ingredient and on the finished product in the packaging that we propose for commercial sales. This includes testing of stability, identification of impurities and testing of other product specifications by validated test methods. In addition, we will be required to consistently produce Iluvien in commercial quantities and of specified quality in a reproducible manner and document our ability to do so. This requirement is referred to as process validation. With respect to Iluvien, although we have validated the manufacturing process at pilot scale batches, some of the steps in the manufacturing processes will need to be revalidated when we begin to manufacture commercial scale batches. If the required testing or process validation is delayed or produces unfavorable results, we may have to launch the product using smaller pilot scale batches, which may impact our ability to fulfill demand for the product.

The FDA and similar foreign regulatory bodies may also implement new standards, or change their interpretation and enforcement of existing standards and requirements, for the manufacture, packaging, or testing of products at any time. If we are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business.

Any failure or delay in completing clinical trials for our product candidates could severely harm our business.

Preclinical studies and clinical trials required to demonstrate the safety and efficacy of our product candidates are time consuming and expensive and together take several years to complete. The completion of clinical trials for our product candidates may be delayed by many factors, including:

- our inability to manufacture or obtain from third-parties materials sufficient for use in preclinical studies and clinical trials;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- unforeseen safety issues or side effects; and
- governmental or regulatory delays and changes in regulatory requirements and guidelines.

If we fail to successfully complete our clinical trials for any of our product candidates, we may not receive the regulatory approvals needed to market that product candidate. Therefore, any failure or delay in commencing or completing these clinical trials would harm our business materially.

If we are required to conduct additional clinical trials or other studies with respect to any of our product candidates beyond those that we initially contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these trials or studies are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for that product candidate, we may not be able to obtain marketing approval or we may obtain approval for indications that is not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays could allow our competitors to bring

products to market before we do and impair our ability to commercialize our products or potential products. If any of this occurs, our business will be materially harmed.

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We currently have no sales or marketing organization. If we are unable to establish satisfactory sales and marketing capabilities, we may not succeed in commercializing Iluvien.

At present, we have no sales personnel and a limited number of marketing personnel. In anticipation of receiving FDA approval for the commercial launch of Iluvien, we plan to begin hiring additional sales and marketing personnel to establish our own sales and marketing capabilities in the United States in time for our anticipated commercial launch of Iluvien. We plan to add our first sales representatives in the fourth quarter of 2010. Therefore, at the time of our commercial launch of Iluvien, assuming regulatory approval by the FDA, our sales and marketing team will have worked together for only a limited period of time.

We may not be able to establish a direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of retinal specialists to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If appropriate regulatory approvals are obtained, we intend to commercialize Iluvien and our other product candidates in international markets through collaboration arrangements with third-parties. We have not yet entered into any agreements related to the marketing of Iluvien or any of our other product candidates in international markets and we may not be able to enter into any arrangements with respect to international collaborations on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into appropriate marketing arrangements for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize Iluvien and our other product candidates in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue outside of North America would be limited.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into appropriate collaboration arrangements with third-parties, we will have difficulty commercializing Iluvien and our other product candidates, which would adversely affect our business, operating results and financial condition.

In order to establish our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of March 31, 2010, we had 21 employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a

substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize Iluvien and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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Iluvien and our other potential products may not be commercially viable if we fail to obtain an adequate level of reimbursement for these products from private insurers, the Medicare program and other third-party payors which could be affected by the recently enacted U.S. healthcare reform. The market for our products may also be limited by the indications for which their use may be reimbursed or the frequency at which they may be administered.

