

# SOMAXON PHARMACEUTICALS, INC.

## FORM 10-Q (Quarterly Report)

Filed 11/06/09 for the Period Ending 09/30/09

Address	420 STEVENS AVENUE SUITE 210 SOLANA BEACH, CA 92075
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2009

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 000-51665

**Somaxon Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-0161599**  
(I.R.S. Employer  
Identification No.)

**420 Stevens Avenue, Suite 210, Solana Beach, CA**  
(Address of principal executive offices)

**92075**  
(Zip Code)

**(858) 480-0400**  
(Registrant's telephone number, including area code)

(Former name, former address and formal fiscal year, if changed since last report)

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

The number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, as of November 2, 2009 was 23,639,469.

**SOMAXON PHARMACEUTICALS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**For the Quarter Ended September 30, 2009**  
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## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements

**SOMAXON PHARMACEUTICALS, INC.**  
(A development stage company)  
**CONDENSED BALANCE SHEETS (Unaudited)**  
(In thousands, except par value)

	<u>September 30,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 2,926	\$ 11,185
Marketable securities	2,503	3,105
Total cash, cash equivalents and marketable securities	5,429	14,290
Restricted cash	—	8,100
Other current assets	602	479
<b>Total current assets</b>	<u>6,031</u>	<u>22,869</u>
Property and equipment, net	782	788
Other assets	60	60
<b>Total assets</b>	<u>\$ 6,873</u>	<u>\$ 23,717</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 932	\$ 1,825
Accrued liabilities	1,864	1,786
Debt	—	15,000
<b>Total current liabilities</b>	<u>2,796</u>	<u>18,611</u>
Commitments and contingencies: (Note 4)		
<b>Stockholders' equity</b>		
Preferred stock, \$0.0001 par value; 10,000 shares authorized, none issued and outstanding	—	—
Common stock and additional paid-in capital; \$0.0001 par value; 100,000 shares authorized; 23,619 and 18,430 shares outstanding at September 30, 2009 and December 31, 2008, respectively	180,196	168,693
Deficit accumulated during the development stage	(176,120)	(163,596)
Accumulated other comprehensive income	1	9
<b>Total stockholders' equity</b>	<u>4,077</u>	<u>5,106</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 6,873</u>	<u>\$ 23,717</u>

*The Accompanying Notes are an Integral Part of these Unaudited Condensed Financial Statements*

**SOMAXON PHARMACEUTICALS, INC.**  
(A development stage company)  
**CONDENSED STATEMENTS OF OPERATIONS (Unaudited)**  
(In thousands, except per share amounts)

	Three months ended		Nine months ended		Period from August 14, 2003 (inception) through September 30, 2009
	September 30,		September 30,		
	2009	2008	2009	2008	
<b>Operating expenses</b>					
License fees	\$ —	\$ 153	\$ (999)	\$ 161	\$ 5,861
Research and development	506	4,594	3,497	13,619	106,894
Marketing, general and administrative	1,339	5,232	9,793	14,045	63,695
Remeasurement of Series C warrant liability	—	—	—	—	5,649
Net operating expenses	<u>1,845</u>	<u>9,979</u>	<u>12,291</u>	<u>27,825</u>	<u>182,099</u>
<b>Loss from operations</b>	<u>(1,845)</u>	<u>(9,979)</u>	<u>(12,291)</u>	<u>(27,825)</u>	<u>(182,099)</u>
Interest and other income	2	216	26	819	8,848
Interest and other (expense)	—	(549)	(259)	(768)	(2,869)
<b>Net loss</b>	<u>(1,843)</u>	<u>(10,312)</u>	<u>(12,524)</u>	<u>(27,774)</u>	<u>(176,120)</u>
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	—	(86)
<b>Net loss applicable to common stockholders</b>	<u>\$ (1,843)</u>	<u>\$ (10,312)</u>	<u>\$ (12,524)</u>	<u>\$ (27,774)</u>	<u>\$ (176,206)</u>
Basic and diluted net loss per share	\$ (0.08)	\$ (0.56)	\$ (0.63)	\$ (1.52)	
Shares used to calculate net loss per share	23,122	18,290	19,923	18,277	

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**SOMAXON PHARMACEUTICALS, INC.**  
(A development stage company)  
**CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)**  
(In thousands)

	Nine Months Ended September 30,		Period from August 14, 2003 (inception) through September 30, 2009
	2009	2008	2009
<b>Cash flows from operating activities</b>			
Net loss	\$ (12,524)	\$ (27,774)	\$ (176,120)
Adjustments to reconcile net loss to net cash used in operating activities			
Share-based expense	5,605	4,839	26,702
Depreciation	79	88	491
Amortization of investment discount or premium	(36)	166	2
Accretion of debt discount and issuance costs	—	214	1,145
Issuance of stock for license agreement	—	—	101
Remeasurement of Series C warrant	—	—	5,649
Loss on disposal of equipment	1	—	6
Changes in operating assets and liabilities			
Other current and non-current assets	(123)	(462)	(662)
Accounts payable	(893)	2,516	932
Accrued current and non-current liabilities	123	(701)	1,910
Net cash used in operating activities	<u>(7,768)</u>	<u>(21,114)</u>	<u>(139,844)</u>
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(74)	(389)	(1,279)
Purchases of marketable securities	(2,505)	(13,091)	(99,445)
Sales and maturities of marketable securities	3,134	28,419	96,940
Restricted cash	8,100	(7,500)	—
Net cash provided (used) in investing activities	<u>8,655</u>	<u>7,439</u>	<u>(3,784)</u>
<b>Cash flows from financing activities</b>			
Issue common stock and warrants, net of issuance costs	5,732	—	55,552
Issue preferred stock, net of issuance costs	—	—	90,051
Net proceeds from issuance of debt	—	14,777	14,777
Repayment of debt	(15,000)	—	(15,000)
Exercise of stock options	122	25	1,224
Purchase of treasury stock	—	(50)	(50)
Net cash provided (used) in financing activities	<u>(9,146)</u>	<u>14,752</u>	<u>146,554</u>
Increase (Decrease) in cash and cash equivalents	(8,259)	1,077	2,926
Cash and cash equivalents at beginning of the period	11,185	12,554	—
Cash and cash equivalents at end of the period	<u>\$ 2,926</u>	<u>\$ 13,631</u>	<u>\$ 2,926</u>
<b>Non-cash investing and financing activities</b>			
Accretion to redemption value of redeemable convertible preferred stock	\$ —	\$ —	\$ 86
Conversion of preferred stock into common stock upon completion of initial public offering	—	—	89,489
Committed Equity Financing Facility Warrant	—	389	389
Warrants related to Loan Agreement	44	922	966
<b>Supplemental cash flow information</b>			
Cash paid for interest	\$ 984	\$ 403	\$ 1,746

*The Accompanying Notes are an Integral Part of these Unaudited Condensed Financial Statement*

**SOMAXON PHARMACEUTICALS, INC.**  
(A development stage company)

**CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS**  
For the period from August 14, 2003 (inception) through September 30, 2009 (Unaudited)  
(In thousands, except per share amounts)

	Series C Redeemable Convertible Preferred Stock		Convertible Preferred Stock		Common Stock and Additional Paid-in Capital			Deferred Stock Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income	Total
	# Shares	\$ Amount	# Shares	\$ Amount	# Shares	# Warrants	\$ Amount				
Issue common stock for cash in August to founders at \$0.0006 per share	—	\$ —	—	\$ —	583	—	\$ —	\$ —	\$ —	\$ —	\$ —
Issue Series A convertible preferred stock for cash in August, November, and December at \$1.00 per share	—	—	2,282	2,282	—	—	—	—	—	—	2,282
Net Loss	—	—	—	—	—	—	—	—	(1,463)	—	(1,463)
<b>Balance at December 31, 2003</b>	<b>—</b>	<b>\$ —</b>	<b>2,282</b>	<b>\$ 2,282</b>	<b>583</b>	<b>—</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (1,463)</b>	<b>\$ —</b>	<b>\$ 819</b>
Issue Series A convertible preferred stock for cash in January at \$1.00 per share	—	\$ —	18	\$ 18	—	—	\$ —	\$ —	\$ —	\$ —	\$ 18
Issue Series B convertible preferred stock for cash at \$1.00 per share in April and June, net of issuance costs of \$97	—	—	23,000	22,903	—	—	—	—	—	—	22,903
Issue common stock in April at \$1.20 per share for license agreement	—	—	—	—	84	—	101	—	—	—	101
Exercise of stock options	—	—	—	—	56	—	4	—	—	—	4
Deferred compensation associated with employee stock option grants	—	—	—	—	—	—	111	(111)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	—	13	—	—	13
Consultant share-based expense	—	—	—	—	—	—	14	—	—	—	14
Net loss	—	—	—	—	—	—	—	—	(13,598)	—	(13,598)
<b>Balance at December 31, 2004</b>	<b>—</b>	<b>\$ —</b>	<b>25,300</b>	<b>\$ 25,203</b>	<b>723</b>	<b>—</b>	<b>\$ 230</b>	<b>\$ (98)</b>	<b>\$ (15,061)</b>	<b>\$ —</b>	<b>\$ 10,274</b>
Issue Series C redeemable convertible preferred stock for cash at \$1.35 per share in June and September, net of issuance costs of \$152	48,148	\$ 64,848	—	\$ —	—	—	\$ —	\$ —	\$ —	\$ —	\$ —
Series C proceeds allocated to warrant	—	(648)	—	—	—	—	—	—	—	—	—
Additional paid-in capital from the exercise of the Series C warrant	—	—	—	—	—	—	6,297	—	—	—	6,297
Accretion of Series C redeemable convertible preferred stock to redemption value	—	86	—	—	—	—	(86)	—	—	—	(86)
Issue common stock in initial public offering in December at \$11.00 per share, net of issuance costs of \$5,180	—	—	—	—	5,000	—	49,820	—	—	—	49,820
Conversion of preferred stock into common stock	(48,148)	(64,286)	(25,300)	(25,203)	12,242	—	89,489	—	—	—	64,286

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For the period from August 14, 2003 (inception) through September 30, 2009 (Unaudited)  
(In thousands, except per share amounts)

	Series C Redeemable Convertible Preferred Stock		Convertible Preferred Stock		Common Stock and Additional Paid-in Capital			Deferred Stock Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income	Total
	# Shares	\$ Amount	# Shares	\$ Amount	# Shares	# Warrants	\$ Amount				
Exercise of stock options	—	—	—	—	80	—	177	—	—	—	177
Deferred compensation associated with employee stock option grants	—	—	—	—	—	—	4,741	(4,741)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	—	1,037	—	—	1,037
Consultant share-based expense	—	—	—	—	—	—	137	—	—	—	137
Net loss	—	—	—	—	—	—	—	—	(38,487)	—	(38,487)
<b>Balance at December 31, 2005</b>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>18,045</u>	<u>—</u>	<u>\$150,805</u>	<u>\$ (3,802)</u>	<u>\$ (53,548)</u>	<u>\$ —</u>	<u>\$ 93,455</u>
Net loss	—	\$ —	—	\$ —	—	—	\$ —	\$ —	\$ (46,410)	\$ —	\$(46,410)
Unrealized gain on available-for- sale investments	—	—	—	—	—	—	—	—	—	2	2
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	(46,408)
Deferred stock compensation eliminated upon adoption of new accounting standard	—	—	—	—	—	—	(3,802)	3,802	—	—	—
Exercise of stock options	—	—	—	—	37	—	146	—	—	—	146
Share-based compensation related to employee awards	—	—	—	—	—	—	4,959	—	—	—	4,959
Consultant share-based expense	—	—	—	—	—	—	158	—	—	—	158
Vesting of early exercised stock options	—	—	—	—	—	—	47	—	—	—	47
<b>Balance at December 31, 2006</b>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>18,082</u>	<u>—</u>	<u>\$152,313</u>	<u>\$ —</u>	<u>\$ (99,958)</u>	<u>\$ 2</u>	<u>\$ 52,357</u>
Net loss	—	\$ —	—	\$ —	—	—	\$ —	\$ —	\$ (26,411)	\$ —	\$(26,411)
Unrealized gain on available-for- sale investments	—	—	—	—	—	—	—	—	—	46	46
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	(26,365)
Exercise of stock options	—	—	—	—	171	—	682	—	—	—	682
Share-based compensation related to employee awards	—	—	—	—	—	—	8,407	—	—	—	8,407
Consultant share-based expense	—	—	—	—	—	—	73	—	—	—	73
Vesting of early exercised stock options	—	—	—	—	—	—	22	—	—	—	22
Restricted stock issued in October at \$0.0001 per share	—	—	—	—	200	—	—	—	—	—	—
Restricted stock repurchased in December at \$0.0001 per share	—	—	—	—	(20)	—	—	—	—	—	—
<b>Balance at December 31, 2007</b>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>18,433</u>	<u>—</u>	<u>\$161,497</u>	<u>\$ —</u>	<u>\$ (126,369)</u>	<u>\$ 48</u>	<u>\$ 35,176</u>
Net loss	—	\$ —	—	\$ —	—	—	\$ —	\$ —	\$ (37,227)	\$ —	\$(37,227)
Unrealized (loss) on available-for- sale investments	—	—	—	—	—	—	—	—	—	(39)	(39)
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	(37,266)

**SOMAXON PHARMACEUTICALS, INC.**  
(A development stage company)

**CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS**  
For the period from August 14, 2003 (inception) through September 30, 2009 (Unaudited)  
(In thousands, except per share amounts)

	Series C Redeemable Convertible Preferred Stock		Convertible Preferred Stock		Common Stock and Additional Paid-in Capital			Deferred Stock Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income	Total
	# Shares	\$ Amount	# Shares	\$ Amount	# Shares	# Warrants	\$ Amount				
Exercise of stock options	—	—	—	—	8	—	25	—	—	—	25
Share-based compensation related to employee awards	—	—	—	—	—	—	6,283	—	—	—	6,283
Consultant share-based expense	—	—	—	—	—	—	16	—	—	—	16
Restricted stock repurchased in April at \$4.66 per share	—	—	—	—	(11)	—	(50)	—	—	—	(50)
Warrants issued in May pursuant to the Loan Agreement	—	—	—	—	—	239	922	—	—	—	922
Warrants issued in May pursuant to the Committed Equity Financing Facility	—	—	—	—	—	165	389	—	—	—	389
Financing cost of warrant issued pursuant to the Committed Equity Financing Facility	—	—	—	—	—	—	(389)	—	—	—	(389)
<b>Balance at December 31, 2008</b>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>18,430</u>	<u>404</u>	<u>\$168,693</u>	<u>\$ —</u>	<u>\$ (163,596)</u>	<u>\$ 9</u>	<u>\$ 5,106</u>
Net loss	—	\$ —	—	\$ —	—	—	\$ —	\$ —	\$ (12,524)	\$ —	\$(12,524)
Change in unrealized gain on available-for-sale investments	—	—	—	—	—	—	—	—	—	(8)	(8)
Comprehensive loss	—	—	—	—	75	—	122	—	—	—	(12,532)
Exercise of stock options	—	—	—	—	—	—	5,602	—	—	—	5,602
Share-based compensation related to employee awards	—	—	—	—	—	—	3	—	—	—	3
Consultant share-based expense	—	—	—	—	—	—	44	—	—	—	44
Warrants issued in March pursuant to loan payoff	—	—	—	—	—	200	—	—	—	—	—
Issue common stock in July at \$1.05 per share and warrants at \$0.125 per share, net of issuance costs of \$268	—	—	—	—	5,106	5,106	5,732	—	—	—	5,732
Issue common stock pursuant to vesting of restricted stock units	—	—	—	—	23	—	—	—	—	—	—
Restricted stock repurchased in July at \$0.0001 per share	—	—	—	—	(15)	—	—	—	—	—	—
<b>Balance at September 30, 2009</b>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>23,619</u>	<u>5,710</u>	<u>\$180,196</u>	<u>\$ —</u>	<u>\$ (176,120)</u>	<u>\$ 1</u>	<u>\$ 4,077</u>

*The Accompanying Notes are an Integral Part of these Unaudited Condensed Financial Statements*

**SOMAXON PHARMACEUTICALS, INC.**  
(A development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

**Note 1. Organization and Summary of Significant Accounting Policies**

***Business***

Somaxon Pharmaceuticals, Inc. (“Somaxon” or the “Company”) is a specialty pharmaceutical company focused on the in-licensing, development and commercialization of proprietary branded products and late-stage product candidates for the treatment of diseases and disorders in the central nervous system therapeutic area. Somaxon is a Delaware corporation founded on August 14, 2003 upon in-licensing its first product candidate, Silenor<sup>®</sup> (doxepin) for the treatment of insomnia. The Company is currently seeking approval of Silenor by the U.S. Food and Drug Administration (the “FDA”).

***Basis of Presentation***

The accompanying condensed balance sheet as of December 31, 2008, which has been derived from audited financial statements, and the unaudited interim condensed financial statements have been prepared by the Company in accordance with U.S. generally accepted accounting principles and the rules and regulations of the Securities and Exchange Commission (“SEC”) related to a quarterly report on Form 10-Q. Certain information and note disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to those rules and regulations, although the Company believes that the disclosures made are adequate to make the information presented not misleading. The unaudited interim condensed financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. These unaudited condensed financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2008.

The operating results presented in these unaudited condensed financial statements are not necessarily indicative of the results that may be expected for any future periods.

***Capital Resources***

Somaxon is a development stage company and has not derived any revenue from product sales to date. The Company has incurred losses from operations and negative cash flows since inception and expects to continue to incur substantial losses for the foreseeable future as it pursues approval of its New Drug Application (“NDA”) for Silenor, seeks to commercialize Silenor, if approved, and potentially pursues the development of other product candidates.

