

# ALSERES PHARMACEUTICALS INC /DE

## FORM 10-Q (Quarterly Report)

Filed 08/14/08 for the Period Ending 06/30/08

Address	85 MAIN STREET HOPKINTON, MA 01748
Telephone	508-497-2360
CIK	0000094784
Symbol	ALSE
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

## Table of Contents

---

---

**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 June 30, 2008

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 0-6533

---

**ALSERES PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

---

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

87-0277826  
(IRS Employer  
Identification No.)

85 Main Street, Hopkinton, Massachusetts  
(Address of Principal Executive Offices)

01748  
(Zip Code)

(508) 497-2360  
(Registrant's Telephone Number, Including Area Code)

None  
(Former Name, Former Address and Former 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 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  Smaller reporting company   
(Do not check if a smaller reporting company)

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

As of August 4, 2008 there were 20,807,645 shares of Common Stock outstanding.

---

---



ALSERES PHARMACEUTICALS, INC.

INDEX TO FORM 10-Q

	<u>Page</u>
<b>Part I Financial Information</b>	
Item 1 Financial Statements (Unaudited)	
Condensed Consolidated Balance Sheets as of June 30, 2008 and December 31, 2007	3
Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2008 and 2007, and for the period from inception (October 16, 1992) to June 30, 2008	4
Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2008 and 2007, and for the period from inception (October 16, 1992) to June 30, 2008	5
Notes to Condensed Consolidated Financial Statements	6
Item 2 Management’s Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3 Quantitative and Qualitative Disclosures About Market Risk	26
Item 4T Controls and Procedures	26
<b>Part II Other Information</b>	
Item 1A Risk Factors	27
Item 2 Unregistered Sales of Equity Securities and Use of Proceeds	46
Item 4 Submission of Matters to a Vote of Security Holders	46
Item 6 Exhibits	47
<b>SIGNATURES</b>	
EX-31.1 SECTION 302 CERTIFICATION OF THE CEO	
EX-31.2 SECTION 302 CERTIFICATION OF THE CFO	
EX-32.1 SECTION 906 CERTIFICATION OF THE CEO	
EX-32.2 SECTION 906 CERTIFICATION OF THE CFO	

In this report, “we”, “us”, and “our” refer to Alseres Pharmaceuticals, Inc. The following are trademarks of ours that are mentioned in this Quarterly Report on Form 10-Q: Alseres<sup>®</sup>, Cethrin<sup>®</sup>, Altropane<sup>®</sup> and Fluoratec<sup>™</sup>. All other trade names, trademarks or service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners and are not the property of Alseres Pharmaceuticals, Inc. or any of our subsidiaries.

## Table of Contents

### Part I — Financial Information

#### Item 1 — Financial Statements

**Alseres Pharmaceuticals, Inc.**  
(A Development Stage Enterprise)  
Condensed Consolidated Balance Sheets

	(Unaudited) June 30, 2008	December 31, 2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,399,215	\$ 2,933,292
Marketable securities	—	1,240,543
Prepaid expenses and other current assets	1,176,676	1,018,459
Total current assets	6,575,891	5,192,294
Fixed assets, net	75,823	88,484
Other assets	299,276	342,899
Total assets	<u>\$ 6,950,990</u>	<u>\$ 5,623,677</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,630,298	\$ 3,726,478
Accrued lease (Note 6)	51,643	43,929
Total current liabilities	4,681,941	3,770,407
Convertible notes payable (Note 5)	33,243,127	23,335,110
Accrued interest payable (Note 5)	1,439,723	740,417
Accrued lease, excluding current portion (Note 6)	167,359	192,214
Total liabilities	39,532,150	28,038,148
Commitments and contingencies (Note 7)		
Stockholders' deficit:		
Preferred stock, \$.01 par value; 1,000,000 shares authorized; 25,000 shares designated Convertible Series A, 500,000 shares designated Convertible Series D, and 800 shares designated Convertible Series E; no shares issued and outstanding at June 30, 2008 and December 31, 2007	—	—
Common stock, \$.01 par value; 80,000,000 shares authorized; 20,807,645 and 20,778,217 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively	208,076	207,782
Additional paid-in capital	141,703,365	140,420,314
Accumulated other comprehensive income	—	9,310
Deficit accumulated during development stage	(174,492,601)	(163,051,877)
Total stockholders' deficit	(32,581,160)	(22,414,471)
Total liabilities and stockholders' deficit	<u>\$ 6,950,990</u>	<u>\$ 5,623,677</u>

The accompanying notes are an integral part of the condensed consolidated financial statements.

**Alseres Pharmaceuticals, Inc.**  
(A Development Stage Enterprise)  
Condensed Consolidated Statements of Operations  
(Unaudited)

	Three months ended June 30,		Six months ended June 30,		From Inception (October 16, 1992) to June 30, 2008
	2008	2007	2008	2007	
Revenues	\$ —	\$ —	\$ —	\$ —	\$ 900,000
Operating expenses:					
Research and development	3,630,292	2,678,439	6,289,266	5,257,185	107,217,471
General and administrative	1,958,868	2,468,669	4,203,239	4,066,007	55,845,524
Purchased in-process research and development	—	—	—	—	12,146,544
Total operating expenses	<u>5,589,160</u>	<u>5,147,108</u>	<u>10,492,505</u>	<u>9,323,192</u>	<u>175,209,539</u>
Loss from operations	(5,589,160)	(5,147,108)	(10,492,505)	(9,323,192)	(174,309,539)
Other expenses	—	—	—	—	(1,582,878)
Interest expense, net	(541,080)	(186,718)	(1,000,498)	(109,698)	(6,268,736)
Investment income	15,454	41,077	52,279	59,000	7,668,552
Net loss	<u>(6,114,786)</u>	<u>(5,292,749)</u>	<u>(11,440,724)</u>	<u>(9,373,890)</u>	<u>(174,492,601)</u>
Preferred stock beneficial conversion feature	—	—	—	—	(8,062,712)
Accrual of preferred stock dividends and modification of warrants held by preferred stockholders	—	—	—	—	(1,229,589)
Net loss attributable to common stockholders	<u>(6,114,786)</u>	<u>(5,292,749)</u>	<u>(11,440,724)</u>	<u>(9,373,890)</u>	<u>\$(183,784,902)</u>
Basic and diluted net loss attributable to common stockholders per share	<u>\$ (0.29)</u>	<u>\$ (0.30)</u>	<u>\$ (0.55)</u>	<u>\$ (0.55)</u>	
Weighted average common shares outstanding	<u>20,807,645</u>	<u>17,401,371</u>	<u>20,807,260</u>	<u>16,998,399</u>	

The accompanying notes are an integral part of the condensed consolidated financial statements.