The availability and levels of reimbursement by governmental and other third-party payors affect the market for products such as Iluvien and others that we may develop. These third-party payors continually attempt to contain or reduce the costs of health care by challenging the prices charged for medical products and services. In the United States, we will need to obtain approvals for payment for Iluvien from private insurers, including managed care organizations, and from the Medicare program. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. These reforms could significantly reduce payments from Medicare and Medicaid over the next ten years. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling payments or the imposition of enrollment limitations on new providers, may change the availability, methods and rates of reimbursements from Medicare, private insurers and other third-party payors for Iluvien and our other potential products. Some of these changes and proposed changes could result in reduced reimbursement rates for Iluvien and our other potential products, which would adversely affect our business strategy, operations and financial results.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of Iluvien in determining whether to approve reimbursement for Iluvien and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of Iluvien from private insurers on a timely or satisfactory basis. Although drugs that are not self-administered are covered by Medicare, the Medicare program has taken the position that it can decide not to cover particular drugs if it determines that they are not reasonable and necessary for Medicare beneficiaries. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Our business could be materially adversely affected if the Medicare program, local Medicare carriers or fiscal intermediaries were to make such a determination and deny or limit the reimbursement of Iluvien. Our business also could be adversely affected if retinal specialists are not reimbursed by Medicare for the cost of the procedure in which they administer Iluvien on a basis satisfactory to the administering retinal specialists. If the local contractors that administer the Medicare program are slow to reimburse retinal specialists for Iluvien, the retinal specialists may pay us more slowly, which would adversely affect our working capital requirements.

Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which Iluvien will be reimbursed to a smaller set than we believe it is effective in treating or establish a limitation on the frequency with which Iluvien may be administered that is less often than we believe would be effective.

In some foreign countries, particularly Canada and the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In Canada, each province has a publicly funded drug plan with each having its own formulary citing specific criteria for reimbursement and prior authorization. Each provincial government except Québec considers the clinical and cost-effectiveness recommendations of the Common Drug Review performed by the Canadian Agency for Drugs and Technologies in Health. Québec has a separate drug review process that is performed by its Medication Council. In the European Union, each country has a different reviewing body that evaluates reimbursement dossiers submitted by manufacturers of new drugs and then makes recommendations as to whether or not the drug should be reimbursed. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval and product launch. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that

compares the cost-effectiveness of our products, including Iluvien, to other available therapies. If reimbursement for our products is

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unavailable, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We expect to experience pricing pressures in connection with the sale of Iluvien and our future products due to the potential healthcare reforms discussed above, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drugs is highly competitive and the commercial success of Iluvien will depend on several factors, including, but not limited to, its efficacy and side effect profile, reimbursement acceptance by private insurers and Medicare, acceptance of pricing, the development of our sales and marketing organization, an adequate payment to physicians for the insertion procedure (based on a cost assigned by the American Medical Association to the procedure, also known as a CPT code) and our ability to differentiate Iluvien from our competitors products. We will face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to Iluvien and any products that we may develop or commercialize in the future. Our competitors may develop products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. The active pharmaceutical ingredient in Iluvien is FA, which is not protected by currently valid patents. As a result, our competitors could develop an alternative formulation or delivery mechanisms to treat diseases of the eye with FA. We do not have the right to develop and sell pSivida s proprietary delivery device for indications for diseases outside of the eye or for the treatment of uveitis. Further, our agreement with pSivida permits pSivida to grant to any other party the right to use its intellectual property (i) to treat DME through an incision smaller than that required for a 25-gauge needle, unless using a corticosteroid delivered to the back of the eye, (ii) to deliver any compound outside the back of the eye unless it is to treat DME through an incision required for a 25-gauge or larger needle, or (iii) to deliver non-corticosteroids to the back of the eye, unless it is to treat DME through an incision required for a 25-gauge or larger needle.

There are no ophthalmic drug therapies approved by the FDA for the treatment of DME. Retinal specialists are currently using laser photocoagulation and off-label therapies for the treatment of DME, and may continue to use these therapies in competition with Iluvien. Additional treatments for DME are in various stages of preclinical or clinical testing. Later stage products include Lucentis, a drug sponsored by Genentech, Inc., a wholly-owned member of the Roche Group and Ozurdex, a drug sponsored by Allergan, Inc. If approved, these treatments would also compete with Iluvien. Other laser, surgical or pharmaceutical treatments for DME may also compete against Iluvien. These competitive therapies may result in pricing pressure if we receive marketing approval for Iluvien, even if Iluvien is otherwise viewed as a preferable therapy.

Many of our competitors have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated by our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields.

We currently do not have any collaborations with third-parties. We expect to depend on collaborations to develop and commercialize our products. If we are unable to identify or enter into an agreement with any material third-party collaborator, if our collaborations with any such third-party are not scientifically or commercially successful or if our agreement with any such third-party is terminated or allowed to expire, we could be adversely affected financially or our business reputation could be harmed.