In July 2009, Somaxon raised \$6,000,000 through a private placement of 5,106,000 shares of its common stock and seven-year warrants to purchase up to 5,106,000 additional shares of its common stock. The Company believes, based on its current operating plan, that its cash, cash equivalents and marketable securities as of September 30, 2009 will be sufficient to fund its operations through the expected duration of the FDA’s review of its resubmission of the Silenor NDA and through the second quarter of 2010. The Company will need to obtain additional funds to finance its operations beyond that point, or if its operating plan is modified to accelerate commercialization activities relating to Silenor. The Company intends to obtain any additional funding it requires through strategic relationships, public or private equity or debt financings, assigning receivables or royalty rights, or other arrangements and cannot assure such funding will be available on reasonable terms, or at all. Additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

If the Company’s efforts in raising additional funds when needed are unsuccessful, it may be required to delay, scale-back or eliminate plans or programs relating to its business, relinquish some or all rights to Silenor or renegotiate less favorable terms with respect to such rights than it would otherwise choose or cease operating as a going concern. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may

**SOMAXON PHARMACEUTICALS, INC.**  
(A development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

receive less than the value at which those assets are carried on its financial statements, and it is likely that investors will lose all or a part of their investment.

These unaudited condensed financial statements do not include any adjustments that might result from the outcome of this uncertainty, except that at December 31, 2008, the Company's outstanding debt with Silicon Valley Bank and Oxford Finance Corporation was classified as a current liability, the debt discount and debt issuance costs were fully accreted, the final lump sum payment and fair value of the warrants issued in lieu of the prepayment penalty were fully accrued, and the related restricted cash collateralizing this debt was classified as a current asset. The Company repaid the entire outstanding balance of the debt in full in March 2009. For more information, see Note 5, "Financing Arrangements."

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

As described more fully in Note 4 "Commitments and Contingencies," based on the terms of a lease termination agreement entered into with the lessor in March 2009, the Company reduced its accrual for the lease termination fee from \$350,000 at December 31, 2008 to \$161,000 at March 31, 2009, and paid the termination fee in full during the second quarter of 2009. In addition, the period over which deferred rent was being accreted was shortened to end in April 2009 rather than July 2009, and the useful lives of certain fixed assets were reduced. The net effect of these changes was a benefit of \$205,000, which was recorded in the first quarter of 2009 in operating expenses.

***Fair Value***

The Company's accounts payable and accrued liabilities are presented in the financial statements at their carrying amounts, which are reasonable estimates of fair value due to their short maturities. The Company's cash equivalents, marketable securities and restricted cash are presented in the financial statements at fair value. The Company considers highly liquid investments with maturities at the time of purchase of three months or less to be cash equivalents. Marketable securities are investments with maturities at the date of purchase greater than three months. All of the Company's cash equivalents and marketable securities have liquid markets and high credit ratings. The Company classifies marketable securities as available-for-sale with unrealized holding gains or losses reported as a separate component of stockholders' equity. Changes in unrealized gains or losses are included in comprehensive loss. At September 30, 2009, the Company's investment holdings consisted of money market funds and investments in United States government debt securities. There were no realized gains or losses on sales of available-for-sale securities for the three or nine month periods ended September 30, 2009.

The fair value of financial assets and liabilities is measured under a framework that establishes "levels" which are defined as follows: Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities. Level 2 fair value is determined from quoted prices for similar items in active markets or quoted prices for identical or similar items in markets that are not active. Level 3 fair value is determined using the entity's own assumptions about the inputs that market participants would use in pricing an asset or liability.

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The fair values of the Company's cash equivalents and marketable securities as of September 30, 2009 are summarized in the following table (in thousands):

	Total Fair Value	Fair Value Determined Under:		
		(Level 1)	(Level 2)	(Level 3)
<b>Cash equivalents</b>				
Money market funds	\$ 1,384	\$ 1,384	\$ —	\$ —
U.S. government debt securities	1,509	—	1,509	—
Total cash equivalents	<u>\$ 2,893</u>	<u>\$ 1,384</u>	<u>\$ 1,509</u>	<u>\$ —</u>
<b>Marketable Securities</b>				
U.S. government debt securities	<u>\$ 2,503</u>	<u>\$ —</u>	<u>\$ 2,503</u>	<u>\$ —</u>

**Net Loss per Share**

Basic earnings per share ("EPS") excludes the effects of common stock equivalents and is calculated by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding for the period, reduced by the weighted average number of unvested common shares outstanding subject to repurchase. Diluted EPS is computed in the same manner as basic EPS, but includes the effects of common stock equivalents to the extent they are dilutive, using the treasury-stock method. For Somaxon, basic and dilutive net loss per share are equivalent because the Company incurred a net loss in all periods presented, causing any potentially dilutive securities to be anti-dilutive.

Net loss per share was determined as follows (in thousands, except per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
<b>Numerator:</b>				
Net loss	<u>\$ (1,843)</u>	<u>\$ (10,312)</u>	<u>\$ (12,524)</u>	<u>\$ (27,774)</u>
<b>Denominator:</b>				
Weighted average common shares outstanding	23,242	18,425	20,052	18,427
Weighted average unvested common shares subject to repurchase	(120)	(135)	(129)	(150)
Denominator	<u>23,122</u>	<u>18,290</u>	<u>19,923</u>	<u>18,277</u>
Basic and diluted net loss per share	<u>\$ (0.08)</u>	<u>\$ (0.56)</u>	<u>\$ (0.63)</u>	<u>\$ (1.52)</u>
<b>Weighted average anti-dilutive securities not included in diluted net loss per share calculation:</b>				
Weighted average stock options outstanding	5,477	4,504	4,670	4,097
Weighted average restricted stock units outstanding	1,289	—	1,161	—
Weighted average warrants outstanding	5,318	405	2,131	195
Weighted average unvested common shares subject to repurchase	120	135	129	150
Total weighted average anti-dilutive securities not included in diluted net loss per share	<u>12,204</u>	<u>5,044</u>	<u>8,091</u>	<u>4,442</u>

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**Income Taxes**

The Company reduces its deferred tax assets for unrecognized tax benefits which arise from uncertain tax positions. At December 31, 2008, the Company had unrecognized tax benefits of approximately \$877,000. It is expected that the amount of unrecognized tax benefits may change over the course of the year; however, because the Company's deferred tax assets are fully reserved, the Company does not expect the change to have a significant impact on its results of operations, cash flows or financial position.

The Company is subject to taxation in the United States and California. The Company is currently not under examination by the Internal Revenue Service or any other taxing authority. The Company's tax years from inception in 2003 and forward can be subject to examination by the tax authorities due to the carryforward of net operating losses and research and development credits. The Company's accounting policy is to record interest and penalties related to unrecognized tax benefits in income tax expense. No interest or penalties have been accrued as of September 30, 2009.

**Recent Accounting Pronouncements**

In June 2009, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 166 *Accounting for Transfers of Financial Assets, an Amendment to SFAS No. 140*, which was codified into the Accounting Standards Code ("ASC") under Topic 860 *Transfers and Servicing*. This accounting standard eliminates qualified special purpose entities. SFAS No. 166 provides more stringent criteria for transferred financial assets to qualify as a sale and for the de-recognition of financial assets if interest in the asset remains after the transfer. This accounting standard is effective for the first reporting period beginning after November 15, 2009. The Company does not anticipate that the adoption of SFAS No. 166 will have a material impact on the Company's financial statements.

In June 2009, the FASB issued SFAS No. 167 *Amendments to FASB Interpretation No. 46(R)*, which was codified into the ASC under Topic 810 *Consolidation*. This accounting standard requires analysis of whether variable interest entities are consolidated into a company's financial statements. Consolidation is appropriate if the company is the primary beneficiary of the variable interest entity, which occurs if the company has both: 1) the power to direct most significant activities, and 2) the potential to absorb most of the losses or benefits from performance by the variable interest entity. Ongoing reassessment as to whether a variable interest entity should be consolidated is also required. This accounting standard is effective for the first reporting period beginning after November 15, 2009. The Company does not anticipate that the adoption of SFAS No. 167 will have a material impact on the Company's financial statements.

In September 2009, the FASB issued Accounting Standards Update ("ASU") No. 2009-12, which provides guidance on measuring the fair value of an investment in an entity or holding that reports its value on a per share basis. This standard provides that the fair value of such investments may be measured at the net asset value per share so long as such net asset value is calculated in a manner consistent with accounting principles governing fair value measurement. This accounting standard is effective for the first reporting period ending after December 15, 2009. The Company does not anticipate the adoption of ASU No. 2009-12 will have a material impact on the Company's financial statements.

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**Note 2. Composition of Certain Balance Sheet Items**

**Cash, Cash Equivalents, and Marketable Securities**

Cash, cash equivalents, and marketable securities consisted of the following (in thousands):

	September 30, 2009	December 31, 2008
Cash and money market funds	\$ 1,417	\$ 11,185
U.S. government agency notes and debt securities	4,012	3,105
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$ 5,429</b>	<b>\$ 14,290</b>

At December 31, 2008, the Company had an additional \$8,100,000 of restricted cash, which consisted of \$7,500,000 relating to the Company's Loan Agreement and \$600,000 for a lease deposit on the Company's building. As discussed more fully in Note 5, "Financing Arrangements," the \$7,500,000 of restricted cash pertaining to the Loan Agreement was released upon full repayment of the underlying debt in March 2009. As discussed more fully in Note 4, "Commitments and Contingencies," the \$600,000 of restricted cash pertaining to the building lease deposit was released in April 2009 upon termination of the lease. The Company no longer has any restricted cash holdings.

**Other Current Assets**

Other current assets consisted of the following (in thousands):

	September 30, 2009	December 31, 2008
Interest receivable on marketable securities	\$ 9	\$ 32
Deposits and prepaid expenses	511	250
Other current assets	82	197
<b>Total other current assets</b>	<b>\$ 602</b>	<b>\$ 479</b>

**Property and Equipment**

Property and equipment consisted of the following (in thousands):

	September 30, 2009	December 31, 2008
Furniture and equipment	\$ 58	\$ 233
Tooling	772	700
Computer equipment	147	249
Property and equipment, at cost	977	1,182
Less: accumulated depreciation	(195)	(394)
<b>Property and equipment, net</b>	<b>\$ 782</b>	<b>\$ 788</b>

Property and equipment at September 30, 2009 reflects the disposal of fixed assets upon termination of the building lease as discussed more fully in Note 4, "Commitments and Contingencies." Within tooling is \$749,000 at September 30, 2009 pertaining to manufacturing equipment not yet placed in service. Depreciation expense was \$1,000 and \$29,000 for the three month periods ended September 30, 2009 and 2008, respectively. Depreciation expense was \$79,000 and \$88,000 for the nine month periods ended September 30, 2009 and 2008, respectively.

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**Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

	September 30, 2009	December 31, 2008
Accrued compensation and benefits	\$ 1,864	\$ 500
Accrued building lease termination fee	—	350
Interest payable	—	770
Other accrued liabilities	—	166
<b>Total accrued liabilities</b>	<b>\$ 1,864</b>	<b>\$ 1,786</b>

Within accrued compensation and benefits is \$1,659,000 of obligations owed under severance agreements as discussed more fully in Note 4, "Commitments and Contingencies." At December 31, 2008, interest payable included a \$600,000 final payment due upon repayment of the Company's debt. As discussed more fully in Note 5 "Financing Arrangements," such payment occurred in March 2009.

**Note 3. License Agreements**

Costs associated with the Company's in-license agreements are expensed as incurred since the underlying technology is in the research and development phase. The Company does not have any future minimum obligations for milestones and license payments; however, the Company is obligated to make a \$1,000,000 milestone payment to ProCom One, Inc. ("ProCom") upon approval of the Silenor NDA by the FDA. The Company is also obligated to make royalty payments upon generating product sales of Silenor.

In 2004, the Company licensed nalmefene from BioTie Therapies Corp. ("BioTie") for the treatment of impulse control and substance abuse disorders. In March 2009, the Company and BioTie entered into an agreement to mutually terminate the license agreement. Pursuant to the termination agreement, BioTie paid the Company a \$1,000,000 termination fee, which the Company included as a benefit in license fees in the first quarter of 2009. In June 2009, the Company exercised its contractual right to terminate its license agreement with the University of Miami for nalmefene for the treatment of nicotine dependence. The Company has no further commitments under the nalmefene program.

**Note 4. Commitments and Contingencies**

The Company has contracted with various consultants, drug manufacturers, and other vendors to assist in drug development work, including clinical trials and non-clinical studies, data analysis, the submission and regulatory review of the NDA, preparation for the potential commercial launch of Silenor, and for other general corporate and administrative matters. The contracts are terminable at any time, but obligate the Company to reimburse the providers for any time or costs incurred through the date of termination.

In September 2008, the Company requested that its packaging supplier for Silenor, Anderson Packaging, Inc. ("Anderson"), prepare for the manufacture of commercial launch batches of finished products of Silenor by purchasing specified quantities of certain raw materials for use in such manufacturing. At Anderson's request, in the third and fourth quarters of 2008, Somaxon submitted to Anderson written authorizations for Anderson to purchase such raw materials in an aggregate amount of \$755,000. Pursuant to the terms of the supply agreement, Anderson will receive reimbursement for such raw materials through the purchase price for the delivery of finished packaged product, which has not occurred to date as a result of the delay in FDA approval for Silenor. The Company does not have title to such raw materials and it is the Company's judgment that this is not a liability at this time. Accordingly, no such amounts have been recognized to date in the Company's financial statements at September 30, 2009.

The Company has employment agreements with its current employees that provide for severance payments and accelerated vesting for certain share-based awards if their employment with the Company is terminated under

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specified circumstances. In order to reduce expenditures, the Company terminated the employment of six employees in March 2009 and one additional employee on April 1, 2009. Each of the terminated employees entered into a separation agreement under which the Company paid two months of the employee's base salary upon separation and agreed to pay 110% of the remaining benefits to which the employee was contractually entitled upon the earliest to occur of: 1) the completion of a financing or series of financings of at least \$10,000,000 2) a change of control, or 3) an insolvency event involving the Company, in each case provided that such event occurs prior to February 15, 2010, after which the remaining severance benefits are eliminated. As of September 30, 2009, the Company had completed financing activities resulting in proceeds of \$7,122,000 of the \$10,000,000 which would trigger payment of these deferred severance obligations. The Company paid \$208,000 upon separation, and the deferred severance payments total \$597,000. Each of the affected employees entered into a consulting agreement with the Company that will expire on December 31, 2009. The former employees will continue to vest in their share-based awards during the term of the consulting agreements. In total, the Company recorded charges totaling \$1,532,000 during the first quarter of 2009 in conjunction with this reduction in workforce for severance paid, severance owed, accelerated vesting for certain share-based awards, and continued vesting of share-based awards under consulting agreements.

In April 2009, in order to further reduce expenditures, the Company undertook a process to reduce its workforce by an additional six employees, which process was completed on May 15, 2009. Each of the terminated employees entered into a separation agreement pursuant to which the Company paid two months of the employee's base salary upon separation and agreed to pay 110% of the remaining benefits to which the employee was contractually entitled upon the earliest to occur of: 1) the completion of a financing or series of financings of at least \$10,000,000 2) a change of control, 3) an insolvency event involving the Company, or 4) December 31, 2010. As of September 30, 2009, the Company had completed financing activities resulting in proceeds of \$6,122,000 of the \$10,000,000 which would trigger payment of these deferred severance obligations. The Company paid \$242,000 upon separation and paid an additional \$63,000 during the third quarter of 2009 pertaining to the reimbursement of relocation costs. At September 30, 2009, deferred severance payments totaled \$1,062,000. Each of the affected employees entered into a consulting agreement with the Company that will expire ten months after the employee's termination of employment. The former employees will continue to vest in their share-based awards during the terms of their consulting agreements. In total, the Company recorded charges during the second quarter of 2009 in conjunction with this reduction in workforce totaling \$3,000,000 for severance paid, severance owed, accelerated vesting for certain share-based awards, and continued vesting of share-based awards under consulting arrangements.

The following table summarizes the severance benefits for the terminated employees, excluding share-based charges (amounts in thousands).

	Three months ended September 30, 2009	Nine months ended September 30, 2009
Beginning severance liability	\$ 1,727	\$ —
Severance benefits incurred	—	2,177
Severance benefits paid	(63)	(513)
Change in estimate	(5)	(5)
Ending severance liability	<u>\$ 1,659</u>	<u>\$ 1,659</u>

In June 2006, the Company entered into a sublease agreement effective July 2006 to rent approximately 25,700 square feet of office space for its corporate headquarters pursuant to a lease that was to expire in February 2013. As part of the sublease agreement, the Company paid a security deposit in the form of a letter of credit in the amount of \$600,000, which was included in restricted cash. In November 2008, the Company notified the lessor that it was exercising its contractual right to terminate the sublease effective July 28, 2009, subject to the payment in June 2009 of a termination fee of \$350,000, plus any costs to restore the subleased premises to their condition prior to the Company's occupancy.

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In March 2009, the Company and the lessor entered into an agreement to terminate the sublease effective as of April 30, 2009. Under the agreement, the Company paid \$600,000 and transferred ownership of certain leasehold improvements and furniture and fixtures to the lessor in full satisfaction of all rent and other charges, including any termination fees, payable under the sublease. In exchange, the Company has no further obligations under the lease agreement. The \$600,000 payment consisted of \$439,000 of unpaid rent owed through April 30, 2009, plus termination charges of \$161,000.

When the Company initially notified the lessor in November 2008 of its intent to terminate the sublease, it fully accrued the resulting \$350,000 lease termination fee. Upon entering into the March 2009 agreement to terminate the sublease effective as of April 30, 2009, the Company reduced this accrual to reflect the \$161,000 termination charge and recognized the decrease of \$189,000 as a reduction in operating expenses. Additionally, the Company changed the period over which deferred rent was being accreted to coincide with the revised sublease termination date of April 30, 2009. Such change in the accretion period decreased rent expense by \$34,000, which was recorded during the first quarter of 2009. To reflect the transfer of ownership of certain leasehold improvements and furniture and fixtures to the lessor upon termination of the sublease, the Company modified the useful lives of these fixed assets to provide for their full depreciation by April 30, 2009, which increased depreciation expense by \$36,000 over this period.