**Alseres Pharmaceuticals, Inc.**  
(A Development Stage Enterprise)

Condensed Consolidated Statements of Cash Flows  
(Unaudited)

	<u>Six Months Ended June 30,</u>		<u>From Inception (October 16, 1992) to June 30, 2008</u>
	<u>2008</u>	<u>2007</u>	
<b>Cash flows from operating activities:</b>			
Net loss	\$(11,440,724)	\$ (9,373,890)	\$(174,492,601)
<b>Adjustments to reconcile net loss to net cash used for operating activities:</b>			
Purchased in-process research and development	—	—	12,146,544
Write-off of acquired technology	—	—	3,500,000
Interest expense settled through issuance of notes payable	—	—	350,500
Non-cash interest expense	296,569	21,818	2,166,767
Loss on disposal of fixed assets	—	9,054	—
Non-cash charges related to options, warrants and common stock	900,804	861,122	8,725,261
Amortization and depreciation	20,657	62,426	2,686,650
<b>Changes in operating assets and liabilities:</b>			
Increase in prepaid expenses and other current assets	(192,423)	(534,168)	(351,919)
Increase (decrease) in accounts payable and accrued expenses	903,820	(7,144,190)	3,857,633
Increase in accrued interest payable	699,306	—	1,439,723
(Decrease) increase in accrued lease	(17,141)	(14,696)	219,002
Net cash used for operating activities	<u>(8,829,132)</u>	<u>(16,112,524)</u>	<u>(139,752,440)</u>
<b>Cash flows from investing activities:</b>			
Cash acquired through Merger	—	—	1,758,037
Purchases of fixed assets	(7,996)	(52,947)	(1,516,998)
Decrease (increase) in other assets	69,277	12,670	(575,948)
Purchases of marketable securities	—	—	(132,004,923)
Sales and maturities of marketable securities	<u>1,231,233</u>	<u>—</u>	<u>132,004,923</u>
Net cash provided by (used for) investing activities	1,292,514	(40,277)	(334,909)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock	2,541	6,102	63,731,339
Proceeds from issuance of preferred stock	—	—	35,022,170
Preferred stock conversion inducement	—	—	(600,564)
Proceeds from issuance of promissory notes	10,000,000	17,000,000	51,585,000
Proceeds from issuance of convertible debentures	—	—	9,000,000
Principal payments of notes payable	—	—	(7,146,967)
Dividend payments on Series E Cumulative Convertible Preferred Stock	—	—	(516,747)
Payments of financing costs	—	—	(5,587,667)
Net cash provided by financing activities	<u>10,002,541</u>	<u>17,006,102</u>	<u>145,486,564</u>
Net increase in cash and cash equivalents	2,465,923	853,301	5,399,215
Cash and cash equivalents, beginning of period	2,933,292	1,508,665	—
Cash and cash equivalents, end of period	<u>\$ 5,399,215</u>	<u>\$ 2,361,966</u>	<u>\$ 5,399,215</u>
<b>Supplemental cash flow disclosures:</b>			
Non-cash transactions (see Note 5)			
Cash paid for interest	\$ —	\$ —	\$ 628,406

The accompanying notes are an integral part of the condensed consolidated financial statements.

**Alseres Pharmaceuticals, Inc.**  
(A Development Stage Enterprise)

Notes to Condensed Consolidated Financial Statements (Unaudited)  
June 30, 2008

**1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, these financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements.

The interim unaudited condensed consolidated financial statements contained herein include, in management's opinion, all adjustments (consisting of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations, and cash flows for the periods presented. The results of operations for the interim period shown on this report are not necessarily indicative of results for a full year. These financial statements should be read in conjunction with the Company's consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The uncertainty inherent in the need to raise additional capital and the Company's recurring losses from operations raise substantial doubt about the Company's ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As of June 30, 2008, the Company has experienced total net losses since inception of approximately \$174,493,000 and stockholders' deficit of approximately \$32,581,000. For the foreseeable future, the Company expects to experience continuing operating losses and negative cash flows from operations as the Company's management executes its current business plan. The cash and cash equivalents available at June 30, 2008 will not provide sufficient working capital to meet the Company's anticipated expenditures for the next twelve months. The Company believes that the cash and cash equivalents available at June 30, 2008 and its ability to control certain costs, including those related to clinical trial programs, preclinical activities, and certain general and administrative expenses will enable the Company to meet its anticipated cash expenditures into October 2008.

In order to continue as a going concern, the Company will therefore need to raise additional capital through one or more of the following: a debt financing, an equity offering, or a collaboration, merger, acquisition or other transaction with one or more pharmaceutical or biotechnology companies. The Company is currently engaged in fundraising efforts. There can be no assurance that the Company will be successful in its fundraising efforts or that additional funds will be available on acceptable terms, if at all. The Company also cannot be sure that it will be able to obtain additional credit from, or effect additional sales of debt or equity securities to the Purchasers (as defined in Note 5). If the Company is unable to raise additional or sufficient capital, it will need to cease operations or reduce, cease or delay one or more of its research or development programs, adjust its current business plan and may not be able to continue as a going concern. If the Company violates a debt covenant or defaults under the March 2008 Amended Purchase Agreement or the June 2008 Purchase Agreement (as defined in Note 5), it may need to cease operations or reduce, cease or delay one or more of its research or development programs, adjust its current business plan and may not be able to continue as a going concern.

In connection with the common stock financing completed by the Company in March 2005 (the "March 2005 Financing"), the Company agreed with the purchasers in such financing, including Robert Gipson, Thomas Gipson and Arthur Koenig, (the "March 2005 Investors") that, subject to certain exceptions, it would not issue any shares of its common stock at a per share price less than \$2.50 without the prior consent of the March 2005 Investors holding at least a majority of the shares issued in the March 2005 Financing. The failure to receive the requisite waiver or consent of the March 2005 Investors could have the effect of delaying or preventing the consummation of a financing by the Company should the price per share in such financing be set at less than \$2.50.

**2. Net Loss Per Share**

Basic and diluted net loss per share attributable to common stockholders has been calculated by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. All potentially dilutive common shares have been excluded from the calculation of weighted average common shares outstanding since their inclusion would be anti-dilutive.

Stock options and warrants to purchase approximately 4.2 million and 4.8 million shares of common stock were outstanding at June 30, 2008 and 2007, respectively, but were not included in the computation of diluted net loss per common share because they were anti-dilutive. The exercise of those stock options and warrants outstanding at June 30, 2008 could potentially dilute earnings per share in the future.

**3. Comprehensive Loss**

The Company had a total comprehensive loss of \$6,114,786 and \$5,292,749 for the three months ended June 30, 2008 and 2007, respectively. For the six months ended June 30, 2008 and 2007, total comprehensive loss was \$11,450,034 and \$9,373,890, respectively. The difference between total comprehensive loss and net loss for the three and six months ended June 30, 2008 is due to unrealized gains and losses on marketable securities.

**4. Accounting for Stock-Based Compensation**

At June 30, 2008, the 2005 Stock Incentive Plan (the “2005 Plan”) provided for the issuance of nonqualified and incentive stock options, restricted stock, restricted stock units, stock appreciation rights or other stock-based awards to purchase 3,050,000 shares of the Company’s common stock to employees, officers, consultants and scientific advisors of the Company. The 2005 Plan contains a provision that allows for an annual increase in the number of shares available for issuance under the 2005 Plan on the first day of each of the Company’s fiscal years through the second day of fiscal year 2014. The annual increase in the number of shares shall be equal to the lowest of 400,000 shares; 4% of the Company’s outstanding shares on the first day of the fiscal year; and an amount determined by the Board of Directors. On January 1, 2008, the number of shares available for issuance under the 2005 Plan was increased by 400,000 shares.

The Company also has outstanding stock options in three other stock option plans, the 1998 Omnibus Plan, the Amended and Restated Omnibus Stock Option Plan and the Amended and Restated 1990 Non-Employee Directors’ Non-Qualified Stock Option Plan. These plans have expired and no future issuance of awards is permissible.

The Company’s Board of Directors determines the term, vesting provisions, price, and number of shares for each award that is granted. The term of each option cannot exceed ten years. The Company has outstanding options with performance conditions which, if met, would accelerate vesting upon achievement of the applicable milestones.