Our business strategy includes entering into collaborations with corporate and academic collaborators for the research, development and commercialization of additional product candidates. We currently do not have

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any collaborations with third-parties. Areas in which we anticipate entering into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing of Iluvien outside of North America, and future product development arrangements. If we are unable to identify or enter into an agreement with any material third-party collaborator we could be adversely affected financially or our business reputation could be harmed. Any arrangements we do enter into may not be scientifically or commercially successful. The termination of any of these future arrangements might adversely affect our ability to develop, commercialize and market our products.

The success of our future collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. We expect that the risks which we face in connection with these future collaborations will include the following:

- our collaboration agreements are expected to be for fixed terms and subject to termination under various circumstances, including, in many cases, on short notice without cause;

- we expect to be required in our collaboration agreements not to conduct specified types of research and development in the field that is the subject of the collaboration. These agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in cooperation with third-parties;

- our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with our products which are the subject of their collaboration with us; and

- our collaborators may change the focus of their development and commercialization efforts. In recent years there have been a significant number of mergers and consolidations in the pharmaceutical and biotechnology industries, some of which have resulted in the participant companies reevaluating and shifting the focus of their business following the completion of these transactions. The ability of our products to reach their potential could be limited if any of our future collaborators decreases or fails to increase spending relating to such products.

Collaborations with pharmaceutical companies and other third-parties often are terminated or allowed to expire by the other party. With respect to our future collaborations, any such termination or expiration could adversely affect us financially as well as harm our business reputation.

We may not be successful in our efforts to expand our portfolio of products.

A key element of our strategy is to commercialize a portfolio of new ophthalmic drugs in addition to Iluvien. We are seeking to do so through our internal research programs and through licensing or otherwise acquiring the rights to potential new drugs and drug targets for the treatment of ophthalmic disease.

A significant portion of the research that we are conducting involves new and unproven technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates; or

potential product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

We may be unable to license or acquire suitable product candidates or products from third-parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products in the ophthalmic field. These established companies may have a competitive advantage over us due to their size,

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cash resources and greater clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable product candidates include the following:

- we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return from the product;
- companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or
- we may be unable to identify suitable products or product candidates within our areas of expertise.

Additionally, it may take greater human and financial resources to develop suitable potential product candidates through internal research programs or by obtaining rights than we will possess, thereby limiting our ability to develop a diverse product portfolio.

If we are unable to develop suitable potential product candidates through internal research programs or by obtaining rights to novel therapeutics from third-parties, our business will suffer.

We may acquire additional businesses or form strategic alliances in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third-parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may have difficulty in developing, manufacturing and marketing the products of a newly acquired company that enhances the performance of our combined businesses or product lines to realize value from expected synergies. We cannot assure that, following an acquisition, we will achieve the revenues or specific net income that justifies the acquisition.

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims, which is inherent in the manufacturing, testing and marketing of drugs and related products. If the use of one or more of our products harms people, we may be subject to costly and damaging product liability claims. We have primary product liability insurance that covers our clinical trials for a $5.0 million general aggregate limit and excess product liability insurance that covers our clinical trials for an additional $5.0 million general aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of the products that we may develop. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our product development and commercialization efforts.

In addition, our business is exposed to the risk of product liability claims related to our sale and distribution of our over-the-counter dry eye product prior to its acquisition by Bausch & Lomb Incorporated in July 2007. Our primary product liability insurance and excess product liability insurance policies cover product liability claims related to the product. To the extent this insurance is insufficient to cover any product related claims we may be exposed to significant liabilities, which may materially and adversely affect our business and financial condition.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to identify, develop and commercialize product candidates.

We are highly dependent on principal members of our management team, including C. Daniel Myers, our President and Chief Executive Officer, Susan Caballa, our Senior Vice President of Regulatory Affairs, and Kenneth Green, Ph.D., our Senior Vice President and Chief Scientific Officer. These executives each have

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significant ophthalmic and regulatory industry experience. The loss of any such executives or any other principal member of our management team, would impair our ability to identify, develop and market new products.

In addition, our growth will require us to hire a significant number of qualified technical, commercial and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

If our contract research organizations (CROs), third-party vendors and investigators do not successfully carry out their duties or if we lose our relationships with them, our development efforts with respect to Iluvien or any of our other product candidates could be delayed.