In April 2009 the Company entered into a sublease with aAd Capital Management, L.P. ("aAd"), under which the Company is renting approximately 1,320 square feet of office space on a month-to-month basis. The Company paid aAd an upfront payment of \$12,000, which was charged to expense because payment is non-refundable unless the sublease is terminated other than by the Company. The Company pays rent of \$6,000 per month plus other pass-thru charges.

Rent expense was \$23,000 and \$262,000 for the three month periods ended September 30, 2009 and 2008, respectively. Rent expense was \$66,000 and \$789,000 for the nine month periods ended September 30, 2009 and 2008, respectively. Rent expense for the nine months ended September 30, 2009 includes the effect of the decrease in the termination fee and the change in the period over which deferred rent was being accreted.

The Company is also obligated under various operating leases for office equipment. At September 30, 2009, the future minimum lease payments under these operating leases for each of the years ended December 31, are as follows (in thousands).

Remaining three months in 2009	\$	4
2010		9
2011		7
2012		—
2013		—
Thereafter		—
Total	<u>\$</u>	<u>20</u>

**Note 5. Financing Arrangements**

*Common Stock Financing*

In July 2009, the Company issued 5,106,000 shares of common stock at \$1.05 per share and 5,106,000 warrants at \$0.125 per share for aggregate combined gross proceeds of \$6,000,000. Financing costs were \$268,000, resulting in net proceeds from the offering of \$5,732,000.

The warrants have an exercise price of \$1.155, are immediately exercisable, and expire in July 2016. The warrants do not include a net cash settlement provision or any other provisions that would create liability classification. Accordingly, the warrants are included within stockholder's equity.

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In connection with the private placement, the Company filed a registration statement with the SEC for the resale of both the shares of common stock purchased by the investors and the shares of common stock issuable upon exercise of the warrants. The Company also agreed to other customary obligations regarding registration, including matters relating to indemnification, maintenance of the registration statement and payment of expenses. The resale registration statement was declared effective by the SEC in August 2009.

The Company may be liable for liquidated damages if the Company does not maintain the effectiveness of the registration statement or the listing of the common stock on the Nasdaq Capital Market, the Nasdaq Global Market, the New York Stock Exchange or the American Stock Exchange, in each case for a period of ten consecutive days or for more than thirty days in any 365-day period. The amount of the liquidated damages is one percent per applicable ten or thirty day period, subject to an aggregate maximum of eight percent per calendar year, of the aggregate purchase price of the common stock purchased in the private placement then held by each investor that are registrable securities. The Company does not believe it is probable that it will be required to pay liquidated damages and has not recognized any amounts in its financial statements related to such potential liquidated damages.

***Loan and Security Agreement***

In May 2008, the Company entered into the Loan Agreement with Silicon Valley Bank and Oxford Finance Corporation (the "Lenders") under which the Company borrowed \$15,000,000 less debt issuance costs of \$223,000, including a \$75,000 upfront fee paid to the Lenders, for net proceeds of \$14,777,000. In March 2009, the Company repaid the remaining \$13,656,000 of outstanding principal, together with a \$600,000 final payment required under the Loan Agreement. The Company also issued to one of the Lenders 200,000 warrants to purchase common stock with a ten-year term and an exercise price of \$0.25 per share, which was the closing stock price of the Company's common stock on the date of grant. The Lenders accepted these warrants in lieu of the \$900,000 prepayment penalty required under the Loan Agreement. The fair value of these warrants on the date of issuance was determined to be \$44,000, which was calculated using the Black Scholes valuation model with a stock price of \$0.25 per share, risk free interest rate of 2.95%, volatility of 92%, a ten year term, and no dividend yield. At December 31, 2008, the debt discount and debt issuance costs were fully accreted and the final lump sum payment and fair value of the warrants issued in lieu of the prepayment penalty were fully accrued to interest expense. The Company no longer has any obligations under the Loan Agreement, and there are no further encumbrances on the Company's assets under the Loan Agreement.

Prior to repaying the debt in full in March 2009, the Company was required to maintain a minimum cash balance at Silicon Valley Bank of at least 50% of the aggregate amount outstanding under the loan. At December 31, 2008, the Company had \$15,000,000 of debt outstanding, resulting in a minimum cash balance of \$7,500,000, which was classified as restricted cash on the balance sheet. Upon repayment of the debt, all restrictions on the Company's cash related to the Loan Agreement were removed.

***Committed Equity Financing Facility***

In May 2008, the Company entered into a Committed Equity Financing Facility ("CEFF") with Kingsbridge Capital Limited ("Kingsbridge"), pursuant to which Kingsbridge committed to provide capital financing for a period of three years through the purchase of a maximum of approximately 3,672,000 newly-issued shares of the Company's common stock, subject to certain conditions and limitations.

In July 2009, the Company terminated the CEFF and no longer has any obligations under the agreements relating to the CEFF. The Company did not issue and sell any shares of its common stock under the CEFF. In connection with entering into the CEFF, the Company issued to Kingsbridge a warrant to purchase 165,000 shares of its common stock at the purchase price of \$5.4175 per share. The warrant remains exercisable, subject to certain exceptions, until November 21, 2013.

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**Note 6. Equity and Share-based Compensation**

The Company has restricted stock, restricted stock units (“RSUs”) and stock options outstanding under its equity incentive award plans. The following table summarizes non-cash compensation expense recognized in the Company’s statement of operations for the Company’s employees and directors. Share-based expense for employees and directors is based on the grant-date fair value of the award. Share-based expense for consultants is based on the fair value of the award at the time the award vests. The following tables include only share-based awards granted to employees and directors. Awards granted to consultants are discussed separately. Amounts are in thousands.

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Share-based compensation expense included in research and development expense	\$ 96	\$ 489	\$ 1,427	\$ 1,525
Share-based compensation expense included in marketing, general and administrative expense	481	947	4,175	3,313
<b>Total share-based compensation expense for employees and directors</b>	<b>\$ 577</b>	<b>\$ 1,436</b>	<b>\$ 5,602</b>	<b>\$ 4,838</b>

The following table summarizes share-based compensation expense recognized for each type of share-based award the Company has granted to its employees and directors (in thousands).

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Restricted stock	\$ —	\$ —	\$ —	\$ 273
RSUs	25	—	161	—
Stock options	552	1,436	5,441	4,565
<b>Total share-based compensation expense for employees and directors</b>	<b>\$ 577</b>	<b>\$ 1,436</b>	<b>\$ 5,602</b>	<b>\$ 4,838</b>

The effects from the termination of employment for certain individuals are included in the expense amounts presented in these tables. During the nine month period ended September 30, 2009, fifteen individuals ceased employment with the Company. Upon separation, each of the employees entered into a consulting agreement with the Company, one of which expired June 30, 2009 and the others of which expire between December 31, 2009 and March 31, 2010. The consulting agreements are not considered substantive for accounting purposes for the fourteen individuals that have agreements expiring between December 31, 2009 and March 31, 2010 because additional service is not required to be rendered by the consultants in order to continue vesting in their share-based awards. In addition, upon separation from the Company, certain individuals received accelerated vesting of their share-based awards. As a result of such non-substantive consulting arrangements and accelerated vesting, the Company recognized zero and \$2,370,000 of share-based compensation expense on the date of termination during the three and nine month periods ended September 30, 2009, respectively.

The tables above also include the effect of the Company’s one-time stock option exchange program that was completed in June 2009, and described in more detail in the “Stock Options” section of this footnote.

Not included in the tables above is share-based expense for consultant awards. The fair value of consultant awards considered probable of vesting is periodically re-measured and the related expense or income is recognized over the vesting period. Expense is not recognized for awards with performance conditions considered improbable of being achieved. Share-based expense for consultant awards recognized during the three and nine month periods ended September 30, 2009 and 2008 periods was negligible.

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**Shares Available for Future Grants under Share-Based Awards**

The Company has equity awards outstanding for the benefit of its eligible employees, directors and consultants under the 2004 Equity Incentive Award Plan (the “2004 Plan”) and the 2005 Equity Incentive Award Plan (the “2005 Plan”) which was adopted in November 2005. No additional equity awards will be granted under the 2004 Plan and all equity awards previously granted under the 2004 Plan that expire or are repurchased, forfeited, or cancelled will become available for grant under the 2005 Plan. The 2005 Plan contains an “evergreen provision” that allows annual increases in the number of shares available for issuance on the first day of each year through January 1, 2015 in an amount equal to the lesser of: (i) 2,000,000 shares, (ii) 5% of the outstanding capital stock on each January 1, or (iii) an amount determined by the Company’s board of directors.

The Company also has an employee stock purchase plan (“ESPP”) which allows employees to contribute up to 20% of their cash earnings, subject to certain maximums, to be used to purchase shares of the Company’s common stock on each semi-annual purchase date. The purchase price is equal to 95% of the market value per share on each purchase date. The Company’s ESPP is non-compensatory pursuant to the provisions of generally accepted accounting principles for share-based compensation expense. The ESPP contains an “evergreen provision” with annual increases in the number of shares available for issuance on the first day of each year through January 1, 2015 equal to the lesser of: (i) 300,000 shares, (ii) 1% of the outstanding capital stock on each January 1, or (iii) an amount determined by the Company’s board of directors. No shares have been issued under the ESPP through September 30, 2009.

The following table summarizes the number of shares available for issuance under the Company’s equity compensation plans (in thousands).

	Share-Based Awards	ESPP
<b>Shares available for issuance at December 31, 2007</b>	<b>463</b>	<b>481</b>
Increase in authorized shares	2,422	184
Grants and issuances	(2,421)	—
Forfeitures and surrendered restricted stock held in treasury	657	—
<b>Shares available for issuance at December 31, 2008</b>	<b>1,121</b>	<b>665</b>
Increase in authorized shares	922	184
Grants and issuances	(5,523)	—
Forfeitures and surrendered restricted stock held in treasury	4,898	—
<b>Shares available for issuance at September 30, 2009</b>	<b>1,418</b>	<b>849</b>

The year-to-date September 30, 2009 activity includes the effect of the Company’s one-time stock option exchange program which was completed in June 2009, and is discussed in more detail under the “Stock Options” section of this footnote. Under the stock option exchange program, 4,320,000 stock options were forfeited in exchange for 2,880,000 new stock options.

**SOMAXON PHARMACEUTICALS, INC.**  
(A development stage company)

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**Restricted Stock**

The following table summarizes the Company's restricted stock activity through September 30, 2009, including the weighted average grant date fair value per share, which is used in recording share-based compensation expense for employees and directors. Amounts are in thousands, except per share amounts.

	<u>Employee and Director</u>		<u>Consultant</u>	<u>Total</u>
	<u># Shares</u>	<u>Weighted Average Grant Date Fair Value per Share</u>	<u># Shares</u>	<u># Shares</u>
<b>December 31, 2007</b>	180	\$ 11.40	—	180
Vested	(45)	—	—	(45)
<b>December 31, 2008</b>	135	\$ 11.40	—	135
Transferred to consultant	(75)	—	75	—
Repurchased and held in treasury	—	—	(15)	(15)
<b>September 30, 2009</b>	<b>60</b>	<b>\$ 11.40</b>	<b>60</b>	<b>120</b>

At September 30, 2009, the Company had 120,000 shares of unvested restricted common stock outstanding which would vest upon approval of the Silenor NDA by the FDA. During the nine month period ended September 30, 2009, five holders of restricted stock left the Company's employ, four of which continue to be eligible to vest in their 60,000 shares under consulting agreements that expire between December 31, 2009 and March 31, 2010. One of the consulting agreements expired on June 30, 2009 and the Company repurchased the consultant's 15,000 unvested shares at par in July 2009. Such shares are held in treasury at cost.

The Company filed a resubmission of its Silenor NDA in June 2009, resulting in a PDUFA action date of December 4, 2009. While the analyses included in the Company's NDA resubmission were focused on the issues raised by the FDA in its Complete Response Letter relating to the NDA, the regulatory approval process is inherently complex, and clinical and non-clinical data is subject to varying interpretations. As a result, as of September 30, 2009, the Company does not consider FDA approval of the NDA for Silenor to be probable in accordance with the criteria used for accounting purposes. Accordingly, as of September 30, 2009, no expense was recognized for the unvested shares that would vest upon achieving this performance condition. An additional \$684,000 of non-cash compensation expense would be recognized for the 60,000 unvested shares held by current employees and members of the board of directors when the performance condition of FDA approval is considered probable and as the service period elapses for those awards.

Similarly, no expense was recognized for the 60,000 unvested shares held under consulting arrangements. At September 30, 2009, the performance condition of achieving FDA approval of the Silenor NDA was not considered probable, as such term is used for accounting purposes, and the lowest aggregate fair value of the awards was zero. For restricted stock held by consultants, when the performance condition of FDA approval is considered probable of being achieved, and as the service period elapses for those awards, the fair value at that time would be recognized as a non-cash expense.

The intrinsic value of the 120,000 aggregate shares of restricted stock outstanding was \$286,000 at September 30, 2009, based on a closing stock price on such date of \$2.38.

**Restricted Stock Units**

The following table summarizes the Company's RSU activity through September 30, 2009, including the weighted average grant date fair value per share, which is used in recording share-based compensation expense for employees and directors. Amounts are in thousands, except per share amounts.

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	Employee and Director		Consultant	Total
	# Shares	Weighted Average Grant Date Fair Value per Share	# Shares	# Shares
<b>December 31, 2007</b>	—	\$ —	—	—
Granted	539	\$ 1.21	99	638
Forfeited	—	—	—	—
<b>December 31, 2008</b>	539	\$ 1.21	99	638
Granted	814	\$ 1.31	—	814
Forfeited	—	—	(38)	(38)
Transfer to consultant	(465)	1.57	465	—
Vested	—	—	(43)	(43)
<b>September 30, 2009</b>	<b>888</b>	<b>\$ 1.11</b>	<b>483</b>	<b>1,371</b>

During the nine month period ended September 30, 2009, fifteen holders of RSUs left the Company's employ, fourteen of which continue to be eligible to vest in their RSUs under consulting agreements which expire between December 31, 2009 and March 31, 2010. One of the consulting agreements expired on June 30, 2009. Upon expiration of consulting agreements, the unvested RSUs are forfeited.

The Company's outstanding RSUs vest as follows (amounts are in thousands):

Vesting Condition	Assessment at September 30, 2009 (1)	Number of Shares Would Vest		
		Employees and Directors	Consultant	Total
Upon reaching December 31, 2009	Probable	81	42	123
FDA approval of the Silenor NDA	Not Probable	81	85	166
First commercial sale of Silenor in the U.S.	Not Probable	568	85	653
Completion of \$25 million in financing (2)	Not Probable	158	172	330
FDA approval of the Silenor NDA and rehire (3)	Not Probable	—	99	99
<b>Total unvested RSUs</b>		<b>888</b>	<b>483</b>	<b>1,371</b>

- (1) In each case, "probable" or "not probable" relates to the criteria used for accounting purposes.
- (2) Shares would vest six months after completing a financing or strategic transaction, or series of such transactions, resulting in an aggregate of \$25 million of net unrestricted cash proceeds received by December 31, 2009.
- (3) Shares would vest upon achieving both the approval of the Silenor NDA and rehire as an employee of Somaxon by December 31, 2009.

The Company filed a resubmission of its Silenor NDA in June 2009, resulting in a PDUFA action date December 4, 2009. While the analyses included in the Company's NDA resubmission were focused on the issues raised by the FDA in its Complete Response Letter relating to the NDA, the regulatory approval process is inherently complex, and clinical and non-clinical data is subject to varying interpretations. As a result, as of September 30, 2009, the Company does not consider FDA approval of the NDA for Silenor to be probable in accordance with the criteria used for accounting purposes. Accordingly, and as summarized in the table above, the only awards with a vesting condition considered probable of occurring (as such term is used for accounting purposes) as of September 30, 2009 were those that vest upon reaching the service condition of December 31, 2009. The fair value of these awards is \$201,000 which is being recognized over the requisite service period through December 31, 2009. As of September 30, 2009, \$178,000 has been expensed and \$23,000 remains to be expensed through December 31, 2009 for these awards.

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As of September 30, 2009, all of the remaining awards vest upon achieving performance conditions that are not considered probable of being achieved as such term is used for accounting purposes. Accordingly, no expense was recognized as of September 30, 2009 for the unvested shares. When the performance conditions are considered probable of being achieved, and as the service period elapses for those awards, an additional \$888,000 of non-cash compensation expense would be recognized for the RSUs held by employees and directors as the service period elapses for those awards.

Similarly, as of September 30, 2009, no expense was recognized for the unvested RSUs held under consulting arrangements with performance conditions not considered probable of being achieved as such term is used for accounting purposes, and the lowest aggregate fair value of the awards was zero. For RSU's held by consultants, when the performance conditions are considered probable of being achieved, and as the service period elapses for those awards, the fair value at that time would be recognized as a non-cash expense.

The intrinsic value of the 1,371,000 aggregate shares underlying unvested RSUs outstanding was \$3,263,000 at September 30, 2009 based on a closing stock price of \$2.38 on such date.

**Stock Options**

The following table summarizes the Company's activity for employee and director stock options (in thousands, except per share amounts).

	Shares	Weighted Average Exercise Price
<b>Outstanding at December 31, 2007</b>	<b>3,133</b>	<b>\$ 9.70</b>
Granted	1,783	\$ 4.41
Exercised	(8)	3.00
Forfeited	(646)	7.82
<b>Outstanding at December 31, 2008</b>	<b>4,262</b>	<b>\$ 7.78</b>
Granted	4,564	\$ 1.45
Exercised	(25)	2.40
Forfeited	(4,636)	7.09
Transfer to consultant awards	(115)	7.07
<b>Outstanding at September 30, 2009</b>	<b>4,050</b>	<b>\$ 1.49</b>

The table above includes the effect of the Company's one-time stock option exchange program that was completed in June 2009. Under the program, employees and directors as of March 1, 2009 were eligible to elect to exchange all of their stock options having exercise prices above \$1.00 for the grant of a lesser number of replacement awards having an exercise price of the greater of \$1.00 or the closing price of the Company's common stock on the Nasdaq Stock Market on June 9, 2009. The participants received two new options for every three options tendered for exchange. All of the eligible participants tendered some or all of their stock options for exchange. In total, 4,320,000 stock options were tendered in exchange for 2,880,000 replacement awards. The exercise price of the replacement awards was \$1.23 per share, which was the closing price of the Company's common stock on June 9, 2009. One-third of the replacement awards were vested upon grant and the remainder of the replacement stock options will vest, subject to the participant's continued service, in equal monthly installments over the following two year period such that all the shares will be fully vested in June 2011.