Stock-based employee compensation expense recorded during the three and six months ended June 30, 2008 and 2007 is as follows:

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Research and development	\$131,149	\$115,423	\$275,698	\$230,382
General and administrative	256,603	417,076	539,965	625,512
	<u>\$387,752</u>	<u>\$532,499</u>	<u>\$815,663</u>	<u>\$855,894</u>

Impact on basic and diluted net loss attributable to common stockholders per share	\$ (0.02)	\$ (0.03)	\$ (0.04)	\$ (0.05)
--	-----------	-----------	-----------	-----------

The Company uses the Black-Scholes valuation model to calculate the fair value of each option grant on the date of grant. The fair value of stock options granted during the three and six months ended June 30, 2008 and 2007 was calculated using the following estimated weighted-average assumptions:

## Table of Contents

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Expected term	5 years	6 years	5 years	6 years
Risk-free interest rate	3.7%	4.7% - 5.0%	2.5% - 3.7%	4.5% - 5.0%
Stock volatility	76%	90%	76%	90%
Dividend yield	0%	0%	0%	0%

Expected term — The Company determined the weighted-average expected term assumption for “plain vanilla” and performance-based option grants based on historical data on exercise behavior.

Risk-free interest rate — The risk-free interest rate used for each grant is equal to the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected term.

Expected volatility — The Company’s expected stock-price volatility assumption is based on historical volatilities of the underlying stock which is obtained from public data sources.

Expected dividend yield — The Company has never declared or paid any cash dividends on its common stock and does not expect to do so in the foreseeable future. Accordingly, the Company uses an expected dividend yield of zero to calculate the grant-date fair value of a stock option.

As of June 30, 2008, there remained approximately \$2,422,000 of compensation costs related to non-vested stock options to be recognized as expense over a weighted-average period of approximately 1.10 years.

A summary of the Company’s outstanding stock options for the six months ended June 30, 2008 and 2007 is presented below.

	Six months ended June 30, 2008		Six months ended June 30, 2007	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Outstanding at beginning of year	4,457,965	\$ 3.37	3,512,704	\$ 3.46
Granted	78,000	2.39	1,060,000	2.86
Exercised	(1,100)	2.31	—	—
Forfeited and expired	(291,170)	9.98	(32,084)	2.50
Outstanding at end of period	<u>4,243,695</u>	<u>\$ 2.90</u>	<u>4,540,620</u>	<u>\$ 3.33</u>
Options exercisable at end of period	<u>2,774,827</u>	<u>\$ 2.98</u>	<u>2,470,292</u>	<u>\$ 3.77</u>

The weighted-average fair value of options granted was \$1.52 and \$2.15 during the six months ended June 30, 2008 and 2007, respectively.

The following table summarizes information about stock options outstanding at June 30, 2008:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price
\$1.35 – \$2.00	100,500	7.1 years	\$ 1.97	98,556	7.2 years	\$ 1.97
\$2.01 – \$3.00	2,914,592	7.5 years	2.55	1,650,870	6.9 years	2.48
\$3.10 – \$4.65	1,178,363	7.1 years	3.56	975,161	6.8 years	3.59
\$4.99 – \$6.96	28,500	5.5 years	5.47	28,500	5.5 years	5.47
\$8.95 – \$13.06	8,740	3.2 years	10.55	8,740	3.2 years	10.55
\$15.62 – \$22.36	13,000	1.9 years	17.09	13,000	1.9 years	17.09
	<u>4,243,695</u>	<u>7.3 years</u>	<u>\$ 2.90</u>	<u>2,774,827</u>	<u>6.8 years</u>	<u>\$ 2.98</u>

## Table of Contents

The aggregate intrinsic value of outstanding options and exercisable options as of June 30, 2008 was \$97,176 and \$87,812, respectively. The intrinsic value of options vested during the six months ended June 30, 2008 was \$10,215. The intrinsic value of options exercised during the six months ended June 30, 2008 was \$759.

As of June 30, 2008, 804,783 shares were available for grant under the 2005 Plan.

## 5. Notes Payable and Debt

### *Convertible Notes Payable to Significant Stockholders*

In August 2006, the Company issued to Robert Gipson an unsecured promissory note (the "RG Note"), pursuant to which the Company could borrow up to an aggregate principal amount of \$3,000,000 from Robert Gipson. In October 2006, the Company issued an amended and restated unsecured promissory note (the "Amended RG Note") to Robert Gipson to replace the RG Note. Under the Amended RG Note, (i) the aggregate principal amount that could be borrowed by the Company was increased from \$3,000,000 to \$4,000,000, and (ii) one of the dates triggering repayment under the definition of Maturity Date (as discussed below) was changed from December 31, 2007 to June 30, 2007.

In October 2006, the Company issued to Thomas Gipson (together with Robert Gipson, the "Lenders") an unsecured promissory note, pursuant to which the Company could borrow up to an aggregate principal amount of \$4,000,000 (the "TG Note," together with Amended RG Note, the "First Amended Notes"). The Company borrowed a total of \$8,000,000 pursuant to the First Amended Notes. The outstanding principal amount borrowed under the First Amended Notes was due and payable upon the earliest to occur of: (i) June 30, 2007; (ii) the date on which the Company consummates an equity financing in which the gross proceeds to the Company total at least \$10,000,000; and (iii) the date on which a Lender declares an event of default (as defined in the First Amended Notes), the first of these three events to occur referred to as the "Maturity Date." Interest accrued on the outstanding principal amount under the First Amended Notes was initially payable on the Maturity Date at a rate of 9% per annum from the date of the advance to the Maturity Date.

In February 2007, the Company issued amended and restated unsecured promissory notes to the Lenders to replace the First Amended Notes (the "Second Amended Notes"). Under the Second Amended Notes, the aggregate principal amount that may be collectively borrowed by the Company was increased from \$8,000,000 to \$10,000,000. The Company borrowed an additional \$2,000,000 from the Lenders, or \$10,000,000 in the aggregate, pursuant to the Second Amended Notes.

In March 2007, the Company issued an amended and restated unsecured promissory note of \$5,000,000 to each of the Lenders (the "Amended Notes"). The Amended Notes eliminated all outstanding principal and accrued interest due under the Second Amended Notes and the Company's right to prepay any portion of the Amended Notes. The Amended Notes also required the Lenders to effect a conversion of the outstanding principal under the Amended Notes into shares of the Company's common stock at a conversion price of \$2.50 per share (the "Amended Notes Conversion") upon approval by the Company's stockholders of the conversion. The Company recorded a gain related to the forgiveness of interest of approximately \$273,000 to net interest expense on the Company's Condensed Consolidated Statements of Operations during the three months ended March 31, 2007. On June 7, 2007, the Company's stockholders approved the Amended Notes Conversion. On June 15, 2007, the Lenders converted the outstanding principal under the Amended Notes into 4,000,000 shares of the Company's common stock.

### *Purchase Agreements*

In March 2007, the Company entered into a convertible promissory note purchase agreement (the "March 2007 Purchase Agreement") with Robert Gipson, Thomas Gipson and Arthur Koenig (the "Purchasers" and also referred to as the "March 2007 Note Holders") pursuant to which the Company could borrow up to \$15,000,000 from the March 2007 Note Holders prior to December 31, 2007. In March 2007, the Company issued convertible promissory notes to the March 2007 Note Holders (the "March Notes") in the aggregate principal amount of \$9,000,000 pursuant to the March 2007 Purchase Agreement. Certain of the material terms of the convertible promissory notes are described below.

## Table of Contents

In May 2007, the Company amended and restated the March 2007 Purchase Agreement (the “May 2007 Amended Purchase Agreement”) to (i) eliminate the requirement for the March 2007 Note Holders to make further advances under the March 2007 Purchase Agreement and (ii) add Highbridge International, LLC (“Highbridge”) as a Purchaser. In May 2007, the Company issued a convertible promissory note to Highbridge (the “Highbridge Note”) in the aggregate principal amount of \$6,000,000 pursuant to the May 2007 Amended Purchase Agreement.