We are dependent on CROs, third-party vendors and investigators for preclinical testing and clinical trials related to our discovery and development efforts with respect to Iluvien or any of our other product candidates and we will likely continue to depend on them to assist in our future discovery and development efforts. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our development programs with respect to Iluvien or any of our other product candidates or if their performance is substandard, it will delay the development and commercialization of our product candidates. The parties with which we contract for execution of clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in identifying another comparable provider and contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current Good Laboratory Practices (cGLP) and similar foreign standards, and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed.

Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our products, when and if any of them is approved.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval pharmacovigilance, advertising and promotional activities for such product, will be subject to continual requirements, review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in:

- restrictions on such products or manufacturing processes;

- withdrawal of the products from the market;

voluntary or mandatory recall;

fines;

suspension of regulatory approvals;

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product seizure; and

injunctions or the imposition of civil or criminal penalties.

We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.

We intend to market our products outside North America with one or more commercial partners. In order to market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could harm our business materially.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit their marketability.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. Possible side effects of Iluvien include, but are not limited to, extensive blurred vision, cataracts, eye irritation, eye pain, increased IOP, which may increase the risk of glaucoma, ocular discomfort, reduced visual acuity, visual disturbance, endophthalmitis, or long-standing vitreous floaters.

In addition, if any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product, we could face one or more of the following consequences:

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;

regulatory authorities may withdraw their approval of the product;

we may be required to change the way that the product is administered, conduct additional clinical trials or change the labeling of the product; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from its sale.

Risks Related to Intellectual Property and Other Legal Matters

If we or our licensors are unable to obtain and maintain protection for the intellectual property incorporated into our products, the value of our technology and products will be adversely affected.

Our success will depend in large part on our ability or the ability of our licensors to obtain and maintain protection in the United States and other countries for the intellectual property incorporated into our products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We or our licensors may not be able to obtain additional issued patents relating to our technology. Our success will depend in part on the ability of our licensors to

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obtain, maintain (including making periodic filings and payments) and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Under our license with pSivida, pSivida controls the filing, prosecution and maintenance of all patents. Our licensors may not successfully prosecute or continue to prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing these patents, or may pursue such litigation less aggressively than we ordinarily would. Without protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Moreover, FA is an off-patent active ingredient that is commercially available in several forms including the extended release ocular implant Retisert.

Even if issued, patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products. In addition, our patents and our licensors patents may not afford us protection against competitors with similar technology.

Litigation or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our development, regulatory approval or commercialization of our product candidates.

We may not have rights under some patents or patent applications that may be infringed by our products or potential products. Third-parties may now or in the future own or control these patents and patent applications in the United States and abroad. These third-parties could bring claims against us or our collaborators that would cause us to incur substantial expenses or divert substantial employee resources from our business and, if successful, could cause us to pay substantial damages or prevent us from developing one or more product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

Several issued and pending U.S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of Iluvien. For example, one of our potential competitors holds issued and pending U.S. patents with claims covering devices for injecting an ocular implant into a patient s eye similar to the Iluvien inserter. There is also an issued U.S. patent with claims covering implanting a steroidal anti-inflammatory agent to treat an inflammation-mediated condition of the eye. If these or any other patents were held by a court of competent jurisdiction to be valid and to cover aspects of Iluvien, then the owners of such patents would be able to block our ability to commercialize Iluvien unless and until we obtain a license under such patents (which license might require us to pay royalties or grant a cross-license to one or more patents that we own), until such patents expire or unless we are able to redesign our product to avoid any such valid patents.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U.S. Patent

and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any

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litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third-parties, we could lose license rights that are important to our business.

Our licenses are important to our business, and we expect to enter into additional licenses in the future. We hold a license from pSivida under intellectual property relating to Iluvien. This license imposes various commercialization, milestone payment, profit sharing, insurance and other obligations on us. We also hold a license from Dainippon Sumitomo Pharma Co., Ltd. under patents relating to Iluvien. This license imposes a milestone payment and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the applicable license, in which event we would not be able to market products, such as Iluvien, that may be covered by such license.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure or misappropriation by third-parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third-parties. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff were previously employed by other pharmaceutical or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their drug development activities for us.

If our efforts to protect the proprietary nature of the intellectual property related to our products are not adequate, we may not be able to compete effectively in our markets.