The fair value of the replacement award is generally expensed over the new award's vesting period, except for participants under non-substantive consulting arrangements. For these participants, the fair value for the portion of the replacement award vesting through the end of the consulting agreement was expensed immediately upon exchange. In total, the stock option exchange program, along with the immediate vesting of one-third of the replacement awards, resulted in \$658,000 of non-cash compensation expense which was recorded during the second

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quarter of 2009. The remaining incremental fair value of the replacement awards immediately after the options were exchanged of \$449,000, along with the remaining unrecognized grant date fair value from the original awards, will be recognized over the replacement award's remaining service period through June 2011 for employees and directors.

Employees and directors exercised 25,000 stock options during the nine month period ended September 30, 2009 and 8,000 stock options during the nine month period ended September 30, 2008, with an intrinsic value of \$28,000 and \$8,000, respectively. Of the 4,050,000 employee and director stock options outstanding at September 30, 2009, approximately 1,618,000 were vested and 2,432,000 were unvested. The weighted average remaining vesting term was 1.3 years and the weighted average remaining life was 6.7 years. At September 30, 2009, the Company had unrecognized non-cash compensation expense related to stock options of \$3,962,000, of which \$480,000 pertains to stock options which would vest upon achieving performance conditions not considered probable of being attained as such term is used for accounting purposes. The other \$3,482,000 of unrecognized stock option compensation expense is being expensed over the remaining vesting term of the stock options. At September 30, 2009, the intrinsic value of the Company's outstanding stock options was \$4,116,000, and the intrinsic value of the Company's vested stock options was \$1,397,000, based on closing stock price of the Company's common stock of \$2.38 per share.

In addition to the stock options held by employees and directors and under non-substantive consulting agreements, at September 30, 2009, there were 34,000 stock options outstanding and fully vested for consultants under substantive consulting agreements. For the nine month period ended September 30, 2009, approximately 49,000 stock options were exercised by consultants with an aggregate intrinsic value of \$83,000.

**Note 7. Related Party Transactions**

The Company has in-licensed certain intellectual property from ProCom (see Note 3, "License Agreements"). As part of the in-license agreement, ProCom has the right to designate one nominee for election to the Company's board of directors (Terrell Cobb, a principal of ProCom). The in-license agreement also provided for a consulting arrangement for Mr. Cobb and Dr. Neil Kavey, who is the other principal of ProCom. Under the consulting agreements, the Company paid a total of \$34,000 for both of the three month periods ended September 30, 2009 and 2008, and \$101,000 and \$136,000 for the nine month periods ended September 30, 2009 and 2008, respectively. Payments under the consulting arrangement ceased for Mr. Cobb in April 2008 and will cease in April 2010 for Dr. Kavey.

As of September 30, 2009, Mr. Cobb and Dr. Kavey held an aggregate of 119,000 outstanding stock options of which 71,000 have vested. The weighted average exercise price was \$3.57, and none of the stock options were exercised as of September 30, 2009. The Company has also granted Mr. Cobb an aggregate of 40,000 RSUs with a weighted average grant date fair value of \$0.72 per share.

The Company's outside legal counsel holds 12,000 shares of the Company's common stock as a result of purchases of preferred shares which were converted into common shares during the Company's initial public offering in December 2005. The Company paid \$89,000 and \$175,000 for legal services rendered by the Company's outside counsel for the three month periods ended September 30, 2009 and 2008, respectively and \$317,000 and \$314,000 for the nine month periods ended September 30, 2009 and 2008, respectively.

In July 2009, Somaxon raised \$6,000,000 through a private placement of 5,106,000 shares of its common stock and seven-year warrants to purchase up to 5,106,000 additional shares of its common stock. Among the investors in the private placement were a trust of which Kurt von Emster, a member of our board of directors, is a trustee and beneficiary; 2) investment funds affiliated with Jesse I. Treu, Ph.D., a member of our board of directors, and 3) investment funds affiliated with Kurt C. Wheeler, a member of our board of directors.

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**Note 8. Subsequent Events**

The Company has evaluated for disclosure in these financial statements events occurring subsequent to its Balance Sheet date through November 6, 2009, which is the date these financial statements were issued and filed with the Securities and Exchange Commission.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2008, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2008. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption "Risk Factors" in the Form 10-K for the year ended December 31, 2008 and the caption "Risk Factors" in this Form 10-Q for the quarter ended September 30, 2009.*

### Overview

#### Background

We are a specialty pharmaceutical company focused on the in-licensing, development and commercialization of proprietary branded products and late-stage product candidates for the treatment of diseases and disorders in the central nervous system therapeutic area. We submitted our New Drug Application, or NDA, for Silenor<sup>®</sup> (doxepin) for the treatment of insomnia to the U.S. Food and Drug Administration, or FDA, on January 31, 2008. The FDA accepted the NDA for filing effective March 31, 2008. Pursuant to Prescription Drug User Fee Act, or PDUFA, guidelines, the FDA was expected to complete its review and provide an action letter with respect to the NDA by December 1, 2008. However, in November 2008, the FDA indicated that its review of the NDA would be extended for up to three additional months, resulting in a new PDUFA date of February 28, 2009.

On February 25, 2009, we received a Complete Response Letter from the FDA relating to the NDA. In the Complete Response Letter, the FDA stated that the NDA could not be approved in its then-current form. The FDA raised a number of issues relating to the interpretation of the efficacy data contained in the NDA and indicated that the FDA was open to a discussion of these concerns. The FDA did not request us to conduct additional clinical trials of Silenor.

With respect to safety, the FDA noted that there were no adverse events observed that would preclude approval, but asked us to address the possibility that doxepin may prolong the cardiac QT interval. We responded by submitting to the FDA the results of our completed clinical trial of doxepin that evaluated the potential for electrocardiogram, or ECG, effects. The results of this clinical trial demonstrated that doxepin had no effect on QT interval prolongation when administered at 6 mg or under exaggerated exposure conditions of 50 mg.

We held a meeting with the FDA on April 6, 2009 to discuss the issues raised in the Complete Response Letter. In the meeting, the FDA stated that to obtain approval of a chronic insomnia treatment, objective and subjective efficacy must be established in both adult and elderly patient populations, and efficacy must be shown both at the beginning of treatment and on a persistent basis, defined to be at least one month. No additional safety issues were raised in the meeting.

Based on the feedback we received at the meeting, we conducted additional analyses of our Silenor clinical data focused on the durability of subjective sleep maintenance efficacy in adults with primary insomnia. We completed these analyses and included the results in a resubmission of the NDA to the FDA submitted on June 4, 2009. The resubmission also included the results of our completed clinical trial of doxepin that evaluated the potential for ECG effects, which were previously submitted to the doxepin investigational new drug, or IND, application. The FDA acknowledged receipt of the resubmission for review and confirmed that the review cycle will be six months, resulting in a new FDA action date of December 4, 2009.

Based on the Complete Response Letter and our meeting with the FDA, we will no longer pursue approval of a 1 mg dose of Silenor, nor will we seek approval of a statement in the indication section of the label that clinical trials of Silenor have demonstrated improvement in sleep onset.

We believe that Silenor is highly differentiated from currently available insomnia treatments, and if approved, could have significant advantages in a large and growing market. We continue to engage in discussions with third parties with the goal of securing a commercial partnership relating to the commercialization of Silenor.

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We are a development stage company and have incurred significant net losses since our inception. As of September 30, 2009, we had an accumulated deficit of \$176.1 million. We expect our accumulated deficit to continue to increase as we seek FDA approval of Silenor, seek to commercialize Silenor and potentially pursue development of other product candidates. In July 2009, we completed a private placement of 5.1 million shares of our common stock at a price of \$1.05 per share and seven-year warrants to purchase up to 5.1 million additional shares of our common stock, exercisable in cash or by net exercise at a price of \$1.155 per share, for aggregate gross proceeds of \$6.0 million and net proceeds of \$5.7 million. We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of September 30, 2009 will be sufficient to fund our operations through the expected duration of the FDA's review of our resubmission of the Silenor NDA and through the second quarter of 2010. We will need to obtain additional funds to finance our operations beyond that point, or if our operating plan is modified to accelerate commercialization activities relating to Silenor. We intend to obtain any additional funding we require through strategic relationships, public or private equity or debt financings, assigning receivables or royalty rights, or other arrangements and cannot assure that such funding will be available on reasonable terms, or at all. Additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. If we are unsuccessful in our efforts to maintain sufficient financial resources, including by raising additional funds when needed, we may be required to reduce or curtail our operations and costs, and we may be unable to continue as a going concern.

### ***Revenues***

As a development stage company, we have not generated any revenues to date, and we do not expect to generate any revenues from licensing, achievement of milestones or product sales until we enter into a strategic collaboration or are able to commercialize Silenor.

### ***License Fees***

Our license fees consist of the costs incurred to in-license our product candidates. We expense all license fees and milestone payments for acquired development and commercialization rights to operations as incurred since the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future use at this time.

In March 2009, we entered into an agreement with BioTie Therapies Corp., or BioTie, to mutually terminate our license for nalmefene for the treatment of impulse control and substance abuse disorders. Pursuant to the termination agreement, BioTie paid us a \$1.0 million termination fee which we included as an offset to our license fees. In June 2009, we exercised our contractual right to terminate our agreement with the University of Miami for nalmefene for the treatment of nicotine dependence. We have no further commitments under our nalmefene program.

### ***Research and Development Expenses***

To date, our research and development expenses consist primarily of costs associated with clinical trials managed by our contract research organizations, costs associated with our non-clinical development program for Silenor, costs associated with submitting and seeking approval of our NDA for Silenor, regulatory expenses, drug development costs, salaries and related employee benefits, as well as share-based compensation expense. For the nine months ended September 30, 2009 our most significant internal research and development costs were salaries, benefits and share-based compensation expense related to our research and development personnel, while our most significant external costs were associated with our development program for Silenor, including the conduct of our continuing two-year carcinogenicity study and the resubmission of our Silenor NDA to the FDA.

We expense all research and development expenses to operations as incurred. Although we are not currently contemplating any new clinical or non-clinical studies, we expect our research and development expenses to remain a significant component of our operating expenses in the future as we seek NDA approval for Silenor and continue our Silenor drug development program, including the conduct of our ongoing non-clinical study.

At this time, due to the risks inherent in the regulatory approval process for our NDA for Silenor, and because it is uncertain whether we will pursue other drug development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of product candidates for potential commercialization. Non-clinical and

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clinical development timelines, the probability of success and the costs of development of product candidates vary widely. The lengthy process of completing non-clinical testing, conducting clinical trials and seeking regulatory approval requires the expenditure of substantial resources. Any failure by us or delay in completing development work or obtaining regulatory approval for Silenor or any future product candidates would cause our research and development expense to increase and, in turn, have a material adverse effect on our results of operations.

We cannot forecast with any degree of certainty whether Silenor will be subject to future collaborations or other strategic transactions, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. As a result, we cannot be certain when and to what extent we will receive cash inflows from the commercialization of Silenor or collaboration agreements, if at all.

### ***Marketing, General and Administrative Expenses***

Our marketing, general and administrative expenses consist primarily of salaries, benefits, share-based compensation expense, advertising, market research costs, insurance and facility costs, and professional fees related to our marketing, administrative, finance, human resources, legal and internal systems support functions. For the nine month period ended September 30, 2009, our most significant marketing, general and administrative expenses were salaries and benefits, severance costs, professional service fees and share-based compensation expense. We would anticipate increases in marketing, general and administrative expenses if Silenor is approved by the FDA and we begin preparing for its commercialization.

### ***Interest and Other Income***

Interest and other income consist primarily of interest earned on our cash, cash equivalents, and marketable securities.

### ***Interest and Other (Expense)***

Interest and other (expense) consist primarily of interest expense incurred on our outstanding debt. In March 2009, we repaid in full our outstanding secured credit facility which resulted in no future interest expense under this loan obligation.

## **Critical Accounting Policies and Estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our condensed financial statements.

### ***Going Concern***

We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of September 30, 2009 will be sufficient to fund our operations through the expected duration of the FDA's review of our resubmission of the Silenor NDA and through the second quarter of 2010. We will need to obtain additional funds to finance our operations beyond that point, or if our operating plan is modified to accelerate commercialization activities relating to Silenor.

We have not derived any revenue from product sales to date, and we have incurred losses from operations and negative cash flows since inception. We expect our losses to continue to increase as we pursue regulatory approval of our Silenor NDA, seek to commercialize Silenor and potentially pursue development of other product candidates. We intend to obtain any additional funding we require through strategic relationships, public or private equity or debt financings, assigning receivables or royalty rights, or other arrangements and cannot assure such funding will be available on reasonable terms, or at all. Additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

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If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, we may be required to delay, scale-back or eliminate plans or programs relating to our business, relinquish some or all rights to Silenor or renegotiate less favorable terms with respect to such rights than we would otherwise choose or cease operating as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment.

The financial statements contained herein do not include any adjustments that might result from the outcome of this uncertainty, except that at December 31, 2008, our outstanding debt was classified as a current liability, the debt discount and debt issuance costs were fully accreted, the final lump sum payment and fair value of the warrants issued in lieu of the prepayment penalty were fully accrued, and the related restricted cash collateralizing this debt was classified as a current asset. We repaid the entire outstanding balance of the debt in full in March 2009.

### *License Fees*

To date, the costs related to patents and acquisition of our intellectual property have been expensed as incurred since the underlying technology associated with these expenditures is in connection with our development efforts and has no alternative future use. Certain of our license agreements contain provisions which obligate us to make milestone payments or provide other consideration if specified events occur. For instance, upon FDA approval of Silenor, we would owe a \$1.0 million milestone payment to our licensor. Determining whether these events will occur, and the timing of such events, requires judgment on the part of management. As of September 30, 2009, we have not recognized this milestone in our financial statements.

Additionally, we would capitalize costs related to our intellectual property once technological feasibility has been established, and such capitalized amounts would be amortized over the expected life of the intellectual property. Determining when technological feasibility has been achieved, and determining the related amortization period for capitalized intellectual property requires the use of estimates and subjective judgment.

### *Research and Development Expenses*

Our research and development costs are expensed as incurred and include expenditures relating to our NDA filing, drug development costs and non-clinical studies for Silenor. Measurement of research and development expenses performed by external service providers often requires judgment as we may not have been invoiced or otherwise notified of actual costs incurred, making it necessary to estimate the efforts completed to date and the related expense. The period over which services are performed, the level of services performed as of a given date and the cost of such services are often subjective determinations. Our principal vendors operate within terms of contracts which establish program costs and estimated timelines. We assess the status of our programs through regular discussions between our program management personnel and the related vendors. Based on these assessments, we determine the progress of our programs in relation to the scope of work outlined in the contracts, and recognize the related amount of expense accordingly. We adjust our estimates as actual costs become known to us. Changes in estimates could materially affect our results of operations.

### *Share-based Compensation*

Share-based compensation expense for employees and directors is recognized in the Statement of Operations over the expected service period based on the estimated grant date fair value for the award. The grant date fair value for stock options is determined using an option valuation model, such as the Black-Scholes model which we use. The grant date fair value is affected by many complex and subjective assumptions, including estimates of our future volatility, the expected term for our stock options, which takes into consideration expected option exercise behavior, and the number of shares expected to ultimately vest.

Our stock did not have a readily available market prior to our initial public offering in December 2005, creating a relatively short history from which to obtain data to estimate volatility for our stock price. Consequently, we generally estimate our expected future volatility based on comparable companies and our own stock price volatility to the extent such history is available. Our future volatility may differ from our estimated volatility at the grant date. We apply a formula-driven approach in determining the expected term for our share-based awards pursuant to guidance from Staff Accounting Bulletins, from the Securities and Exchange Commission, or SEC. Share-based compensation is based on awards expected

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to ultimately vest and is reduced for estimated forfeitures. Our estimated forfeiture rates may differ from forfeitures actually experienced, which would affect the amount of expense recognized during the period.

Certain of our share-based awards vest upon the achievement of performance conditions. Share-based compensation expense for these awards is recognized over the period from the date the performance condition is determined to be probable of occurring through the time the applicable condition is met. Determining the likelihood and timing of achieving performance conditions is a subjective judgment made by management which may affect the amount and timing of expense related to these share-based awards. For example, we filed a resubmission of our Silenor NDA in June 2009, resulting in a PDUFA action date of December 4, 2009. While the analyses included in our NDA resubmission were focused on the issues raised by the FDA in its Complete Response Letter relating to our NDA, the regulatory approval process is inherently complex, and clinical and non-clinical data is subject to varying interpretations. As a result, as of September 30, 2009, we do not consider FDA approval of the NDA for Silenor to be probable in accordance with the criteria used for accounting purposes. Accordingly, we have not recognized in our financial statements expense related to certain of our performance based awards. Share-based compensation is adjusted to reflect the value of options which ultimately vest as such amounts become known in future periods.

As a result of these subjective and forward-looking estimates, the actual value realized with respect to our share-based awards could differ significantly from the amounts recorded in our financial statements.