In August 2007, the Company amended and restated the May 2007 Amended Purchase Agreement (the “August 2007 Amended Purchase Agreement”) to (i) increase the amount the Company could borrow by \$10,000,000 to \$25,000,000 and (ii) add Ingalls & Snyder Value Partners LP (“ISVP”) as a Purchaser. In August 2007, the Company issued a convertible promissory note to ISVP (the “2007 ISVP Note”) in the aggregate principal amount of \$10,000,000 pursuant to the August 2007 Amended Purchase Agreement.

In March 2008, the Company amended and restated the August 2007 Amended Purchase Agreement (the “March 2008 Amended Purchase Agreement”) to (i) increase the amount the Company could borrow by \$5,000,000 to \$30,000,000 and (ii) provide that the Company may incur up to an additional \$5,000,000 of indebtedness from the Purchasers upon the same terms and conditions pursuant to the March 2008 Amended Purchase Agreement. In March 2008, the Company issued a convertible promissory note to Robert Gipson (the “March 2008 RG Note”) in the aggregate principal amount of \$5,000,000 pursuant to the March 2008 Amended Purchase Agreement.

However, all terms of the cumulative \$30,000,000 in convertible promissory notes remain as originally agreed to. The amounts borrowed by the Company under the March 2008 Amended Purchase Agreement bear interest at the rate of 5% per annum and may be converted, at the option of the Purchasers, into (i) shares of the Company’s common stock at a conversion price per share of \$2.50, (ii) the right to receive future royalty payments related to the Company’s molecular imaging products (including Altropane and Fluoratec) in amounts equal to 2% of the Company’s pre-commercial revenue related to such products plus 0.5% of future net sales of such products for each \$1,000,000 of outstanding principal and interest that a Purchaser elects to convert into future payments, or (iii) a combination of (i) and (ii). Any outstanding notes that are not converted into the Company’s common stock or into the right to receive future payments will become due and payable by the earlier of December 31, 2010 or the date on which a Purchaser declares an event of default (as defined in the March 2008 Amended Purchase Agreement). However, each Purchaser is prohibited from effecting a conversion if at the time of such conversion the common stock issuable to such Purchaser, when taken together with all shares of common stock then held or otherwise beneficially owned by a Purchaser exceeds 19.9%, or 9.99% for Highbridge and ISVP, of the total number of issued and outstanding shares of the Company’s common stock immediately prior to such conversion unless and until the Company’s stockholders approve the conversion of all of the shares of common stock issuable thereunder.

In June 2008, the Company entered into a convertible promissory note purchase agreement (the “June 2008 Purchase Agreement”) with Robert Gipson pursuant to which the Company could borrow up to \$5,000,000. In June 2008, the Company issued a convertible promissory note to Robert Gipson (the “June 2008 RG Note”) in the aggregate principal amount of \$5,000,000 pursuant to the June 2008 Purchase Agreement. The terms of the June 2008 Purchase Agreement are consistent with those of the March 2008 Amended Purchase Agreement described above.

The Highbridge Note was issued with a conversion price of \$2.50 which was below the market price of the Company’s common stock on the date the May 2007 Amended Purchase Agreement was entered into. In accordance with EITF 98-5, “Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios,” the Company recorded a beneficial conversion feature (“BCF”) of \$480,000 (the “Highbridge BCF”) which was recognized as a decrease in the carrying value of the Highbridge Note and an increase to additional paid-in capital. In accordance with EITF 00-27, “Application of EITF 98-5 To Certain Convertible Instruments” the value of the Highbridge BCF is being recognized as interest expense using the effective interest method through December 31, 2010. The Company recorded interest expense related to the Highbridge BCF in the accompanying Condensed Consolidated Statements of Operations of approximately \$31,000 and \$61,000 during the three and six months ended June 30, 2008, respectively. The Company recorded interest expense of approximately \$22,000 during the three months ended June 30, 2007.

## Table of Contents

The 2007 ISVP Note was issued with a conversion price of \$2.50 which was below the market price of the Company's common stock on the date the August 2007 Amended Purchase Agreement was entered into. Accordingly, the Company recorded a BCF of \$1,400,000 (the "ISVP BCF") which was recognized as a decrease in the carrying value of the 2007 ISVP Note and an increase to additional paid-in capital. The ISVP BCF is being recognized as interest expense using the effective interest method through December 31, 2010. The Company recorded interest expense related to the ISVP BCF in the accompanying Condensed Consolidated Statements of Operations of approximately \$97,000 and \$191,000 during the three and six months ended June 30, 2008, respectively.

The March 2008 RG Note was issued with a conversion price of \$2.50 which was below the market price of the Company's common stock on the date the March 2008 Amended Purchase Agreement was entered into. Accordingly, the Company recorded a BCF of \$380,000 (the "2008 RG BCF") which was recognized as a decrease in the carrying value of the March 2008 RG Note and an increase to additional paid-in capital. The 2008 RG BCF is being recognized as interest expense using the effective interest method through December 31, 2010. The Company recorded interest expense related to the 2008 RG BCF in the accompanying Condensed Consolidated Statements of Operations of approximately \$31,000 and \$36,000 during the three and six months ended June 30, 2008, respectively.

At June 30, 2008, the aggregate carrying value of the Highbridge Note, the March Notes, the 2007 ISVP Note, the March 2008 RG Note and the June 2008 RG Note of \$33,243,127 and the related accrued interest was classified as a long-term liability.

The Company is subject to certain debt covenants pursuant to the March 2008 Amended Purchase Agreement and the June 2008 Purchase Agreement (the "Purchase Agreements"). If the Company (i) fails to pay the principal or interest due under the Purchase Agreements, (ii) files a petition for action for relief under any bankruptcy or similar law or (iii) an involuntary petition is filed against the Company, all amounts borrowed under the Purchase Agreements may become immediately due and payable by the Company. In addition, without the consent of the Purchasers, the Company may not (i) create, incur or otherwise permit to be outstanding any additional indebtedness for money borrowed, (ii) declare or pay any cash dividend, or make a distribution on, repurchase, or redeem, any class of the Company's stock, subject to certain exceptions or sell, lease, transfer or otherwise dispose of any of the Company's material assets or property or (iii) dissolve or liquidate.

According to a Schedule 13G/A filed with the SEC on February 12, 2008, Robert Gipson beneficially owned approximately 28.8% of the outstanding common stock of the Company on December 31, 2007. Robert Gipson, who serves as a Senior Director of Ingalls & Snyder LLC and a General Partner of ISVP, served as a director of the Company from June 15, 2004 until October 28, 2004. According to a Schedule 13G/A filed with the SEC on February 12, 2008, Thomas Gipson beneficially owned approximately 29.1% of the outstanding common stock of the Company on December 31, 2007. According to a Schedule 13G/A filed with the SEC on February 12, 2008, Arthur Koenig beneficially owned approximately 9.7% of the outstanding common stock of the Company on December 31, 2007. According to a Schedule 13G filed with the SEC on February 12, 2008, ISVP owned approximately 16.6% of the outstanding common stock of the Company on December 31, 2007. According to a Schedule 13G filed with the SEC on December 12, 2007, Highbridge beneficially owned approximately 9.99% of the outstanding common stock of the Company on November 2, 2007.

## 6. Exit Activities

In September 2005, the Company relocated its headquarters to office space in Hopkinton, Massachusetts. In addition, the Company amended its Lease Agreement (the "Lease Amendment"), dated as of January 28, 2002 by and between the Company and Brentwood Properties, Inc. (the "Landlord") relating to the Company's former principal executive offices (the "Premises") located in Boston, Massachusetts (the "Lease Agreement"). Pursuant to the terms of the Lease Amendment, the Landlord consented to, among other things, two sublease agreements which run through May 30, 2012, the term of the Lease Agreement, and which occupy all rentable square feet of the Premises. In consideration for the Landlord's consent, the Company agreed to increase its security deposit provided for under the Lease Agreement from \$250,000 to \$388,600 subject to periodic reduction pursuant to a predetermined formula. At June 30, 2008, the security deposit under the Lease Agreement was approximately \$242,000.