The strength of our patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. In addition to the rights we have licensed from pSivida relating to our product candidates, we rely upon intellectual property we own relating to our products, including patents, patent applications and trade secrets. As of April 16, 2010, we owned one pending non-provisional U.S. utility patent application, one issued U.S. design patent and one patent Cooperation Treaty Application, relating to our inserter system for Iluvien. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third-parties from developing or designing around these patents.

As of April 16, 2010, the patent rights relating to Iluvien licensed to us from pSivida include three U.S. patents that expire between March 2019 and April 2020 and counterpart filings to these patents in a number of other jurisdictions.

No patent term extension will be available for any of these U.S. patents or any of our licensed U.S. pending patent applications. After these patents expire in April 2020, we will not be able to block others from marketing FA in an insert similar to Iluvien in the U.S. Moreover, it is possible that a

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third-party could successfully challenge the scope (i.e., whether a patent is infringed), validity and enforceability of our licensed patents prior to patent expiration and obtain approval to market a competitive product.

Further, the patent applications that we license or have filed may fail to result in issued patents. Some claims in pending patent applications filed or licensed by us have been rejected by patent examiners. These claims may need to be amended and, even after amendment, a patent may not be permitted to issue. Further, the existing or future patents to which we have rights based on our agreement with pSivida may be too narrow to prevent third-parties from developing or designing around these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of a breach or termination of the license agreement. Manufacturers may also seek to obtain approval to sell a generic version of Iluvien prior to the expiration of the relevant licensed patents. If the sufficiency of the breadth or strength of protection provided by the patents we license with respect to Iluvien or the patents we pursue related to another product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize Iluvien and our other product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market Iluvien and our other product candidates under patent protection would be reduced. We rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our development processes with respect to Iluvien and our other product candidates that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

Third-party claims of intellectual property infringement may prevent or delay our discovery, development and commercialization efforts with respect to Iluvien and our other product candidates.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third-parties. Third-parties may assert that we are employing their proprietary technology without authorization. In addition, at least several issued and pending U.S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of Iluvien.

Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to Iluvien, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may in the future allege that our activities infringe their patents or that we are employing their proprietary technology without authorization. We may not have identified all the patents, patent applications or published literature that affect our business either by blocking our ability to commercialize our product, by preventing the patentability of one or more aspects of our products or those of our licensors or by covering the same or similar technologies that may affect our ability to market our product. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, if at all. Any inability to obtain such a license under the applicable patents on commercially reasonable terms, or at all, may have a material adverse effect on our ability to commercialize Iluvien or other products until such patents expire.

In addition, third-parties may obtain patents in the future and claim that use of our product candidates or technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable

relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event

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of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third-parties or pay royalties, or we may be enjoined from further developing or commercializing our product candidates and technologies. In addition, even in the absence of litigation, we may need to obtain licenses from third-parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain future licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings brought by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. We face a risk of product liability exposure related to the testing of our product candidates in clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our products are inserted into the eye, and it is possible that we may be held liable for eye injuries of patients who receive our product. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products. Although we maintain primary product liability insurance and excess product liability insurance that cover our clinical trials, our aggregate coverage limit under these insurance policies is $10.0 million, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover potential liabilities. In addition, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products.

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Legislative or regulatory reform of the health care system in the United States and foreign jurisdictions may adversely impact our business, operations or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% is effective as of January 1, 2010, and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010. The PPACA also imposes an annual fee on pharmaceutical manufacturers beginning in 2011, based on the manufacturer s sale of branded pharmaceuticals and biologics (excluding orphan drugs); expands the 340B drug discount program (excluding orphan drugs) including the creation of new penalties for non-compliance; and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or doughnut hole. The law also revises the definition of average manufacturer price for reporting purposes (effective October 1, 2010), which could increase the amount of our drug rebates to states, once the provision is effective. Substantial new provisions affecting compliance also have been added, which may require us to modify our business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products candidates. We will continue to evaluate the PPACA, as amended, the implementation of regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially impact on our business over time.

In addition, in September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA s exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to ensure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

Further, in some foreign countries, including the European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Our business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations in both the United States and Canada govern the use, manufacture, storage, handling and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with

applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting

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from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, operating results and financial condition.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial and increasing losses for the foreseeable future.