In June 2009, we completed a one-time stock option exchange program for employees and directors as of March 1, 2009. Under the program, eligible participants were able to elect to exchange all of their stock options having exercise prices above \$1.00 for the grant of a lesser number of replacement awards having an exercise price of the greater of \$1.00 or the closing price of our common stock on the Nasdaq Stock Market on June 9, 2009. The participants received two new options for every three options tendered for exchange. All of the eligible participants tendered some or all of their stock options for exchange. In total, 4,320,000 stock options were tendered in exchange for 2,880,000 replacement awards. The exercise price of the replacement awards was \$1.23 per share, which was the closing price of our common stock on June 9, 2009. One-third of the replacement awards were vested upon grant and the remainder of the replacement stock options will vest, subject to the participant's continued service, in equal monthly installments over the following two year period such that all the awards will be fully vested in June 2011.

The fair value of the replacement awards is generally expensed over the new award's vesting period, except for participants under non-substantive consulting arrangements. For these participants, the fair value for the portion of the replacement award vesting through the end of the consulting agreement is expensed immediately upon exchange. In total, the stock option exchange program, along with the immediate vesting of replacement awards, resulted in \$658,000 of non-cash compensation expense during the second quarter of 2009. The remaining incremental fair value of the replacement awards immediately after the options were exchanged of \$449,000, along with the remaining unrecognized grant date fair value from the original awards, will be recognized over the replacement award's remaining service period through June 2011 for employees and directors.

### *Debt and Interest Expense*

In May 2008, we entered into a loan agreement with Silicon Valley Bank and Oxford Finance Corporation under which we borrowed \$15.0 million, less debt issuance costs of \$0.2 million, for net proceeds of \$14.8 million. In connection with entering the loan agreement, we issued warrants to purchase an aggregate amount of 239,000 shares of common stock at an exercise price of \$4.385 per share. In March 2009, we repaid the entire remaining \$13.7 million principal amount of the loan, together with the final payment of \$0.6 million required under the loan agreement. As part of the repayment, we issued to Oxford Finance Corporation 200,000 warrants to purchase common stock having a ten-year term and an exercise price of \$0.25 per share, which the lenders agreed to accept in lieu of the \$0.9 million prepayment penalty required under the loan agreement. We no longer have any obligations under the loan agreement.

At December 31, 2008, we fully accreted the debt discount and debt issuance costs, and accrued the \$0.6 million final payment and the value of the warrants issued in lieu of the prepayment penalty. The debt was classified as a current liability and the related restricted cash of \$7.5 million which collateralized the debt was classified as a current asset.

**Net Operating Losses and Tax Credit Carryforwards**

We have incurred significant net operating losses to date. As of December 31, 2008, we had federal net operating loss carryforwards of \$132.4 million and California net operating loss carryforwards of \$129.6 million. Federal net operating loss carryforwards begin to expire 20 years after being generated and California net operating loss carryforwards begin to expire ten years after being generated. We also have research and development credits as of December 31, 2008 of \$4.1 million for federal purposes and \$1.9 million for California purposes. Federal research and development credits begin to expire 20 years after being generated and California research and development credits do not expire. We have fully reserved our net operating loss carryforwards and research and development credits until such time that it is more likely than not that they will be realized.

Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of our net operating loss carryforwards and tax credits may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. We determined that such an ownership change occurred as of June 30, 2005 due to various stock issuances used to finance our development activities. This ownership change resulted in limitations on the utilization of tax attributes, including net operating loss carryforwards and tax credits. We estimate that \$0.3 million of our California net operating loss carryforwards were effectively eliminated. Additionally, \$18.3 million of our federal net operating loss carryforwards, \$17.3 million of our state net operating loss carryforwards and \$0.9 million of our federal research and development credits were subject to the Section 382 limitation. A portion of the limited net operating loss carryforwards becomes available for use each year. At December 31, 2008, we estimate that \$8.6 million of our federal net operating loss carryforwards and \$7.7 million of our state net operating loss carryforwards remain limited. Net operating loss carryforwards and research and development credits generated subsequent to the ownership change are currently not subject to limitations, but could be limited in the future if additional ownership changes occur. As of November 2, 2009, we have not updated our Section 382 analysis, which was completed in conjunction with our initial public offering in December 2005.

**Results of Operations**

**Comparisons of the Three Months Ended September 30, 2009 and September 30, 2008**

*License fees.* License fees for the three months ended September 30, 2009 and 2008 were as follows (in thousands, except percentages):

	Three Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Silenor	\$ —	\$ 150	\$ (150)	(100)%
Nalmefene	—	3	(3)	(100)%
Total license fees	\$ —	\$ 153	\$ (153)	(100)%

License fees decreased \$0.2 million due to a license arrangement entered into during the third quarter of 2008 for the exclusive rights to purchase a certain ingredient used in our formulation for Silenor. We were also obligated to make immaterial annual payments to the University of Miami pertaining to our nalmefene program. In June 2009, we exercised our contractual right to terminate our license agreement with the University of Miami, resulting in no further obligations under our nalmefene program.

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*Research and Development Expense.* Research and development expense for the three months ended September 30, 2009 and 2008 were as follows (in thousands, except percentages):

	Three Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Silenor development work	\$ 113	\$ 1,632	\$ (1,519)	(93)%
Personnel and other costs	297	2,473	(2,176)	(88)%
Share-based compensation expense	96	489	(393)	(80)%
Total research and development expense	<u>\$ 506</u>	<u>\$ 4,594</u>	<u>\$ (4,088)</u>	<u>(89)%</u>

Research and development expense decreased \$4.1 million primarily due to a reduction in personnel and related costs, including share-based compensation expense, as a result of a reduction in headcount which occurred as part of our cost reduction measures. Expenses related to Silenor development work decreased due to the completion during 2008 of our cardiac study and a decrease in drug development activities as a result of the delay in the FDA approval process.

*Marketing, General and Administrative Expense .* Marketing, general and administrative expense for the three months ended September 30, 2009 and 2008 were as follows (in thousands, except percentages):

	Three Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Marketing, personnel and general costs	\$ 858	\$ 4,285	\$ (3,427)	(80)%
Share-based compensation expense	481	947	(466)	(49)%
Total marketing, general and administrative expense	<u>\$ 1,339</u>	<u>\$ 5,232</u>	<u>\$ (3,893)</u>	<u>(74)%</u>

Marketing, general and administrative expense decreased \$3.9 million due to a decrease in market preparation activities as a result of the delay in the FDA approval process for Silenor. In addition, personnel and related costs, including share-based compensation expense, decreased as a result of a reduction in headcount which occurred as part of our cost reduction measures.

*Interest and Other Income.* Interest and other income for the three months ended September 30, 2009 and 2008 was as follows (in thousands, except percentages).

	Three Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Interest and other income	<u>\$ 2</u>	<u>\$ 216</u>	<u>\$ (214)</u>	<u>(99)%</u>

Interest and other income decreased \$0.2 million due to lower average cash and marketable security balances as a result of our continued net operating losses and repayment of our debt in March 2009, as well as lower interest rates earned on our cash and marketable securities compared to the prior year.

*Interest and Other (Expense).* Interest and other (expense) for the three months ended September 30, 2009 and 2008 was as follows (in thousands, except percentages).

	Three Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Interest and other (expense)	<u>\$ —</u>	<u>\$ (549)</u>	<u>\$ 549</u>	<u>(100)%</u>

Interest and other (expense) decreased \$0.5 million to zero due to our repayment in full of the outstanding balance of our debt facility in March 2009. We will not incur additional interest expense on this debt going forward.

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### Comparisons of the Nine Months Ended September 30, 2009 and September 30, 2008

*License fees.* License fees for the nine months ended September 30, 2009 and 2008 were as follows (in thousands, except percentages):

	Nine Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Silenor	\$ —	\$ 150	\$ (150)	(100)%
Nalmefene	(999)	11	(1,010)	(9,182)%
Total license fees	<u>\$ (999)</u>	<u>\$ 161</u>	<u>\$ (1,160)</u>	<u>(720)%</u>

License fees decreased \$1.2 million primarily due to the termination of our license agreement with BioTie for nalmefene in March 2009. Pursuant to the termination agreement, BioTie paid us a \$1.0 million termination fee which we included as a reduction of license fees. In addition, during the third quarter of 2008, we paid \$0.2 million under a license arrangement for the exclusive rights to purchase a certain ingredient used in our formulation for Silenor. We were also obligated to make immaterial annual payments to the University of Miami pertaining to our nalmefene program. In June 2009, we exercised our contractual right to terminate our license agreement with the University of Miami, resulting in no further obligations under our nalmefene program.

*Research and Development Expense.* Research and development expense for the nine months ended September 30, 2009 and 2008 were as follows (in thousands, except percentages):

	Nine Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Silenor development work	\$ 583	\$ 5,933	\$ (5,350)	(90)%
Personnel and other costs	1,484	6,160	(4,676)	(76)%
Share-based compensation expense	1,430	1,526	(96)	(6)%
Total research and development expense	<u>\$ 3,497</u>	<u>\$ 13,619</u>	<u>\$ (10,122)</u>	<u>(74)%</u>

Research and development expense decreased \$10.1 million primarily due to a decrease in drug development activities for Silenor as a result of the delay in the FDA approval process and the completion during 2008 of our cardiac study for Silenor. Personnel and other costs decreased as a result of a reduction in headcount, which occurred as part of our cost reduction measures. This reduction in headcount also caused a decrease in share-based compensation expense, but this decrease was partially offset by share-based compensation expense incurred in conjunction with our one-time stock option exchange program in June 2009, and accelerated vesting and continued vesting under consulting arrangements for certain employees whose employment was terminated during 2009 and which were considered non-substantive for accounting purposes.

*Marketing, General and Administrative Expense .* Marketing, general and administrative expense for the nine months ended September 30, 2009 and 2008 were as follows (in thousands, except percentages):

	Nine Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Marketing, personnel and general costs	\$ 5,619	\$ 10,732	\$ (5,113)	(48)%
Share-based compensation expense	4,174	3,313	861	26%
Total marketing, general and administrative expense	<u>\$ 9,793</u>	<u>\$ 14,045</u>	<u>\$ (4,252)</u>	<u>(30)%</u>

Marketing, general and administrative expense decreased \$4.3 million primarily due to a reduction in market preparation activities as a result of the delay in the FDA approval process for Silenor. In addition, personnel and related costs decreased as a result of our cost reduction measures, including our reduction in headcount and our move to a smaller corporate facility. The decrease in personnel costs from the reduction in workforce was partially offset by expenses

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incurred in conjunction with severance arrangements. Share-based compensation expense increased due to our one-time stock option exchange program in June 2009 and share-based compensation expense from accelerated vesting and continued vesting under non-substantive consulting arrangements for certain employees whose employment was terminated during 2009. This increase in share-based compensation expense was partially offset by a decrease in share-based compensation expense from our reduction in headcount.

*Interest and Other Income.* Interest and other income for the nine months ended September 30, 2009 and 2008 was as follows (in thousands, except percentages).

	Nine Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Interest and other income	<u>\$ 26</u>	<u>\$ 819</u>	<u>\$ (793)</u>	<u>(97)%</u>

Interest and other income decreased \$0.8 million due to lower average cash and marketable security balances as a result of our continued net operating losses and repayment of our debt in March 2009, as well as lower interest rates earned on our cash and marketable securities compared to the prior year.

*Interest and Other (Expense).* Interest and other (expense) for the nine months ended September 30, 2009 and 2008 was as follows (in thousands, except percentages).

	Nine Months Ended September 30,		Change	
	2009	2008	Dollar	Percent
Interest and other (expense)	<u>\$ (259)</u>	<u>\$ (768)</u>	<u>\$ 509</u>	<u>(66)%</u>

Interest and other (expense) decreased \$0.5 million due to our repayment in full of the outstanding balance of our debt facility in March 2009. We will not incur additional interest expense on this debt going forward.

## Liquidity and Capital Resources

Since inception, our operations have been financed primarily through the private placement of equity securities, our initial public offering and debt in the form of our secured credit facility, which has since been fully repaid. Through September 30, 2009, we have received net proceeds of \$90.0 million from the sale of shares of our preferred stock and net proceeds of \$56.8 million through sales of our common stock, including the exercise of stock options.

As of September 30, 2009, we had \$5.4 million in cash, cash equivalents and marketable securities. In July 2009, we completed a private placement of 5.1 million shares of our common stock at a price of \$1.05 per share and seven-year warrants to purchase up to 5.1 million additional shares of our common stock, exercisable in cash or by net exercise at a price of \$1.155 per share, for aggregate gross proceeds of \$6.0 million and net proceeds of \$5.7 million. We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of September 30, 2009 will be sufficient to fund our operations through the expected duration of the FDA's review of our resubmission of the Silenor NDA and through the second quarter of 2010. We will need to obtain additional funds to finance our operations beyond that point, or if our operating plan is modified to accelerate commercialization activities relating to Silenor.

We have invested a substantial portion of our available cash in money market funds and U.S. government debt securities. All of our investments in money market funds and U.S. government debt securities continue to be highly rated, highly liquid and have readily determinable fair values. As a result, none of our securities are considered to be impaired. We have established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include but are not limited to the following:

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- the costs of seeking regulatory approval of Silenor, including any clinical studies or other work required to achieve such approval, as well as the timing of such activities and approval;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of establishing or contracting for sales and marketing and other commercial capabilities, if required;
- the extent to which we acquire or in-license new products, technologies or businesses;
- the rate of progress and cost of our non-clinical studies, clinical trials and other development activities;
- the scope, prioritization and number of development programs we pursue;
- the effect of competing technological and market developments; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

### *Cash Flows*

We expect to continue to incur losses and have negative cash flows from operations for the foreseeable future as we pursue NDA approval for Silenor, seek to commercialize Silenor and potentially pursue development of other product candidates. For the nine months ended September 30, 2009, net cash used in operating activities was \$7.8 million, compared to \$21.1 million for the nine months ended September 30, 2008. The decrease in net cash used in operating activities was primarily due to a decrease in our net loss as we implemented cost reduction measures in response to the delay in the approval process for Silenor, concluded our cardiac study of Silenor in 2008, and received \$1.0 million from the termination of our nalmefene license with BioTie in March 2009.

Our independent auditors' report for the year ended December 31, 2008 included an explanatory paragraph stating that our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which these assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment.

We cannot be certain if, when, or to what extent we will receive cash inflows from the commercialization of Silenor or any other product candidate that we may develop. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources and through strategic transactions, public or private equity or debt financings, assigning receivables or royalty rights, or other arrangements.

However, we may not be successful in obtaining required additional financing when needed. If available, financing may not be obtained on terms favorable to us or our stockholders. We also may not be successful in entering into strategic collaboration agreements, or in receiving milestone or royalty payments under those agreements. If we are unsuccessful in raising additional funds when needed, we may be required to delay, scale-back or eliminate development plans or programs relating to our business, relinquish some or all rights to Silenor or renegotiate less favorable terms with respect to such rights than we would otherwise choose or cease operating as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, 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 operate our business.

We have an effective shelf registration statement on Form S-3 on file with the SEC. The effectiveness of this registration statement will expire in December 2009, but we have filed a new shelf registration statement covering the unsold securities included in such registration statement. Under the rules and regulations of the SEC, because we filed the replacement registration statement prior to the expiration of the currently-effective registration statement, we expect that there will be no interruption in our eligibility to use the shelf registration statements to obtain additional financings from

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time to time. However, our ability to obtain such additional financing will still be subject to the SEC's rules and regulations relating to eligibility to use Form S-3. Under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than \$75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements will be limited to an aggregate of one-third of our public float. As of November 2, 2009, our public float was 12.5 million shares, the value of which was \$25.5 million based upon the closing price of our common stock of \$2.04 on such date. The value of one-third of our public float calculated on the same basis was \$8.5 million.

As a result of recent volatility in the capital markets, the cost and availability of financing has been and may continue to be adversely affected. Concern about the stability of the markets in general and the strength of counterparties specifically has led many lenders and institutional investors to reduce and in some cases cease to provide funding to borrowers. Any continued turbulence in the U.S. and international markets and economies may adversely affect our ability to obtain additional financing on terms acceptable to us, or at all. If these market conditions continue, they may limit our ability to access the capital markets to meet liquidity needs.

In response to the FDA's delay of the PDUFA date for Silenor in November 2008, the Complete Response Letter we received from the FDA in February 2009, and our meeting with the FDA in April 2009, we implemented certain cost reduction measures. From December 2008 through May 2009, we completed a reduction in our workforce which eliminated employment for 36 employees in aggregate, resulting in our current six full time employees. In addition, in November 2008, our Board of Directors amended the Director Compensation Policy to provide that non-employee directors receive their quarterly retainers for service on the Board of Directors or committees thereof and their fees for attending meetings of the Board and committees thereof in restricted stock units, or RSUs, under our 2005 Equity Incentive Award Plan in lieu of cash compensation. The compensation arrangement of David Hale, our Executive Chairman of the Board, was also amended in November 2008 so that his cash compensation for such role is payable in RSUs. Mr. Hale has since reassumed his position as our non-Executive Chairman of the Board effective June 9, 2009, and as such he is compensated for his services in RSUs under the Director Compensation Policy. In addition, we did not make a cash bonus award under our 2008 Incentive Plan. We have been and will continue working with certain of our suppliers and vendors to manage our cash expenditures relating to our operations.

### *Common Stock Financing*

In July 2009, we completed a private placement of 5.1 million shares of our common stock at a price of \$1.05 per share and warrants to purchase up to 5.1 million additional shares of our common stock, exercisable in cash or by net exercise at a price of \$1.155 per share, for gross proceeds of \$6.0 million and net proceeds of \$5.7 million. The warrants are immediately exercisable and expire in July 2016.

In connection with the private placement, we filed a registration statement with the SEC for the resale of both the shares of common stock purchased by the investors and the shares of common stock issuable upon exercise of the warrants. We also agreed to other customary obligations regarding registration, including matters relating to indemnification, maintenance of the registration statement and payment of expenses. The resale registration statement was declared effective by the SEC in August 2009.