## Table of Contents

As a result of the Company's relocation, an expense was recorded in accordance with Statement of Financial Accounting Standards ("SFAS") 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). SFAS 146 requires that a liability be recorded for a cost associated with an exit or disposal activity at its fair value in the period in which the liability is incurred. The liability recorded for the Lease Amendment was calculated by discounting the estimated cash flows for the two sublease agreements and the Lease Agreement using an estimated credit-adjusted risk-free rate of 15%. The expense and accrual recorded in accordance with SFAS 146 requires the Company to make significant estimates and assumptions. These estimates and assumptions will be evaluated and adjusted as appropriate on at least a quarterly basis for changes in circumstances. It is reasonably possible that such estimates could change in the future resulting in additional adjustments, and the effect of any such adjustments could be material.

The activity related to the lease accrual at June 30, 2008, is as follows:

	Accrual at December 31, 2007	Cash Payments, Net of Sublease Receipts 2008	Accrual at June 30, 2008
Lease Amendment	\$ 236,143	\$ 17,141	\$ 219,002
Short-term portion of lease accrual	43,929		51,643
Long-term portion of lease accrual	<u>\$ 192,214</u>		<u>\$ 167,359</u>

During the three and six months ended June 30, 2008 the Company recorded approximately \$8,000 and \$19,000, respectively of expense related to the imputed cost of the lease expense accrual included in general and administrative expenses in the accompanying Condensed Consolidated Statements of Operations. During the three and six months ended June 30, 2007, the Company recorded approximately \$9,700 and \$20,000, respectively of expense related to the imputed cost of the lease expense accrual included in general and administrative expenses in the accompanying Condensed Consolidated Statements of Operations.

## 7. Commitments and Contingencies

The Company recognizes and discloses commitments when it enters into executed contractual obligations with third parties. The Company accrues contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

### *License Agreements*

The Company has entered into license agreements (the "CMCC Licenses") with Children's Medical Center Corporation (also known as Children's Hospital Boston) ("CMCC") to acquire the exclusive worldwide rights to certain axon regeneration technologies. The CMCC Licenses provide for future milestone payments of up to an aggregate of approximately \$425,000 for each product candidate upon achievement of certain regulatory milestones. Additionally, the Company entered into two sponsored research agreements with CMCC which provide for a total of \$550,000 in annual expenditures through May 2009.

The Company has entered into license agreements (the "Harvard License Agreements") with Harvard University and its affiliated hospitals ("Harvard and its Affiliates") to acquire the exclusive worldwide rights to certain technologies within its molecular imaging and neurodegenerative disease programs. The Harvard License Agreements obligate the Company to pay up to an aggregate of approximately \$2,520,000 in milestone payments in the future. The future milestone payments are generally payable only upon achievement of certain regulatory milestones.

The Company's license agreements with Harvard and its Affiliates and CMCC generally provide for royalty payments equal to specified percentages of product sales, annual license maintenance fees and continuing patent prosecution costs.

In December 2006, the Company entered into a license agreement (the "Cethrin License") with BioAxone Therapeutic Inc., a Canadian corporation ("BioAxone"), pursuant to which the Company was granted an exclusive, worldwide license to develop and commercialize specified compounds including, but not limited to, Cethrin, as further defined in the Cethrin License. Under the Cethrin License, the Company agreed to pay BioAxone

## Table of Contents

\$10,000,000 in up-front payments, \$25,000,000 upon the achievement of certain milestone events, and royalties based on 10-12% of the worldwide net sales of licensed products, subject to specified minimums, in each calendar year until either the expiration of a valid claim covering a licensed product or a certain time period after the launch of a licensed product, in each case applicable to the specific country.

In April 2008, the Company entered into an option agreement with BioAxone pursuant to which the Company was granted an option to amend the Cethrin License (the “BioAxone Option Agreement”). The BioAxone Option Agreement provides that the Company can exercise its option to amend certain terms of the Cethrin License until the earlier of (a) sale or issuance of shares of capital stock of the Company, including the sale of debt that is convertible into shares of capital stock of the Company, which results in aggregate gross proceeds of not less than \$25,000,000, and (b) October 27, 2008. If the option is exercised, the Company will pay a fee of \$7,000,000 to BioAxone and the parties will enter into an amendment to the Cethrin License.

The amendment to the Cethrin License will replace the existing \$25,000,000 in milestone payments and royalty payments with a requirement that the Company pay \$7,000,000 to BioAxone on or before December 31, 2009, or upon BioAxone’s written request, if the Company assigns all of its rights and interest in and to the underlying licensed intellectual property (as defined in the Cethrin License), prior to December 31, 2009. In addition, the amendment will provide that the Company will make royalty payments to BioAxone based on a percentage of annual net sales of certain products specified in the Cethrin License for the treatment of acute spinal cord injury equal to 4% of such net sales and 1% of such net sales for all other products specified in the Cethrin License for indications other than acute spinal cord injury, until the earlier of December 31, 2021 or the Royalty Expiration Date (as defined in the Cethrin License).

The amendment to the Cethrin License will also provide that BioAxone will grant to the Company a fully paid-up, irrevocable, perpetual worldwide license to the underlying licensed intellectual property, and take steps to transfer to the Company certain ancillary intellectual property rights related thereto. In addition, the amendment will provide that BioAxone will release the Company from certain development and commercialization requirements imposed by the Cethrin License.

### *Contingencies*

The Company is subject to legal proceedings in the ordinary course of business. Two such matters involve claims for cash and/or warrants to purchase shares of common stock of the Company in connection with certain of the Company’s private placements. One other matter involves a claim for cash of \$250,000 in connection with one of the Company’s license agreements. Management has responded to such claims and believes that there is no legal or equitable basis for payment of the claims and that the resolution of these matters and others will not have a material adverse effect on the consolidated financial statements.

### *Guarantor Arrangements*

As permitted under Delaware law, the Company has entered into agreements whereby the Company indemnifies its executive officers and directors for certain events or occurrences while the officer or director is, or was serving, at the Company’s request in such capacity. The term of the indemnification period is for the officer’s or director’s lifetime. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company has a director and officer insurance policy that limits the Company’s exposure and enables the Company to recover a portion of any future amounts paid. As a result of the Company’s insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal.

The Company enters into arrangements with certain service providers to perform research, development and clinical services for the Company. Under the terms of these arrangements, such service providers may use the Company’s technologies in performing their services. The Company enters into standard indemnification agreements with those service providers, whereby the Company indemnifies them for any liability associated with their use of the Company’s technologies. The maximum potential amount of future payments the Company would be required to make under these indemnification agreements is unlimited; however, the Company has product liability and general liability policies that enable the Company to recover a portion of any amounts paid. As a result

## Table of Contents

of the Company's insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal.

### *Lease Commitment*

The Company's current office leases expire in 2008. In July 2008, the Company entered into a noncancelable operating lease agreement for new office space in Hopkinton, Massachusetts. The new lease is for approximately 16,300 square feet of space and expires in September 2011. Under the new lease, the Company will incur approximately \$275,000 in annual rent expense.