We have a limited operating history. We are not currently generating revenues and we cannot estimate with precision the extent of our future losses. We do not currently have any products that have been approved for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the anticipated commercial launch of Iluvien as early as the first quarter of 2011, particularly as we increase our research, clinical development, administrative and sales and marketing activities. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. As of March 31, 2010, we have accumulated a net deficit of $171.7 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and marketed. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

Risks Relating to Our Financial Results and Need for Financing

Fluctuations in our quarterly operating results and cash flows could adversely affect the price of our common stock.

We expect our operating results and cash flows to be subject to quarterly fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including, but not limited to:

- the commercial success of our product candidates;
- the emergence of products that compete with our product candidates;
- the status of our preclinical and clinical development programs;
- variations in the level of expenses related to our existing product candidates or preclinical and clinical development programs;
- execution of collaborative, licensing or other arrangements, and the timing of payments received or made under those arrangements;
- any intellectual property infringement lawsuits to which we may become a party; and
- regulatory developments affecting our product candidates or those of our competitors,

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results and cash flows may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future

performance.

We may need additional financing in the event that we do not receive regulatory approval for Iluvien or the approval is delayed or, if approved, the future sales of Iluvien do not generate sufficient revenues to fund our operations. This financing may be difficult to obtain.

Prior to our IPO, we funded our operations through the private placement of common stock, preferred stock and convertible debt, as well as by the sale of certain assets of the non-prescription business in which

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we were previously engaged. As of March 31, 2010, we had $14.2 million in cash and cash equivalents. On a pro forma as adjusted basis to give effect to our IPO, as of March 31, 2010 we had approximately $65.4 million in cash and cash equivalents, which we believe is sufficient to fund our operations through the projected commercialization of Iluvien and the expected generation of revenue in 2011. The commercialization of Iluvien is dependent upon approval by the FDA, however, and we cannot be sure that Iluvien will be approved by the FDA in the fourth quarter of 2010, if at all, or that, if approved, future sales of Iluvien will generate enough revenue to fund our operations beyond its commercialization. In the event additional financing is needed, we may seek to fund our operations through the sale of equity securities, strategic collaboration agreements and debt financing. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result and the terms of any new equity securities may have a preference over our common stock. If we attempt to raise additional funds through strategic collaboration agreements and debt financing, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize our product candidates or operate as a business.

Risks Related to Our Common Stock

Our existing stockholders have the ability to control the outcome of matters submitted for stockholder approval and may have interests that differ from those of our other stockholders.

As of the closing of our IPO, our existing stockholders, which include certain executive officers, key employees and directors and their affiliates, beneficially owned, in the aggregate, approximately 84.71% of our outstanding common stock. As a result, these stockholders, if acting together, may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions, and this concentration of voting power may have the effect of delaying or impeding actions that could be beneficial to you, including actions that may be supported by our board of directors.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for investors.

The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. In addition, the stock markets, and in particular Nasdaq, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. These broad market and industry factors may materially harm the market price of our common stock irrespective of our operating performance. In the past, following periods of volatility in the overall market and the market price of a company s securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management s attention and resources. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

- actual or anticipated fluctuations in our results of operations;
- changes in, or our failure to meet, securities analysts expectations;
- conditions and trends in the markets we serve;

announcements of significant new services or solutions by us or our competitors, including technological innovations;

additions to or changes in key personnel;

the commencement or outcome of litigation;

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changes in market valuation or earnings of our competitors;

the trading volume of our common stock;

future sales of our equity securities;

changes in the estimation of the future size and growth rate of our markets;

legislation or regulatory policies, practices or actions; and

general economic conditions.

We currently do not intend to pay dividends on our common stock and, consequently, your only opportunity to achieve a return on your investment is if the price of our common stock appreciates.

We do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

Significant sales of our common stock could depress or reduce the market price of our common stock, or cause our shares of common stock to trade below the prices at which they would otherwise trade, or impede our ability to raise future capital.

The market price of our common stock could drop as a result of sales in the market by our existing stockholders of substantial amounts of our common stock or the perception that these sales could occur. All of the shares of common stock sold in our IPO are freely tradable without restrictions or further registration under the Securities Act, as amended, except for any shares purchased by our affiliates as defined in Rule 144 under the Securities Act. Rule 144 defines an affiliate as a person that directly or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, us and would include persons such as our directors and executive officers.