We may be liable for liquidated damages if we do not maintain the effectiveness of the registration statement or the listing of the common stock on the Nasdaq Capital Market, the Nasdaq Global Market, the New York Stock Exchange or the American Stock Exchange, in each case for a period of ten consecutive days or for more than thirty days in any 365-day period. The amount of the liquidated damages is one percent per applicable ten or thirty day period, subject to an aggregate maximum of eight percent per calendar year, of the aggregate purchase price of the common stock purchased in the private placement then held by each investor that are registrable securities. We do not believe it is probable we will be required to pay liquidated damages, and we have not recognized any amounts in our financial statements related to such potential liquidated damages.

### *Loan and Security Agreement*

In March 2009, we repaid the entire remaining \$13.7 million principal amount under our Loan Agreement with Silicon Valley Bank and Oxford Finance Corporation, together with the final payment of \$0.6 million required under the Loan Agreement. In May 2008, we entered into that agreement under which we borrowed \$15.0 million, less debt issuance costs

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of \$0.2 million, for net proceeds of \$14.8 million. In connection with the repayment, we issued to Oxford Finance Corporation 200,000 warrants to purchase common stock having a ten-year term and an exercise price of \$0.25, which the lenders agreed to accept in lieu of the \$0.9 million prepayment penalty required under the Loan Agreement. We no longer have any obligations under the Loan Agreement.

### *Committed Equity Financing Facility*

In May 2008, we entered into a Committed Equity Financing Facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, pursuant to which Kingsbridge committed to provide capital financing for a period of three years through the purchase of a maximum of 3,672,000 newly-issued shares of our common stock, subject to certain conditions and limitations as set forth in the common stock purchase agreement. We did not issue and sell any shares of our common stock under the CEFF. In July 2009, we terminated the CEFF and no longer have any obligations under the agreements relating to the CEFF. In connection with entering into the CEFF, we issued to Kingsbridge a warrant to purchase 165,000 shares of our common stock at the purchase price of \$5.4175 per share. The warrant remains exercisable, subject to certain exceptions, until November 21, 2013.

### *Contractual Obligations*

We have entered into license agreements to acquire the rights to develop and commercialize our product candidate. Pursuant to these agreements, we obtained exclusive, sub-licenseable rights to the patents and know-how for certain indications. We generally are required to make upfront payments as well as additional payments upon the achievement of specific development and regulatory approval milestones. We are also obligated to pay royalties under the agreements until the later of the expiration of the applicable patent or the applicable last date of market exclusivity following the first commercial sale.

The following table describes our commitments to settle contractual obligations in cash as of September 30, 2009 (in thousands):

	Payments Due By Period				Total
	Remainder of 2009	2010 through 2011	2012 through 2013	After 2013	
Operating lease obligations	4	16	—	—	20
Minimum payments under license agreements	—	—	—	—	—
Non-cancellable purchase orders	—	—	—	—	—
Total	<u>\$ 4</u>	<u>\$ 16</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 20</u>

In March 2009, we reduced our operating lease obligations relating to our office space by entering into an agreement to terminate our building sublease with Avnet, Inc., or Avnet, effective as of April 30, 2009. Under the agreement, we agreed to pay Avnet \$0.6 million and transfer ownership to certain leasehold improvements and furniture and fixtures in full satisfaction of all rent and other charges, including any termination fees, payable under the sublease. As a result, we have no further obligations under this lease agreement.

In April 2009, we entered into a sublease with aAd Capital Management, L.P., or aAd, under which we are renting approximately 1,320 square feet of office space on a month-to-month basis. We paid aAd an upfront payment of \$12,000, and pay \$6,000 per month for rent plus other pass-thru charges for utilities. The upfront payment is non-refundable unless the sublease is terminated other than by us.

In March 2009, we and BioTie entered into an agreement to mutually terminate our license agreement for nalmefene. Pursuant to this agreement, BioTie paid us a \$1.0 million termination fee. In June 2009, we exercised our contractual right to terminate our license agreement with the University of Miami. As a result, we have no further minimum payments under license agreements.

We are obligated to make a milestone payment of \$1.0 million to ProCom One Inc. upon approval by the FDA of our NDA for Silenor, and we are also obligated to make revenue-based royalty payments. These milestone and royalty

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payments are not included in the table above because we cannot at this time determine when or if the related milestone will be achieved or the events triggering the commencement of payment obligations will occur.

We have contracted with various consultants, drug manufacturers, and other vendors to assist in drug development work, including clinical trials and non-clinical studies, data analysis, the submission and regulatory review of our NDA, preparation for the potential commercial launch of Silenor, and for other general corporate and administrative matters. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination.

In September 2008, we requested that our packaging supplier for Silenor, Anderson Packaging, Inc., or Anderson, prepare for the manufacture of commercial launch batches of finished products of Silenor by purchasing specified quantities of certain raw materials for use in such manufacturing. At Anderson's request, in the third and fourth quarters of 2008, we submitted to Anderson written authorizations for Anderson to purchase such raw materials in an aggregate amount of \$0.8 million. Pursuant to the terms of the supply agreement, Anderson will receive reimbursement for such raw materials through the purchase price for the delivery of finished packaged product, which has not occurred to date as a result of the delay in the FDA approval process for Silenor. We do not have title to such raw materials and it is our judgment that this is not a liability at this time. Accordingly, no such amounts have been recognized to date in our financial statements at September 30, 2009.

We have employment agreements with each of our current employees that provide for severance payments and accelerated vesting for certain share-based awards if their employment with us is terminated under specified circumstances. In order to reduce expenditures, we terminated the employment of six employees in March 2009 and one additional employee on April 1, 2009. Each of the terminated employees entered into a separation agreement under which we paid two months of the employee's base salary upon separation and agreed to pay 110% of the remaining benefits to which the employee was contractually entitled upon the earliest to occur of: 1) the completion of a financing or series of financings of at least \$10.0 million, 2) a change of control, or 3) an insolvency event involving us, in each case provided such event occurs prior to February 15, 2010, after which the remaining severance benefits are eliminated. As of September 30, 2009, we had completed financing activities resulting in aggregate proceeds of \$7.1 million of the \$10.0 million which would trigger payment of these deferred severance obligations. We paid \$0.2 million upon separation and the deferred severance payments total \$0.6 million. Each of the affected employees entered into a consulting agreement with us that will expire on December 31, 2009. The former employees will continue to vest in their share-based awards during the term of the consulting agreements. In total, we recorded charges totaling \$1.5 million during the first quarter of 2009 in conjunction with this reduction in workforce for severance paid, severance owed, accelerated vesting for certain share-based awards, and continued vesting of share-based awards under consulting agreements.

In April 2009, in order to further reduce expenditures, we undertook a process to reduce our workforce by an additional six employees, which process was completed on May 15, 2009. Each of the terminated employees entered into a separation agreement pursuant to which we paid two months of the employee's base salary upon separation and agreed to pay 110% of the remaining benefits to which the employee was contractually entitled upon the earliest to occur of: 1) the completion of a financing or series of financings of at least \$10.0 million, 2) a change of control, 3) an insolvency event involving us, or 4) December 31, 2010. As of September 30, 2009, we had completed financing activities resulting in aggregate proceeds of \$6.1 million of the \$10.0 million which would trigger payment of these deferred severance obligations. We paid \$0.2 million upon separation and paid an additional \$0.1 million during the third quarter of 2009 pertaining to the reimbursement of relocation costs. Deferred severance payments total \$1.1 million. Each of the affected employees entered into a consulting agreement with us that will expire at the end of the tenth month following the termination date. The former employees will continue to vest in their share-based awards during the terms of their consulting agreements. In total, we recorded charges during the second quarter of 2009 in conjunction with this reduction in workforce totaling \$3.0 million for severance paid, severance owed, accelerated vesting for certain share-based awards, and continued vesting of share-based awards under consulting arrangements.

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The following table summarizes the severance benefits for the terminated employees, excluding share-based charges (amounts in thousands).

	Three months ended September 30, 2009	Nine months ended September 30, 2009
Beginning severance liability	\$ 1,727	\$ —
Severance benefits incurred	—	2,177
Severance benefits paid	(63)	(513)
Change in estimate	(5)	(5)
Ending severance liability	<u>\$ 1,659</u>	<u>\$ 1,659</u>

### Off-Balance Sheet Arrangements

As of September 30, 2009, 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, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

### Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 166 *Accounting for Transfers of Financial Assets an Amendment to SFAS No. 140*, which was codified into the Accounting Standards Code (“ASC”) under Topic 860 *Transfers and Servicing*. This accounting standard eliminates qualified special purpose entities. SFAS No. 166 provides more stringent criteria for transferred financial assets to qualify as a sale and for the de-recognition of financial assets if interest in the asset remains after the transfer. This accounting standard is effective for the first reporting period beginning after November 15, 2009. We do not anticipate that the adoption of SFAS No. 166 will have a material impact on our financial statements.

In June 2009, the FASB issued SFAS No. 167 *Amendments to FASB Interpretation No. 46(R)*, which was codified into the ASC under Topic 810 *Consolidation*. This accounting standard requires analysis of whether variable interest entities are consolidated into a company’s financial statements. Consolidation is appropriate if the company is the primary beneficiary of the variable interest entity which occurs if the company has both: 1) the power to direct most significant activities, and 2) the potential to absorb most of the losses or benefits from performance by the variable interest entity. Ongoing reassessment as to whether a variable interest entity should be consolidated is also required. This accounting standard is effective for the first reporting period beginning after November 15, 2009. We do not anticipate that the adoption of SFAS No. 167 will have a material impact on our financial statements.

In September 2009, the FASB issued Accounting Standards Update (“ASU”) No. 2009-12, which provides guidance on measuring the fair value of an investment in an entity or holding that reports its value on a per share basis. This standard provides that the fair value of such investments may be measured at their net asset value per share so long as such net asset value is calculated in a manner consistent with accounting principals governing fair value measurement. This accounting standard is effective for the first reporting period ending after December 15, 2009. We do not anticipate the adoption of ASU No. 2009-12 will have a material impact on our financial statements.

### Caution on Forward-Looking Statements

Any statements in this report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “expect,” “should” or “would.” Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our interpretation of our communications and interactions with the FDA relating to the requirements for approval of the NDA for Silenor, and the FDA’s agreement with such interpretation; our interpretation of the results of our clinical trials for Silenor, the timing of the interpretation of such results and the FDA’s agreement with such interpretation; the potential for Silenor to receive regulatory approval for one or more indications on a timely basis or at all; the potential

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for the FDA to impose non-clinical, clinical or other requirements to be completed before or after regulatory approval of Silenor; our ability to demonstrate to the satisfaction of the FDA that potential NDA approval of Silenor is appropriate without standard, long-term carcinogenicity studies, given the context of completed trials and pending studies; the timing and results of non-clinical studies for Silenor, and the FDA's agreement with our interpretation of such results; our ability to raise sufficient capital to meet FDA requirements and otherwise fund our operations, to meet our obligations to parties with whom we contract relating to financing activity, and the impact of any such financing activity on the level of our stock price; the impact of any inability to raise sufficient capital to fund ongoing operations, including the potential to be required to restructure the company or to be unable to continue as a going concern; our ability to successfully commercialize Silenor, if it is approved by the FDA; the potential to enter into and the terms of any strategic transaction relating to Silenor; the scope, validity and duration of patent protection and other intellectual property rights for Silenor; whether any approved label for Silenor is sufficiently consistent with such patent protection to provide exclusivity for Silenor; our ability to operate our business without infringing the intellectual property rights of others; inadequate therapeutic efficacy or unexpected adverse side effects relating to Silenor that could delay or prevent regulatory approval or commercialization, or that could result in recalls or product liability claims; other difficulties or delays in development, testing, manufacturing and marketing of and obtaining regulatory approval for Silenor; estimates of the potential markets for Silenor and our ability to compete in these markets; and other risks detailed in this report under Part II — Item 1A — Risk Factors below and previously disclosed in our Annual Report on Form 10-K. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

### Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our cash, cash equivalents and marketable securities at September 30, 2009 consisted primarily of money market funds and U. S. government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing risk. Historically, our primary exposure to market risk is interest rate sensitivity. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment will probably decline. To minimize our interest rate risk, we maintain our portfolio of cash, cash equivalents and marketable securities in a variety of securities consisting primarily of money market funds and U.S. government debt securities, all with various maturities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate. We also generally time the maturities of our investments to correspond with our expected cash needs, allowing us to avoid realizing any potential losses from having to sell securities prior to their maturities.

Recently there has been concern in the credit markets regarding the value of a variety of mortgage-backed securities and the resultant effect on various securities markets. Our cash is invested in accordance with a policy approved by our board of directors which specifies the categories, allocations, and ratings of securities we may consider for investment. We do not believe our cash and cash equivalents have significant risk of default or illiquidity. We made this determination based on discussions with our treasury managers and a review of our holdings. While we believe our cash and cash equivalents are well diversified and do not contain excessive risk, we cannot provide absolute assurance that our investments will not be subject to future adverse changes in market value.

### 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 reports filed pursuant to the Securities Exchange Act of 1934 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, who is both our principal executive officer and our principal financial officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, 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 management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer, who is both our principal executive officer and our principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2009.

### Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. In May 2009, the employment of our Chief Financial Officer was terminated as part of our cost reduction efforts. Upon such termination, our Chief Executive Officer began serving as both our principal executive officer and our principal financial officer.

## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings

Not applicable.

### Item 1A. Risk Factors

*Investing in our common stock involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2008 includes a detailed discussion of our risk factors under the heading "Part I, Item 1A—Risk Factors." Set forth below are certain changes from the risk factors previously disclosed in our Annual Report on Form 10-K. You should carefully consider the risk factors discussed in our Annual Report on Form 10-K and in this report as well as the other information in this report before deciding whether to invest in shares of our common stock. The occurrence of any of the risks discussed in the Annual Report on Form 10-K or this report could harm our business, financial condition, results of operations or growth prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Except with respect to our trademarks, the trademarks, trade names and service marks appearing in this report are the property of their respective owners.*

### Risks Related to Our Business

*We will require substantial additional funding and may be unable to raise capital when needed, which could force us to delay, reduce or eliminate planned activities or result in our inability to continue as a going concern.*

We are a development stage company with no revenues, and our operations to date have generated substantial needs for cash. We expect our negative cash flows from operations to continue until we obtain regulatory approval for Silenor and are able to generate significant cash flows from the commercialization of Silenor.

In July 2009, we completed a private placement of 5.1 million shares of our common stock at a price of \$1.05 per share and seven-year warrants to purchase up to 5.1 million additional shares of our common stock, exercisable in cash or by net exercise at a price of \$1.155 per share, for aggregate gross proceeds of \$6.0 million and net proceeds of \$5.7 million. We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of September 30, 2009 will be sufficient to fund our operations through the expected duration of the FDA's review of our resubmission to the Silenor NDA and through the second quarter of 2010. We will need to obtain additional funds to finance our operations beyond that point, or if our operating plan is modified to accelerate commercialization activities relating to Silenor.

The development and approval of Silenor will require a commitment of significant funds, and any commercialization activities relating to Silenor we undertake are likely to result in the need for substantial additional funds. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

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- the costs of seeking regulatory approval of Silenor, including any clinical studies or other work required to achieve such approval, as well as the timing of such activities and approval;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of establishing or contracting for sales and marketing and other commercial capabilities, if required;
- the extent to which we acquire or in-license new products, technologies or businesses;
- the rate of progress and cost of our non-clinical studies, clinical trials and other development activities;
- the scope, prioritization and number of development programs we pursue;
- the effect of competing technological and market developments; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We intend to obtain any additional funding we require through strategic relationships, public or private equity or debt financings, assigning receivables or royalty rights, or other arrangements and cannot assure that such funding will be available on reasonable terms, or at all.

If we are unsuccessful in raising additional required funds, we may be required to delay, scale-back or eliminate plans or programs relating to our business, relinquish some or all rights to Silenor, renegotiate less favorable terms with respect to such rights than we would otherwise choose or cease operating as a going concern. In addition, if we do not meet our payment obligations to third parties as they come due, we may be subject to litigation claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, and may result in unfavorable results that could further adversely impact our financial condition.

If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If we raise additional funds by incurring debt financing, 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 operate our business.

Our independent auditors' report for the year ended December 31, 2008 included an explanatory paragraph stating that our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment.

***Our success is dependent on the success of Silenor (doxepin).***

To date the majority of our resources have been focused on the development of Silenor, and substantially all of our resources are now focused on seeking regulatory approval of Silenor. Accordingly, any failure or significant delay in the approval of Silenor will have a substantial adverse impact on our business.

***There is no assurance that we will be granted regulatory approval by the FDA for Silenor on a timely basis or at all.***

There can be no assurance that regulatory approval by the FDA will be obtained for Silenor. A failure to obtain requisite FDA approval or to obtain approval of the label that we have proposed will delay or preclude us from marketing Silenor or limit its commercial use, and would have a material and adverse effect on our business, financial condition and results of operations.

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The FDA notified us that our NDA for Silenor for the treatment of insomnia was considered filed as of March 31, 2008. Acceptance of the filing means that the FDA made a threshold determination that the NDA was sufficiently complete to permit an in-depth, substantive review to determine whether to approve Silenor for commercial marketing for the treatment of insomnia. This FDA review process can take substantial time and require the expenditure of substantial and unanticipated resources. As an organization, we have limited experience in filing and pursuing the applications necessary to gain regulatory approval, which may impede our ability to obtain such approval.

Under the policies agreed to by the FDA under PDUFA, the FDA was expected to complete its review and provide an action letter with respect to the NDA for Silenor as of December 1, 2008. Prior to December 1, 2008, the FDA informed us that it would not be able to complete its review by this date and indicated that its review would be extended for up to three additional months, resulting in a new PDUFA date of February 28, 2009. On February 25, 2009, we received a Complete Response Letter from the FDA relating to the NDA. The FDA stated that based on its review the NDA could not be approved in its then-current form.

In the Complete Response Letter the FDA raised a number of issues relating to the interpretation of the efficacy data contained in the NDA and indicated that the FDA was open to a discussion of these concerns. The FDA did not request us to conduct additional clinical trials of Silenor.