## **8. Income taxes**

On January 1, 2007, the Company adopted Financial Accounting Standards Board ("FASB") Interpretation No. 48 ("FIN 48"), "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement 109", which was issued in July 2006. FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction. Unrecognized tax benefits are accounted for as a reduction to deferred tax assets and a corresponding reduction to the valuation allowance. Substantially all of these unrecognized tax benefits, if recognized, would affect the effective tax rate. There was no change to our accumulated deficit as of December 31, 2006 as a result of the adoption of the recognition and measurement provisions of FIN 48.

The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company has no accrual for interest and penalties as of June 30, 2008.

The Company is subject to both federal and state income tax for the jurisdictions within which it operates, which are primarily focused in Massachusetts. Within these jurisdictions, the Company is open to examination for tax years ended December 31, 2004 through December 31, 2007. However, because we are carrying forward income tax attributes, such as net operating losses from 2003 and earlier tax years, these attributes can still be audited when utilized on returns filed in the future. There are currently no tax audits that have commenced with respect to income tax returns in any jurisdiction.

## **9. Fair Value Measurements**

Effective January 1, 2008 the Company adopted SFAS No. 157, "Fair Value Measurements" ("SFAS 157") and SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115, ("SFAS 159") for its financial assets and liabilities. As permitted by FASB Staff Position No. 157-2, "Effective Date of FASB Statement No. 157", the Company elected to defer the adoption of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statement on a recurring basis, until January 1, 2009. SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The Company did not elect to adopt the fair value option for eligible financial instruments under SFAS 159.

SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. Under SFAS 157, fair value is determined based upon the exit price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants exclusive of any transaction costs. The Company did not record any cumulative adjustment as a result of adopting SFAS 157.

SFAS No. 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, described below:

Level 1: Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly.

## Table of Contents

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The following table sets forth our financial assets that were measured at fair value on a recurring basis at June 30, 2008 by level within the fair value hierarchy. We did not have any non-financial assets or liabilities that were measured or disclosed at fair value on a recurring basis at June 30, 2008. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Description	Carrying Value at June 30, 2008	Fair Value Measurement at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market funds — current assets	\$ 5,399,215	\$ 5,399,215	\$ —	\$ —
Money market funds — long term assets	\$ 114,399	\$ 114,399	\$ —	\$ —
Total	\$ 5,513,614	\$ 5,513,614	\$ —	\$ —

Money market funds are measured at fair value using quoted market prices and are classified within Level 1 of the fair value valuation hierarchy.

### 10. New Accounting Pronouncements

In February 2008, the FASB issued FASB Staff Position (“FSP”) No. 157-2, “Effective Date of FASB Statement No. 157.” This FSP delays the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). SFAS 157 will therefore be applicable to non-financial assets and liabilities for the Company's fiscal year commencing January 1, 2009. The Company is currently reviewing the impact of the adoption of SFAS 157 for all non-financial assets and liabilities on its financial statements.

In May 2008, the FASB issued FSP No. APB 14-1, “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion” (“FSP APB 14-1”). FSP APB 14-1 specifies that issuers of convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) should separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact that the adoption of FSP APB 14-1 will have on its financial position, results of operations and cash flow.

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

Our management's discussion and analysis of our financial condition and results of operations include the identification of certain trends and other statements that may predict or anticipate future business or financial results that are subject to important factors that could cause our actual results to differ materially from those indicated. See Item 1A, “Risk Factors.” The information in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2007.

### Overview

#### *Description of Company*

We are a biotechnology company engaged in the development of therapeutic and diagnostic products primarily for disorders in the central nervous system, or CNS. Our clinical and preclinical product candidate pipeline is based on three proprietary technology platforms:

- Regenerative therapeutics program, primarily focused on nerve repair and restoring movement and sensory function in patients who have had significant loss of CNS function resulting from traumas such as spinal cord injury, or SCI, stroke, traumatic brain injury, or TBI, and optic nerve damage utilizing technology referred to as axon regeneration;
- Molecular imaging program focused on the diagnosis of i) Parkinsonian Syndromes, or PS, including Parkinson's Disease, or PD, and ii) Dementia with Lewy Bodies, or DLB; and
- Neurodegenerative disease program focused on treating the symptoms of PD and slowing or stopping the progression of PD.

At June 30, 2008, we were considered a "development stage enterprise" as defined in Statement of Financial Accounting Standards, or SFAS, No. 7, "Accounting and Reporting by Development Stage Enterprises."

As of June 30, 2008, we have experienced total net losses since inception of approximately \$174,493,000, and stockholders' deficit of approximately \$32,581,000. For the foreseeable future, we expect to experience continuing operating losses and negative cash flows from operations as our management executes our current business plan. The cash and cash equivalents available at June 30, 2008 will not provide sufficient working capital to meet our anticipated expenditures for the next twelve months. We believe that the cash and cash equivalents available at June 30, 2008 and our ability to control certain costs, including those related to clinical trial programs, preclinical activities, and certain general and administrative expenses will enable us to meet our anticipated cash expenditures into October 2008.

In order to continue as a going concern, we will therefore need to raise additional capital through one or more of the following: a debt financing, an equity offering, or a collaboration, merger, acquisition or other transaction with one or more pharmaceutical or biotechnology companies. We are currently engaged in fundraising efforts. There can be no assurance that we will be successful in our fundraising efforts or that additional funds will be available on acceptable terms, if at all. We also cannot be sure that we will be able to obtain additional credit from, or effect additional sales of debt or equity securities to the Purchasers (described below). If we are unable to raise additional or sufficient capital, we will need to cease operations or reduce, cease or delay one or more of our research or development programs, adjust our current business plan and may not be able to continue as a going concern. If we violate a debt covenant or default under the March 2008 Amended Purchase Agreement or the June 2008 Purchase Agreement (described below), we may need to cease operations or reduce, cease or delay one or more of our research or development programs, adjust our current business plan and may not be able to continue as a going concern.

In connection with the common stock financing completed by us in March 2005, or the March 2005 Financing, we agreed with the purchasers in such financing, including Robert Gipson, Thomas Gipson, and Arthur Koenig, or the March 2005 Investors, that, subject to certain exceptions, we would not issue any shares of our common stock at a per share price less than \$2.50 without the prior consent of the March 2005 Investors holding at least a majority of the shares issued in the March 2005 Financing. On August 4, 2008, the closing price of our common stock was \$2.18. The failure to receive the requisite waiver or consent of the March 2005 Investors could have the effect of delaying or preventing the consummation of a financing by us should the price per share in such financing be set at less than \$2.50.

Our ability to continue to advance our clinical programs, including the development of Cethrin and the Altropane molecular imaging agent, and our preclinical programs will be affected by the availability of financial resources to fund each program. Financial considerations may cause us to modify planned development activities for one or more of our programs, and we may decide to suspend development of one or more programs until we are able to secure additional working capital. If we are not able to raise additional capital, we will not have sufficient funds to complete the clinical trial programs for Cethrin or the Altropane molecular imaging agent.

## Table of Contents

We continually evaluate possible acquisitions of, or investments in, businesses, technologies and products that are complementary to our nerve repair program. The consideration paid in connection with an acquisition would also affect our financial results. If we were to proceed with one or more significant acquisitions in which the consideration included cash, we could be required to use a substantial portion of our available cash to consummate any such acquisition or acquisitions. To the extent we issue shares of stock or other rights to purchase stock, including options or other rights, existing stockholders may be diluted. In addition, acquisitions may result in the incurrence of debt, large one-time write-offs and restructuring charges. Acquisitions may also result in goodwill and other intangible assets that are subject to impairment tests, which could result in future impairment charges. To the extent that we use common stock for all or a portion of the consideration to be paid for future acquisitions, our existing stockholders may experience significant dilution.