The holders of substantially all of our outstanding common stock prior to our IPO, including our officers and directors, entered into lock-up agreements with the underwriters of our IPO that, among other things, prohibit the sale of shares of our common stock during the period ending 180 days after the completion of our IPO, subject to certain exceptions, without the written consent of Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. After these lock-up agreements expire, the shares subject to these lock-up agreements will also be eligible for sale in the public market, subject in some cases to volume limitations and manner of sale requirements.

Actual or perceived significant sales of our common stock could depress or reduce the market price of our common stock, or cause our shares of common stock to trade below the prices at which they would otherwise trade, or impede our ability to raise future capital.

Future sales and issuances of our equity securities or rights to purchase our equity securities, including pursuant to our equity incentive plans, would result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders.

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Pursuant to our 2010 Equity Incentive Plan, our board of directors is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2010 Equity Incentive Plan increases each year by an amount equal to the lesser of 4% of all shares of our capital stock outstanding as of January 1st of each year, 2,000,000 shares, or such lesser number as determined by our board of directors.

Anti-takeover provisions in our charter and bylaws and in Delaware law could prevent or delay acquisition bids for us that you might consider favorable and could entrench current management.

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may deter, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders. In addition, our restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our restated certificate of incorporation and bylaws:

Authorize the issuance of blank check preferred stock that could be issued by our board of directors to thwart a takeover attempt;

Do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of our outstanding common stock to elect some directors;

Establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election;

Require that directors only be removed from office for cause;

Provide that vacancies on the board of directors, including newly created directorships, may be filled only by a majority vote of directors then in office;

Limit who may call special meetings of stockholders;

Prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders; and

Establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

Our ability to use our net operating loss carry-forwards may be limited.

At March 31, 2010, we had U.S. federal and state net operating loss (NOL) carryforwards of approximately $80.6 million and $63.8 million, respectively, which expire at various dates beginning in 2018 through 2029. Section 382 of the Internal Revenue Code limits the annual utilization of NOL carryforwards and tax credit carryforwards following an ownership change in our company. If it is determined that significant ownership changes have occurred since we generated these NOL carryforwards, we may be subject to annual limitations on the use of these NOL carryforwards under Internal Revenue Code Section 382 (or comparable provisions of state law).

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We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission and Nasdaq, have imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel are required to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time consuming and costly. These rules and regulations may make it more difficult and more expensive for us to maintain our existing director and officer liability insurance or to obtain similar coverage from an alternative provider.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), we will be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report, commencing in our annual report on Form 10-K for the year ending December 31, 2011, on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

On January 8, 2010 warrants to purchase shares of our Series C-1 preferred stock were exercised resulting in $10.0 million in gross proceeds and the issuance of 1,935,700 additional shares of Series C-1 preferred stock.

During the three months ended March 31, 2010, 39,688 warrants to purchase shares of our common stock were exercised at a weighted average exercise price of $4.03 per share resulting in gross proceeds of $148,000.

On April 21, 2010, our Registration Statement on Form S-1 was declared effective by the SEC for our IPO, pursuant to which we sold 6,550,000 shares of our common stock at a public offering price of $11.00 per share. We received net proceeds of approximately $68.4 million from this transaction, after underwriting discounts and commissions. On April 27, 2010 we used $15.2 million of the proceeds to pSivida to satisfy our $15.0 million note payable and accrued but unpaid interest. We anticipate using the remaining net proceeds from the exercise of warrants to purchase shares of our preferred stock and common stock in part as follows:

approximately $13.0 million to complete the clinical development and registration of Iluvien for DME;

$25.0 million to pay a milestone payment to pSivida upon the FDA approval of Iluvien pursuant to our agreement with pSivida; and

to commence the commercial launch of Iluvien, to continue to develop our product pipeline and for working capital and other general corporate purposes.

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our final prospectus filed pursuant to Rule 424(b) under the Securities Act with the Securities and Exchange Commission on April 22, 2010.

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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.

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.

/s/ C. Daniel Myers
C. Daniel Myers
Chief Executive Officer and President
(Principal executive officer)

June 7, 2010

/s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
Chief Financial Officer
(Principal financial and accounting officer)

June 7, 2010

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ALIMERA SCIENCES, INC.

EXHIBIT INDEX

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32.1	Certification of the Chief Executive Officer and Acting Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.

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.