With respect to safety, the FDA noted that there were no adverse events observed in the clinical studies included in the NDA that would preclude approval, but asked us to address the possibility that doxepin may prolong the cardiac QT interval. We have responded by submitting to the FDA the results of our completed clinical trial of doxepin that evaluated the potential for ECG effects. The results of this clinical trial demonstrated that doxepin had no effect on QT interval prolongation when administered at 6 mg or under exaggerated exposure conditions of 50 mg.

We held a meeting with the FDA on April 6, 2009 to discuss the issues raised in the Complete Response Letter. In the meeting, the FDA stated that to obtain approval of a chronic insomnia treatment, objective and subjective efficacy must be established in adult and elderly patient populations, and efficacy must be shown both at the beginning of treatment and on a persistent basis, defined as at least one month. No additional safety issues were raised in the meeting.

Based on the feedback we received at the meeting, we conducted additional analyses of our Silenor clinical data focused on the durability of subjective sleep maintenance efficacy in adults with primary insomnia. We completed these analyses and included the results in a resubmission of the NDA to the FDA which was submitted on June 4, 2009. The resubmission also included the results of our completed clinical trial of doxepin that evaluated the potential for ECG effects, which was previously submitted to the doxepin IND application. The FDA has acknowledged receipt of the resubmission for review and confirmed that the review cycle will be six months, resulting in a new FDA action date of December 4, 2009.

Based on the Complete Response Letter and our meeting with the FDA, we will no longer pursue approval of a 1 mg dose of Silenor, nor will we seek approval of a statement in the indication section of the label that clinical trials of Silenor have demonstrated improvement in sleep onset.

Other NDA applicants have announced that the FDA has notified them that their scheduled review dates were delayed due to the FDA's internal resource constraints. The FDA has also stated that it may fail to meet the review dates of other companies for the same reason. We cannot be certain that the FDA will not impose such a delay on the continued review of our NDA.

The information included in the NDA for Silenor, including the data obtained from our non-clinical testing and clinical trials of this product candidate are susceptible to varying interpretations. The FDA's interpretation of the information included in the Silenor NDA or submitted during the review of the NDA could cause the FDA to impose additional requirements on us as a condition to obtaining regulatory approval. In addition, we may voluntarily undertake additional work if we feel it would be beneficial to support regulatory approval or our proposed labeling for Silenor. The additional requirements or voluntary undertakings could include additional non-clinical testing or clinical trials, analyses of previously-submitted non-clinical or clinical data, post-marketing studies and surveillance or other requirements. If during the review the FDA requests or we otherwise provide additional information or clarification regarding information already submitted, the review process may be further extended by the FDA, or regulatory approval could be limited or prevented.

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If the FDA's evaluations of the NDA and our clinical and manufacturing procedures and facilities are favorable, the FDA may issue an approval letter, authorizing commercial marketing of the drug for a specified indication. If the FDA is not sufficiently satisfied with the information in the NDA to issue an approval letter, the FDA will issue another Complete Response Letter, which typically would describe all of the specific deficiencies that the FDA has identified in the NDA and, when possible, recommend actions that we may take to address the identified deficiencies.

In addition, delays or rejections may be encountered based upon changes in FDA policy for drug approval during the period of FDA regulatory review. For example, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2) under the Federal Food, Drug and Cosmetic Act over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If these companies successfully challenge the FDA's interpretation of Section 505(b)(2), the FDA may be required to change its interpretation of Section 505(b)(2). This could delay or even prevent the FDA from approving our NDA for Silenor.

If we are unable to secure approval by the FDA of the Silenor NDA in a timely manner, in the absence of substantial additional financing, our business, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern.

***Even if Silenor receives regulatory approval, it will still be subject to substantial ongoing regulation.***

Even if U.S. regulatory approval is obtained for Silenor, the FDA may still impose significant restrictions on its indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or other activities. For example, the label ultimately approved for Silenor, if any, may include a restriction on the length of a prescription for its use or the population for which it may be used, or may not include the indication statement we desire or may include a qualification to such statement. Any of these could have an adverse impact on our ability to achieve market acceptance of Silenor and generate revenues from its sale.

Additionally, the FDA has directed manufacturers of all antidepressant drugs to revise their product labels to include a boxed, or "black box," warning and expanded warning statements regarding an increased risk of suicidal thinking and behavior in children, adolescents and young adults being treated with these drugs. The active ingredient in Silenor, doxepin, is used in the treatment of depression and the package insert includes such a "black box" warning statement. Although Silenor is not intended to be indicated for or used in the treatment of depression and our proposed dosage for insomnia is less than one-tenth of that of doxepin for the treatment of depression, and although we have not evaluated and do not currently intend to seek regulatory approval for Silenor for the treatment of insomnia in children or adolescents, we cannot be sure that a similar warning statement will not be required.

Recently, the FDA has also requested that all manufacturers of sedative-hypnotic drug products modify their product labeling to include stronger language concerning potential risks. These risks include severe allergic reactions and complex sleep-related behaviors, which may include sleep-driving. The FDA also recommended that the drug manufacturers conduct clinical studies to investigate the frequency with which sleep-driving and other complex behaviors occur in association with individual drug products. While such complex sleep behaviors were not observed in our clinical program for Silenor, it is unclear how and to what extent, if any, these requests and recommendations will affect Silenor.

Further, some of the drugs that Silenor will compete with if it is approved by the FDA, including Ambien, Ambien CR, Lunesta and Sonata, have been designated by the DEA as Schedule IV controlled substances. Although doxepin, at higher dosages than we have incorporated in Silenor, is not currently and has never been a Schedule IV controlled substance and the FDA has indicated in correspondence relating to our pre-NDA meeting for Silenor that it will recommend that it not be a Schedule IV controlled substance, we cannot be certain that Silenor will be a non-scheduled drug until the FDA and DEA have made final determinations on the matter. In our market research, physicians indicated that they limit their prescribing of Schedule IV controlled substances and that they would most likely increase their prescribing of insomnia medications if those medications were proven to be as effective as the market leading products without having the associated side effects or risk of addiction.

Silenor will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. For example, as a condition to any approval of the NDA for Silenor, the FDA is likely to require us to develop a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of Silenor outweigh its risks. A REMS can include information to accompany the product, such as

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a patient package insert or a medication guide, a communication plan, elements to assure safe use, and an implementation system, and must include a timetable for assessment of the REMS. In addition, the FDA may require modifications to a REMS at a later date if warranted by new safety information. Any requirements imposed by the FDA may require substantial expenditures, and may delay the approval or potential commercialization of the product.

Approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or on us, including requiring withdrawal of the product from the market.

If our operations relating to Silenor fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties, including fines;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

***Although we are pursuing discussions with other companies to facilitate the commercialization of Silenor, we may be unable to complete a collaboration or other strategic transaction on acceptable terms, or at all.***

Even if Silenor receives FDA approval, the commercial success of the product will largely depend on gaining access to the highest prescribing physicians of insomnia treatments. We continue to engage in discussions with third parties with the goal of entering into a collaboration or other strategic transaction relating to the commercialization of Silenor. The outcome of this process and the structure of any resulting transaction could vary depending on the interest and objectives of the parties. However, we cannot assure you that we will complete any collaboration or other strategic transaction, or that, if completed, any collaboration or other strategic transaction will be successful or on attractive terms.

Compared to a commercialization strategy that involves a third party collaborator, the commercialization of Silenor by us without such a collaborator could require substantially greater resources on our part and potentially adversely impact the timing and results of a launch of the product.

We also face competition in our search for parties with whom we may enter into a collaboration or other strategic transaction. These competitors may have access to greater financial resources than us and may have greater expertise in identifying, evaluating and consummating a collaboration or other strategic transaction. Moreover, we may devote resources to potential collaborations or other strategic transactions that are never completed, or we may fail to realize the anticipated benefits of such efforts.

If we are able to complete a collaboration or other strategic transaction, depending on the timing of the transaction and the outlook of the other party to the transaction, such other party could materially impact our plans for commercializing Silenor. Such modifications could result in additional costs or delays in any commercial launch of Silenor.

***We will need to expend significant resources to successfully commercialize Silenor and any other product candidates that we develop, acquire or license.***

We are in the process of developing a commercialization strategy for Silenor that will focus on high-prescribing physicians in the U.S. Even though certain of our employees have been involved in the successful launch of new

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pharmaceutical products, as a company, we have limited commercial infrastructure and experience. We have not commercialized any products, and may be unable to successfully do so.

If Silenor is approved by the FDA, the commercialization process will require the expenditure by us of substantial resources. We would seek such additional required funding through various means. There can be no assurance, however, that such financing will be available on reasonable terms, if at all. If adequate funds are not available, we may be required to delay or cancel planned commercialization activities, the effectiveness of such activities may be adversely impacted or we may be required to enter into one or more outsourcing or strategic transactions relating to such activities on less favorable terms than we would otherwise choose.

If we pursue a relationship with a strategic collaborator or contract sales organization to facilitate our sales efforts, we may not be able to identify a counterparty with the requisite capabilities or capacity to most effectively commercialize the product. In addition, we may not be able to enter into agreements with any such entity on commercially reasonable or acceptable terms, or at all. To the extent that we enter into any such arrangements with third parties, any revenues we receive from sales of our products in the markets covered by such arrangements will depend upon the efforts of such third parties, which in many instances will not be within our control. Any failure by any such strategic collaborator or contract sales organization to effectively sell our products could adversely affect our business.

***We expect intense competition in the insomnia marketplace for Silenor and any other product candidate that we develop, and new products may emerge that provide different and/or better therapeutic alternatives for the disorders that our product candidates are intended to treat.***

We are developing Silenor for the treatment of insomnia, which will compete with well established drugs for this indication, including the branded and generic versions of Sanofi-Synthelabo, Inc.'s Ambien, King Pharmaceuticals, Inc.'s Sonata, and Dainippon Sumitomo Pharma Co., Ltd.'s Lunesta, all of which are GABA-receptor agonists, Takeda Pharmaceuticals North America, Inc.'s Rozerem, a melatonin receptor antagonist, and Sanofi-Synthelabo Inc.'s Ambien CR, a controlled-release formulation of the current GABA-receptor agonist, Ambien.

In March 2009, Meda AB and Orexo AB received approval from the FDA for Edluar, formerly known as Sublinox, a sublingual tablet formulation of zolpidem, for the short-term treatment of insomnia. Meda and Orexo launched this product in the U.S. in the third quarter of 2009. In December 2008, NovaDel Pharma, Inc. received approval from the FDA for ZolpiMist, an oral mist formulation of zolpidem, for the short-term treatment of insomnia characterized by difficulties with sleep initiation. The time to market for this product remains unclear.

Transcept Pharmaceuticals, Inc. submitted an NDA for Intermezzo, a low-dose sublingual tablet formulation of zolpidem in 2008, and on October 29, 2009, Transcept announced that it received a Complete Response Letter from the FDA relating to such NDA. Transcept stated that it intends to meet with the FDA to discuss the implications of the Complete Response Letter, and we do not know the impact that the Complete Response Letter or this meeting will have on the potential approval of this product candidate. Transcept and Purdue Pharmaceutical Products L.P. have entered into an exclusive license and collaboration agreement to commercialize Intermezzo in the United States.

Sanofi-Aventis submitted an NDA for Ciltyri (eplivanserin), a 5HT<sub>2</sub> antagonist, to the FDA for the treatment of insomnia during the fourth quarter of 2008. In September 2009, Sanofi-Aventis announced that it received a Complete Response Letter from the FDA relating to such NDA. The implications for approval of this product candidate or its time to market are unclear.

Vanda Pharmaceuticals Inc. has completed two Phase 3 clinical trials of VEC-162, a melatonin receptor agonist. Takeda Pharmaceuticals North America, Inc. has conducted a clinical study to evaluate the administration of a combination of Takeda's product Rozerem and 3 mg of doxepin in patients with insomnia. We are unaware of the results of this trial.

Organon and Schering-Plough have completed two Phase 3 clinical trials of esmirtazapine, an H<sub>1</sub> antagonist for the treatment of insomnia, and at least one additional Phase 3 clinical trial is ongoing.

Actelion Pharmaceuticals Ltd. initiated a Phase 3 clinical trial of almorexant, an orexin antagonist, in December 2007 and expects results from this clinical trial in the second half of 2009. Actelion and GlaxoSmithKline have entered into a collaboration relating to almorexant under which GlaxoSmithKline received exclusive, worldwide rights to co-develop and co-commercialize almorexant together with Actelion.

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Several other companies, including Dainippon Sumitomo Pharma Co., are evaluating 5HT2 antagonists as potential hypnotics, and Eli Lilly and Company is evaluating a potential hypnotic that is a dual histamine/5HT2 antagonist. Alexza Pharmaceuticals, Inc. has announced positive results from a Phase 1 clinical trial of an inhaled formulation of zaleplon, the active pharmaceutical ingredient in Sonata. Additionally, several other companies are evaluating new formulations of existing compounds and other compounds for the treatment of insomnia.

Furthermore, generic versions of Ambien and Sonata have been launched and are priced significantly lower than approved, branded insomnia products. Sales of all of these drugs may reduce the available market for, and could put downward pressure on the price we are able to charge for, any product developed by us for this indication, which could ultimately limit our ability to generate significant revenues.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of Silenor or any other product candidate that we develop from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others, including the development of other drug technologies and methods of preventing the incidence of disease, will not render Silenor or any other product candidate that we develop obsolete or noncompetitive.

Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- experience conducting non-clinical studies and clinical trials, and related resources;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing resources and experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we can or may obtain patent protection or other intellectual property rights or seek to invalidate or otherwise challenge our intellectual property rights, limiting our ability to develop or commercialize product candidates. Our competitors may also develop drugs that are more effective and useful and less costly than ours and may be more successful than we are in manufacturing and marketing their products.

In addition, if we receive regulatory approvals for Silenor or any other product candidates we develop, manufacturing efficiency and marketing capabilities are likely to be significant competitive factors. We currently have no commercial manufacturing capability and limited sales and marketing infrastructure.

***We are subject to uncertainty relating to health care reform measures and reimbursement policies which, if not favorable to Silenor or any other product candidate that we develop, could hinder or prevent our commercial success.***

Our ability to successfully commercialize Silenor and any other product candidate that we develop, with or without a partner, will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate coverage and reimbursement levels for the cost of our products and related treatments. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;

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- the future revenues and profitability of our potential customers, suppliers and collaborators; and
- the availability of capital.

In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription drugs and the reform of the Medicare and Medicaid systems. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 provides a new Medicare prescription drug benefit which became effective in January 2006 and mandates other reforms. While we cannot predict the full outcome of the implementation of this legislation, it is possible that the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, will result in additional government reimbursement for prescription drugs, which may make some prescription drugs more affordable but may further exacerbate industry-wide pressure to reduce prescription drug prices.

It is also possible that other legislative proposals will be adopted, particularly in view of the current presidential administration. For example, the current presidential administration has proposed a budget that would include significant amounts to finance the reform of the U.S. healthcare system. The U.S. Congress is considering a number of legislative and regulatory proposals with an objective of ultimately reducing healthcare costs by, among other things, limiting the level of reimbursement for pharmaceuticals. Legislative and regulatory actions under consideration in the U.S. include health care reform initiatives that could significantly alter the market for pharmaceuticals (such as private health insurance expansion, the creation of competing public health insurance plans, a variety of proposals that would reduce government expenditures for prescription drugs to help finance healthcare reform, or the eventual transition of the U.S. multiple payor system to a single payor system). Other actions under consideration include proposals for government intervention in pharmaceutical pricing, changes in government reimbursement, an accelerated approval process for “follow-on” biologics, legalization of commercial drug importation into the U.S., and involuntary approval of medicines for over-the-counter, or OTC, use. As a result of new proposals, we may determine to change our current manner of operation or change our contract arrangements, any of which could harm our ability to operate our business efficiently, obtain collaborators and raise capital. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable or insufficient.

Many managed care organizations negotiate the price of medical services and products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization’s patient population. The process for obtaining coverage can be lengthy and time-consuming, and we expect that it could take several months before a particular payor initially reviews our product and makes a decision with respect to coverage. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic or OTC products, our overall business and financial condition could be adversely affected.

In addition, third-party payors are increasingly challenging the prices charged for medical products and services. Also, current and any future legislative proposals to reform health care or reduce government insurance programs may result in lower prices for Silenor and any other product candidate that we develop or exclusion of our product candidates from coverage and reimbursement programs. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could harm our ability to market our products and significantly reduce our revenues from the sale of any approved product.

***We may need to increase the size of our organization, and we may experience difficulties in managing growth.***

As of November 2, 2009 we had six full-time employees. If Silenor is approved by the FDA and we meaningfully participate in its commercialization, we may need to recruit and train a substantial number of sales and marketing personnel to support the commercialization effort. Our management and personnel, systems and facilities currently in place may not be adequate to support this or other future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage the FDA review process relating to our NDA for Silenor;

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- manage our internal development and potential commercialization efforts effectively while carrying out our contractual obligations to collaborators and other third parties and complying with all applicable laws, rules and regulations;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

***We have licensed Silenor from a third party. If we default on any of our obligations under that license, or if the licensor exercises a right to terminate the license, we could lose rights to Silenor.***

We in-licensed rights to Silenor through an exclusive licensing arrangement, and we may enter into similar licenses in the future. Under our license agreement for Silenor, we are required to use commercially reasonable efforts to develop, obtain regulatory approval of and commercialize Silenor. In addition, our licensor for Silenor has the right to terminate the license agreement upon the filing and institution of voluntary bankruptcy, reorganization, liquidation or receivership proceedings involving us, the institution of such proceedings on an involuntary basis that are not dismissed within 60 days after filing, an assignment of our assets for the benefit of our creditors or the appointment of a receiver or custodian for our business. In the event that our licensor for Silenor terminates the license agreement pursuant to a contractual right or in the event of a default by us, even though we would maintain ownership of our clinical data and the other intellectual property we have developed relating to Silenor, we would be unable to continue our development and commercialization activities relating to Silenor and our business and financial condition would be materially harmed.