In order to effect an acquisition, we may need additional financing. We cannot be certain that any such financing will be available on terms favorable or acceptable to us, or at all. If we raise additional funds through the issuance of equity, equity-related or debt securities, these securities may have rights, preferences or privileges senior to those of the rights of our common stockholders, who would then experience dilution. There can be no assurance that we will be able to identify or successfully complete any acquisitions.

### Purchase Agreements

In March 2007, we entered into a convertible promissory note purchase agreement, or the March 2007 Purchase Agreement, with Robert Gipson, Thomas Gipson and Arthur Koenig, referred to as the Purchasers and also the March 2007 Note Holders, pursuant to which we could borrow up to \$15,000,000 from the March 2007 Note Holders prior to December 31, 2007. In March 2007, we issued convertible promissory notes to the March 2007 Note Holders in the aggregate principal amount of \$9,000,000 pursuant to the March 2007 Purchase Agreement. Certain of the material terms of the convertible promissory notes are described below.

In May 2007, we amended and restated the March 2007 Purchase Agreement, or the May 2007 Amended Purchase Agreement, to (i) eliminate the requirement for the March 2007 Note Holders to make further advances under the March 2007 Purchase Agreement and (ii) add Highbridge International, LLC, or Highbridge, as a Purchaser. In May 2007, we issued a convertible promissory note to Highbridge in the aggregate principal amount of \$6,000,000 pursuant to the May 2007 Amended Purchase Agreement.

In August 2007, we amended and restated the May 2007 Amended Purchase Agreement, or the August 2007 Amended Purchase Agreement, to (i) increase the amount we could borrow by \$10,000,000 to \$25,000,000 and (ii) add Ingalls & Snyder Value Partners LP, or ISVP, as a Purchaser. In August 2007, we issued a convertible promissory note to ISVP in the aggregate principal amount of \$10,000,000 pursuant to the August 2007 Amended Purchase Agreement.

In March 2008, we amended and restated the August 2007 Amended Purchase Agreement, or the March 2008 Amended Purchase Agreement, to (i) increase the amount we could borrow by \$5,000,000 to \$30,000,000 and (ii) provide that we may incur up to an additional \$5,000,000 of indebtedness from the Purchasers upon the same terms and conditions pursuant to the March 2008 Amended Purchase Agreement. In March 2008, we issued a convertible promissory note to Robert Gipson in the aggregate principal amount of \$5,000,000 pursuant to the March 2008 Amended Purchase Agreement, or the March 2008 RG Note.

The amounts borrowed by us under the March 2008 Amended Purchase Agreement bear interest at the rate of 5% per annum and may be converted, at the option of the Purchasers into (i) shares of our common stock at a conversion price per share of \$2.50, (ii) the right to receive future royalty payments related to our molecular imaging products (including Altropane and Fluoratec) in amounts equal to 2% of our pre-commercial revenue related to such products plus 0.5% of future net sales of such products for each \$1,000,000 of outstanding principal and interest that a Purchaser elects to convert into future payments, or (iii) a combination of (i) and (ii). Any outstanding notes that are not converted into our common stock or into the right to receive future payments will become due and payable by the earlier of December 31, 2010 or the date on which a Purchaser declares an event of default (as defined in the March 2008 Amended Purchase Agreement). However, each Purchaser is prohibited from effecting a conversion if at the time of such conversion the common stock issuable to such Purchaser, when taken together with all shares of common stock then held or otherwise beneficially owned by a Purchaser exceeds 19.9%, or 9.99% for Highbridge

and ISVP, of the total number of issued and outstanding shares of our common stock immediately prior to such conversion unless and until our stockholders approve the conversion of all of the shares of common stock issuable thereunder.

In June 2008, we entered into a convertible promissory note purchase agreement, or the June 2008 Purchase Agreement, with Robert Gipson pursuant to which we could borrow up to \$5,000,000. In June 2008, we issued a convertible promissory note to Robert Gipson, or the June 2008 RG Note, in the aggregate principal amount of \$5,000,000 pursuant to the June 2008 Purchase Agreement. The terms of the June 2008 Purchase Agreement are consistent with those of the March 2008 Amended Purchase Agreement described above.

We are subject to certain debt covenants pursuant to the March 2008 Amended Purchase Agreement and the June 2008 Purchase Agreement, or Purchase Agreements. If we (i) fail to pay the principal or interest due under the Purchase Agreements, (ii) file a petition for action for relief under any bankruptcy or similar law or (iii) an involuntary petition is filed against us, all amounts borrowed under the Purchase Agreements may become immediately due and payable by us. In addition, without the consent of the Purchasers, we may not (i) create, incur or otherwise, permit to be outstanding any additional indebtedness for money borrowed, (ii) declare or pay any cash dividend, or make a distribution on, repurchase, or redeem, any class of our stock, subject to certain exceptions or sell, lease, transfer or otherwise dispose of any of our material assets or property or (iii) dissolve or liquidate.

### ***Product Development***

#### *Regenerative Therapeutics Program — Nerve Repair*

Our nerve repair program is focused on restoring movement and sensory function in patients who have had significant loss of CNS function resulting from traumas such as SCI, stroke, TBI and optic nerve damage. Our efforts are aimed at the use of proprietary regenerative drugs and/or methods to induce nerve fibers called axons to regenerate and form new connections that restore lost abilities. We support sponsored research that could extend our existing capabilities in nerve repair by potentially providing multiple avenues for intervention in functional CNS recovery. Licensing or acquiring the rights to the technologies of complementary approaches for axon regeneration is part of our strategy of creating competitive advantages in nerve repair by assembling a broad portfolio of related technologies and intellectual property.

Our lead product in clinical development for nerve repair is Cethrin. Cethrin contains a proprietary protein which studies indicate inactivates a key enzyme called Rho resulting in the promotion of axon regeneration. Cethrin is currently being investigated to determine its effectiveness in facilitating the restoration of movement and sensory function following a major injury to the spinal cord. After an SCI, approximately two-thirds of patients undergo decompression/stabilization surgery. During surgery, Cethrin is delivered in a single application to the injured region of the spinal cord using a fibrin sealant as a carrier.

In January 2008, enrollment ended in our open-label, non-placebo-controlled, dose-escalating Phase I/IIa trial in subjects with acute SCI. A total of 48 subjects was enrolled at 9 sites in the United States and Canada. The trial design includes a number of post-treatment evaluations of the subjects for safety and efficacy for up to one year after treatment. The efficacy measurements assess changes in subjects' sensory and motor functions, as well as overall recovery as measured by the impairment scale developed by the American Spinal Injury Association, or ASIA. The ASIA Impairment Scale, or AIS, is used to score subjects within five grades from ASIA Grade A to ASIA Grade E, with ASIA Grade A being complete impairment with no sensory or motor function below the site of injury and ASIA Grade E being normal. ASIA Grade B through ASIA Grade E designate increasing levels of motor and sensory function. At the time of enrollment in the Cethrin Phase I/IIa trial, all subjects had a complete thoracic or cervical SCI, had no motor or sensory function below the level of their injury, and were thus classified as an ASIA Grade A. A component of AIS is the assessment of change in motor score. The measurement is made by assessing five muscle groups in each arm and leg on a 0 to 5 point scale for a total of 100 motor points. Using this assessment, the total change in motor score is measured. The Clinical Guidelines Panel Report issued by the International Campaign for Cures of spinal cord injury Paralysis, or ICCP, indicates that a cervical ASIA Grade A-injured patient is likely to spontaneously improve approximately 10 motor points during the first year after SCI.