### **Risks Related to Our Finances and Capital Requirements**

***Capital raising activities, such as issuing securities, incurring debt, assigning receivables or royalty rights or through collaborations or other strategic transactions, may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights and may be limited by applicable laws and regulations.***

In July 2009, we completed a private placement of 5.1 million shares of our common stock at a price of \$1.05 per share and seven-year warrants to purchase up to 5.1 million additional shares of our common stock, exercisable in cash or by net exercise at a price of \$1.155 per share, for aggregate gross proceeds of \$6.0 million and net proceeds of \$5.7 million. We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of September 30, 2009 will be sufficient to fund our operations through the expected duration of the FDA's review of our resubmission to the Silenor NDA and through the second quarter of 2010. We will need to obtain additional funds to finance our operations beyond that point, or if our operating plan is modified to accelerate commercialization activities relating to Silenor.

To the extent that we raise any required additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. Any such dilution of the holdings of our current stockholders may result in downward pressure on the price of our common stock.

Any debt, receivables or royalty financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments.

Debt financing, receivables assignments, royalty interest assignments and other types of financing are often coupled with an equity component, such as warrants to purchase stock. For example, in connection with our July 2009 private placement of equity securities, we issued to the investors warrants to purchase 5.1 million shares of our common stock. In addition, in connection with our committed equity financing facility transaction with Kingsbridge and our secured loan transaction with Silicon Valley Bank and Oxford Finance Corporation, we issued to Kingsbridge a warrant to purchase 165,000 shares of our common stock, we issued to Silicon Valley Bank a warrant to purchase 80,000 shares of our common stock and we issued to Oxford Finance Corporation a warrant to purchase 159,000 shares of our common stock. In connection with the repayment of our secured loan in March 2009, we issued to Oxford Finance Corporation an additional

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warrant to purchase 200,000 shares of our common stock. To the extent that any of these warrants, or any additional warrants that we issue in the future, are exercised by their holders, dilution of our existing stockholders' ownership interests will result.

If we raise additional funds through collaborations or other strategic transactions, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

In addition, rules and regulations of the SEC or other regulatory agencies may restrict our ability to conduct certain types of financing activities, or may affect the timing of and the amounts we can raise by undertaking such activities. For example, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or our public float, is less than \$75 million, the amount that we can raise through primary public offerings of securities in any twelve-month period using one or more registration statements on Form S-3 will be limited to an aggregate of one-third of our public float. As of November 2, 2009, our public float was less than \$75 million.

***We have never generated revenues or been profitable, and we may not be able to generate revenues sufficient to achieve profitability and, we will need substantial additional financing to operate our business.***

We are a development stage company and have not generated any revenues or been profitable since inception, and it is possible that we will not achieve profitability. We incurred net losses of \$12.5 million for the nine months ended September 30, 2009, \$37.2 million for the year ended December 31, 2008, and \$26.4 million for the year ended December 31, 2007. We expect to continue to incur significant operating and capital expenditures. As a result, we will need to generate significant revenues to achieve and maintain profitability. We cannot assure you that we will achieve significant revenues, if any, or that we will ever achieve profitability. Even if we do achieve profitability, we cannot assure you that we will be able to sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow more slowly than we anticipate or if operating expenses exceed our expectations or cannot be adjusted accordingly, our business, results of operations and financial condition will be materially and adversely affected.

In addition, our independent auditors' report for the year ended December 31, 2008 included an explanatory paragraph stating that our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, it is likely that investors will lose all or a part of their investment.

***Our quarterly operating results may fluctuate significantly.***

We expect our operating results to be subject to quarterly fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including:

- our addition or termination of development programs or funding support;
- variations in the level of expenses related to development of Silenor or any other product candidate that we develop;
- our entering into collaborations;
- any intellectual property infringement lawsuit in which we may become involved;
- non-cash charges which we incur, including relating to share-based compensation;
- regulatory developments; and
- commercialization activities relating to Silenor, if it is approved by the FDA, or any other product candidate that we may develop, or commercialization activities 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 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.

**Risks Relating to Securities Markets and Investment in Our Stock**

*Future sales of our common stock may cause our stock price to decline.*

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock that they are able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

Moreover, the holders of a substantial number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders. In our July 2009 private placement of equity securities, we agreed with the investors to file a registration statement covering the resale of the common stock they purchased and the common stock underlying the warrants they purchased. We filed a registration statement on Form S-3 relating to the resale of such shares, which was declared effective by the SEC in August 2009.

We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In June 2009, we completed a one-time offer to exchange options to purchase shares of our common stock having an exercise price greater than \$1.00 per share outstanding under our 2004 Equity Incentive Award Plan and 2005 Equity Incentive Award Plan, or the 2005 Plan, for replacement options to purchase a lesser number of shares of our common stock to be granted under the 2005 Plan. The exchange offer was open to our employees and directors as of March 1, 2009. All of the eligible participants tendered some or all of their stock options for exchange. Pursuant to the exchange offer, we accepted for exchange eligible options to purchase an aggregate of 4,320,000 shares of our common stock, representing 87% of the total shares of common stock underlying options eligible for exchange in the offer. The weighted average exercise price of the options tendered for exchange was \$6.98. We granted, under the 2005 Plan, replacement options to purchase an aggregate of 2,880,000 shares of common stock in exchange for the eligible options tendered and accepted pursuant to the offer. The exercise price per share of each replacement option granted in the option exchange is \$1.23.

In addition, certain of our directors, executive officers and large stockholders have established or may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for the purpose of effecting sales of common stock. If any of these events causes a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

*There may not be a viable public market for our common stock, and market volatility may affect our stock price and the value of your investment.*

Our common stock had not been publicly traded prior to our initial public offering, which was completed in December 2005, and an active trading market may not develop or be sustained. We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Therefore, investors will have to rely on appreciation in our stock price and a liquid trading market in order to achieve a gain on their investment. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Since our initial public offering on December 15, 2005 through November 2, 2009, the trading prices for our common stock have ranged from a high of \$21.24 to a low of \$0.18.

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The market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

- changes in the regulatory status of our products or product candidates, including requirements to conduct or results or anticipated timing of our non-clinical studies and clinical trials;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- events affecting our existing in-license agreements and any future collaborations or other strategic transactions, commercial agreements and grants;
- variations in our quarterly operating results;
- decreased coverage and changes in securities analysts' estimates of our financial performance;
- regulatory developments in the United States and foreign countries;
- fluctuations in stock market prices and trading volumes of similar companies;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- announcements concerning other financing activities;
- additions or departures of key personnel; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

The realization of any of the risks described in the risk factors disclosed in our Annual Report on Form 10-K or in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility or declines in market price. Any such litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could hurt our business, operating results and financial condition.

***If we are unable to comply with the minimum requirements for listing on the Nasdaq Capital Market, we may be delisted from the Nasdaq Capital Market, which would likely cause the liquidity and market price of our common stock to decline.***

Our stock is listed on the Nasdaq Capital Market. In order to continue to be listed on the Nasdaq Capital Market, we must meet specific quantitative standards, including maintaining a minimum bid price of \$1.00 for our common stock, a public float of \$1.0 million, and either \$2.5 million in stockholders equity or a market capitalization of \$35 million. We are currently in compliance with these standards, but it is possible that we may fail to be in compliance in the future.

If the Nasdaq Stock Market provides us with a notice of non-compliance, we may provide a plan to achieve and sustain compliance with continued listing requirements. If we submit the plan and it is accepted by Nasdaq, Nasdaq may grant us a period of up to 105 days from the date of the notice of non-compliance within which to regain compliance with the listing requirements. If Nasdaq determines that our plan is not sufficient to achieve and sustain compliance, or if we are unable to achieve compliance within such period, Nasdaq will provide written notice that our securities will be delisted. At such time, we may appeal the decision to a Nasdaq Listing Qualifications Panel. If that appeal is unsuccessful, our securities would be delisted.

If we were to be delisted from the Nasdaq Capital Market, trading, if any, in our shares may continue to be conducted on the Over-the-Counter Bulletin Board or in a non-Nasdaq over-the-counter market, such as the "pink sheets." Delisting of our shares would result in limited release of the market price of those shares and limited analyst coverage and could

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restrict investors' interest in our securities. Also, a delisting could have a material adverse effect on the trading market and prices for our shares and our ability to issue additional securities or to secure additional financing. In addition, if our shares were not listed and the trading price of our shares was less than \$5.00 per share, our shares could be subject to Rule 15c-9 under the Exchange Act which, among other things, requires that broker/dealers satisfy special sales practice requirements, including making individualized written suitability determinations and receiving a purchaser's written consent prior to any transaction. In such case, our securities could also be deemed to be a "penny stock" under the Securities Enforcement and Penny Stock Reform Act of 1990, which would require additional disclosure in connection with trades in those shares, including the delivery of a disclosure schedule explaining the nature and risks of the penny stock market. Such requirements could severely limit the liquidity of our securities and our ability to raise additional capital in an already challenging capital market.

***If we are unable to maintain an effective registration statement for the resale of shares under our recently completed private placement, or if we are delisted from the Nasdaq Capital Market, Nasdaq Global Market, the New York Stock Exchange or the American Stock Exchange, we may be required to pay liquidated damages.***

In July 2009, we issued 5.1 million shares of common stock at \$1.05 per share and seven-year warrants to purchase up to 5.1 million additional shares of common stock, exercisable in cash or by net exercise at a price of \$1.155 per share, for aggregate gross proceeds of \$6.0 million and net proceeds of \$5.7 million. In connection with the private placement, we agreed to register for resale both the shares of common stock purchased by the investors and the shares of common stock issuable upon exercise of the warrants. The resale registration statement was filed and declared effective by the SEC in August 2009. We also agreed to other customary obligations regarding registration, including matters relating to indemnification, maintenance of the registration statement and payment of expenses.

We may be liable for liquidated damages if we do not maintain the effectiveness of the registration statement or the listing of our common stock on the Nasdaq Capital Market, the Nasdaq Global Market, the New York Stock Exchange or the American Stock Exchange, in each case for a period of ten consecutive days or for more than thirty days in any 365-day period. The amount of the liquidated damages is one percent per applicable ten or thirty day period, subject to an aggregate maximum of eight percent per calendar year, of the aggregate purchase price of the common stock purchased in the private placement then held by each investor that are registrable securities.

***If our executive officers, directors and largest stockholders choose to act together, they may be able to control our operations and act in a manner that advances their best interests and not necessarily those of other stockholders.***

As of November 2, 2009, our executive officers, directors and holders of 5 percent or more of our outstanding common stock beneficially owned approximately 70% of our common stock. As a result, these stockholders, acting together, would be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

***Investors may incur substantial dilution as a result of future equity issuances, and, as a result, our stock price could decline.***

Based on our recurring losses, negative cash flows from operations and working capital levels, we will have to raise substantial additional funds. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, it is likely that investors will lose all or a part of their investment.

Because we will need to raise additional capital to fund our business, among other things, we may conduct substantial additional equity offerings. For example, in July 2009, we completed a private placement of 5.1 million shares of our common stock at a price of \$1.05 per share and seven-year warrants to purchase up to 5.1 million additional shares of our common stock, exercisable in cash or by net exercise at a price of \$1.155 per share, for aggregate gross proceeds of \$6.0 million and net proceeds of \$5.7 million. This offering resulted, and future equity issuances will result, in dilution to investors. In addition, the exercise of outstanding options or warrants, including the warrants issued in our recent private

placement, and any additional shares issued in connection with acquisitions or incentive programs, will result in dilution to investors.

***We expend substantial costs and management resources as a result of laws and regulations relating to corporate governance matters.***

As a public reporting company, we must comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations adopted by the SEC and by the Nasdaq Stock Market, including expanded disclosures, accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and other requirements has caused us to expend substantial costs and management resources and will continue to do so. Additionally, these laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or as executive officers. In June 2007, the Public Company Accounting Oversight Board approved Auditing Standard No. 5, and at the same time, the SEC issued guidance for management for complying with the requirements of Section 404. This auditing standard and the related management guidance provides a more risk-based approach to compliance and testing under Section 404. However, we still expect to incur substantial costs and to devote significant resources to corporate governance matters.

In addition, as a result of the workforce reductions we undertook in order to reduce expenses, the efforts required to comply with Section 404 and the other corporate governance laws and regulations applicable to us are being undertaken by a smaller number of people. For example, in May 2009 the employment of our Chief Financial Officer was terminated for purposes of reducing expenses, resulting in our Chief Executive Officer undertaking the roles of both principal executive officer and principal financial officer. If we, or the third-party service providers on which we rely, fail to comply with any of these laws or regulations, or if our auditors cannot complete any required attestation of our evaluation of our internal controls in a timely manner, we could be subject to regulatory scrutiny and a loss of public confidence in our corporate governance or internal controls, which could have an adverse effect on our business and our stock price.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

On July 8, 2009, we issued 5.1 million shares of our common stock at a purchase price of \$1.05 per share pursuant to a private placement transaction. In addition to the shares of common stock, warrants to purchase up to 5.1 million additional shares of our common stock were also issued as part of the transaction at a price of \$0.125 per warrant. Each warrant has a seven-year term and is exercisable in cash or by net exercise for one share of common stock at a price of \$1.155. The securities sold in the private placement were not registered under the Securities Act of 1933, as amended, or any state securities laws, and were sold pursuant to Regulation D of the Securities Act. The purchasers in the offering consisted of new investors and our existing stockholders, including investors affiliated with three of our directors.

In August 2009, we filed a registration statement on Form S-3 to register the 5.1 million shares of common stock issued in the private placement and the 5.1 million shares of common stock issuable upon exercise of the warrants. The registration statement became effective in August 2009.

***Use of Proceeds***

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-128871) that was declared effective by the SEC on December 14, 2005. On December 20, 2005, 5,000,000 shares of common stock were sold on our behalf at an initial public offering price of \$11.00 per share, for an aggregate offering price of \$55.0 million, managed by Morgan Stanley & Co. Incorporated, J.P. Morgan Securities Inc., Piper Jaffray & Co. and Thomas Weisel Partners LLC.

We paid to the underwriters underwriting discounts and commissions totaling \$3.9 million in connection with the offering. In addition, we incurred expenses of \$1.3 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of \$5.2 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were \$49.8 million. No

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offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of September 30, 2009, we had used all of the \$49.8 million of net proceeds from our initial public offering. Approximately \$19.5 million was used in the development of Silenor, the preparation of the NDA submission for Silenor and activities to prepare for the potential commercialization of Silenor. An additional \$1.0 million was spent to pursue the development of our other product candidates and for various payments according to the terms of our in-license agreements. Another \$2.0 million was used to pay interest, debt issuance costs, and a final payment fee related to our loan obligation which was fully repaid in March 2009. An additional \$27.3 million was used to fund our working capital requirements and for general corporate purposes.

### Issuer Purchases of Equity Securities

The following table contains information relating to the repurchases of our common stock made by us in the third quarter of 2009 (in thousands, except per share amounts).

Period	Number of Shares Purchased	Average Price Paid per Share	Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1-31, 2009 (1)	15	\$ 0.0001	—	—
August 1-31, 2009	—	—	—	—
Sept 1-30, 2009	—	—	—	—
Total	15	\$ 0.0001	—	—

- (1) On June 30, 2009, our consulting agreement with one of the holders of our restricted stock expired. In accordance with the terms of the restricted stock issuance agreement, we repurchased the shares from the holder at the par value of \$0.0001 per share in July 2009. This repurchase was not made pursuant to a publicly announced plan or program to repurchase our stock.

### Item 3. Defaults Upon Senior Securities

Not applicable.

### Item 4. Submission of Matters to a Vote of Security Holders

Not applicable.

### Item 5. Other Information

Not applicable.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant
3.2(2)	Amended and Restated Bylaws of the Registrant
4.1(3)	Form of the Registrant's Common Stock Certificate
4.2(4)	Amended and Restated Investor Rights Agreement dated June 2, 2005
4.3(5)	Warrant dated May 21, 2008 issued to Silicon Valley Bank
4.4(5)	Warrant dated May 21, 2008 issued to Oxford Finance Corporation
4.5(5)	Warrant dated May 21, 2008 issued to Kingsbridge Capital Limited
4.6(6)	Warrant dated March 11, 2009 issued to Oxford Finance Corporation
4.7(7)	Form of Warrant dated July 2, 2009 issued to certain Purchasers under the Securities Purchase Agreement dated July 2, 2009
10.1(7)	Securities Purchase Agreement between the Registrant and the Purchasers identified therein dated July 2, 2009.
31.1	Certification of chief executive officer pursuant to Rule 13a-14 and Rule 15d-14 of the Securities Exchange Act of 1934, as amended
32.1*	Certification of chief executive officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Filed with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 on November 30, 2005.

(2) Filed with Registrant's Current Report on Form 8-K on December 6, 2007

(3) Filed with Amendment No. 4 to the Registrant's Registration Statement on Form S-1 on December 13, 2005.

(4) Filed with the Registrant's Registration Statement on Form S-1 on October 7, 2005.

(5) Filed with Registrant's Current Report on Form 8-K on May 22, 2008.

(6) Filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.

(7) Filed with Registrant's Current Report on Form 8-K on July 8, 2009.

\* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Somaxon Pharmaceuticals, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**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.

Dated: November 6, 2009

*/s/ Richard W. Pascoe*

\_\_\_\_\_  
Richard W. Pascoe  
President and Chief Executive Officer  
(Duly Authorized Officer and  
Principal Financial Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Richard W. Pascoe, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Somaxon Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 6, 2009

*/s/ Richard W. Pascoe*  
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Richard W. Pascoe  
President and Chief Executive Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

**Certification of Chief Executive Officer**

In connection with the Quarterly Report of Somaxon Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard W. Pascoe, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 6, 2009

*/s/ Richard W. Pascoe*

Richard W. Pascoe  
President and Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.