## Table of Contents

The trial assessed 5 dose levels of Cethrin: 0.3 mg, 1 mg, 3 mg, 6 mg and 9 mg. Each dose level was first given to thoracic SCI subjects and then, following review by an independent Data Safety Monitoring Board, or DSMB, the dose level was initiated in cervical subjects. To date, the safety and tolerability data for each of the five dose levels have indicated that Cethrin appears to be safe and well tolerated. There have been no serious adverse events attributable to Cethrin. There were two deaths of subjects enrolled in the trial. The DSMB and the clinical investigators attributed the two deaths to causes related to the subjects' initial SCI, other injuries, or preexisting conditions and not related to Cethrin.

The 6 and 12 month interim data for the first 37 subjects treated with doses up to 6 mg indicated that 38.5% (5 of 13) of subjects with cervical injuries and 8.3% (2 of 24) of subjects with thoracic injuries improved over the 6 and 12 months to ASIA Grade C or better, as described in the table below. Moreover, 1 cervical injury subject in each of the 1 mg and 3 mg dose improved to ASIA Grade D at 6 and 12 months and 1 subject with a thoracic injury in the 6 mg dose improved to ASIA Grade D at 12 months.

ASIA Grade A Subjects with Improvement to ASIA Grade C (or better) by Dose - 6 and 12 months (Intent to Treat population—Last Observation Carried Forward)		
Dose (mg)	Cervical	Thoracic
0.3	1 of 3	0 of 6
1	1 of 4	1 of 6
3	2 of 3	0 of 6
6	1 of 3	1 of 6
<b>Total</b>	<b>5 of 13</b>	<b>2 of 24</b>

In addition, the 6 and 12 month interim motor score data for the first 37 subjects treated with doses up to 6 mg is described in the table below. At 12 months, the largest mean changes in motor score from baseline were seen in cervical patients treated with 1 mg and 3 mg, where average improvements of 16.3 and 27.3 points, respectively, were observed. As noted by the ICCP, the expected spontaneous motor score change for cervical subjects is approximately 10 motor points during the first year after SCI.

Mean Change in Motor Score from Baseline (Intent to Treat population — Last Observation Carried Forward)				
Dose (mg)	Cervical		Thoracic	
	6 Months	12 Months	6 Months	12 Months
0.3	11.3	11.0	0.0	0.0
1	15.8	16.3	2.7	3.2
3	19.7	27.3	0.0	0.0
6	9.7	11.0	5.2	5.7

Data for the ASIA grade and motor score improvements for the remaining 11 patients, including the 9 mg dose, are still being collected and will be released as the post-treatment evaluations have been collected and reviewed.

We have met with the Food and Drug Administration, or FDA, Health Canada, the European Medicines Agency, and with regulatory authorities in selected European countries to review the Phase I/IIa results and our Cethrin clinical development plan, including our planned Phase IIb trial.

Our preliminary planning for the Phase IIb trial of Cethrin called for us to enroll up to 100 subjects in 80 sites worldwide. Ongoing inputs, including the results to date in the Phase I/IIa trial, discussions with the regulatory authorities and our expert advisors, now indicate that a placebo-controlled trial to demonstrate the potential efficacy of Cethrin can be accomplished with fewer patients and sites, and provide us with results from the trial approximately a year earlier. We are now planning to initiate a randomized, double-blind, placebo-controlled, Phase IIb trial in subjects with acute cervical SCI in the first quarter of 2009 at sites across North America.

We are also exploring the use of other nerve repair drug candidates in a variety of CNS conditions such as SCI, stroke, TBI and optic nerve damage. We initiated a series of comparative studies in which the abilities of our other nerve repair product candidates, including Inosine, Oncomodulin and potentially other compounds, will be assessed for their potential to enhance nerve repair. If successful, these studies may enable the most promising candidates and indications to be taken forward in development.

## Table of Contents

### *Regenerative Therapeutics Program— Bone Repair*

We are evaluating our Rho inhibitors *in vitro* and in animal models to assess their ability to stimulate cells to regenerate bone.

### *Molecular Imaging Program*

The Altoprane molecular imaging agent is being developed for the differential diagnosis of PS, including PD, and non-PS in patients with tremor. In July 2007, our collaborators completed enrollment in a study that optimized the Altoprane image acquisition protocol which we believe will enhance Altoprane's commercial use. After a series of discussions with the FDA and our expert advisors, the Parkinson's or Essential Tremor-2, or POET-2, program was designed as a two-part Phase III program using the optimized Altoprane image acquisition protocol. The first part of the program was initiated in December 2007 in a multi-center clinical study in subjects to acquire the set of Altoprane images which will be used to train the expert readers, as is the customary process for clinical trials of molecular imaging agents. The second part involves two concurrent, replicate, multi-center Phase III trials. These two concurrent trials, the final design of which is under discussion with the FDA, will be initiated once final agreement on the design of the trials is reached with the FDA.

To maximize the value of our molecular imaging program, we are seeking to partner our molecular imaging program for the completion of the Phase III clinical program and launch and commercialization of Altoprane. We believe that the expansion of the program into other indications such as DLB and other countries including those in Europe could increase the value of the program for the partner and us.

In addition to Altoprane, we are developing a second generation technetium-based molecular imaging agent for the diagnosis of PD and DLB. We believe the potential use of our technetium-based molecular imaging agents could be strategic in our partnering efforts for our molecular imaging program.

### *Neurodegenerative Disease Program*

We are developing a Dopamine Transporter, or DAT, blocker for the treatment of the symptoms of PD and slowing or stopping the progression of PD. We have identified several promising lead compounds, some of which have been shown in primate studies to alleviate the symptoms of PD. In some cases, efficacy results with our DAT blocker were comparable to that of a standard dopamine agonist. Dopamine agonists are routinely used to treat the symptoms of PD both as monotherapy agents and in conjunction with the most common treatment, Levodopa. We have shown that our lead compounds bind to the DAT *in vitro* at low concentrations and are effective *in vitro* at blocking DAT re-uptake also at low concentrations. Our lead compounds have also been shown to enter the brain after oral dosing in rodents and to alleviate the symptoms of PD in non-human primates. We are seeking a partner to advance our neurodegenerative disease program into clinical trials.

### *Sales and Marketing and Government Regulation*

To date, we have not marketed, distributed or sold any products and, with the exception of Altoprane and Cethrin, all of our other product candidates are in preclinical development. Our product candidates must undergo a rigorous regulatory approval process which includes extensive preclinical and clinical testing to demonstrate safety and efficacy before any resulting product can be marketed. The FDA has stringent standards with which we must comply before we can test our product candidates in humans or make them commercially available. Preclinical testing and clinical trials are lengthy and expensive and the historical rate of failure for product candidates is high. Clinical trials require sufficient patient enrollment which is a function of many factors. Delays and difficulties in completing patient enrollment can result in increased costs and longer development times. The foregoing uncertainties and risks limit our ability to estimate the timing and amount of future costs that will be required to complete the clinical development of each program. In addition, we are unable to estimate when material net cash inflows are expected to commence as a result of the successful completion of one or more of our programs.

### *Research and Development*

Following is information on the direct research and development costs incurred on our principal scientific technology programs currently under development. These amounts do not include research and development employee and related overhead costs which total approximately \$25,644,000 on a cumulative basis.

## Table of Contents

<b>Program</b>	<b>For the Three Months Ended June 30, 2008</b>	<b>For the Six Months Ended June 30, 2008</b>	<b>From Inception (October 16, 1992) to June 30, 2008</b>
Regenerative therapeutics	\$ 2,053,000	\$ 3,135,000	\$ 27,134,000
Molecular imaging	\$ 420,000	\$ 782,000	\$ 25,577,000
Neurodegenerative disease	\$ —	\$ 20,000	\$ 1,111,000

Estimating costs and time to complete development of a specific program or technology is difficult due to the uncertainties of the development process and the requirements of the FDA which could require additional clinical trials or other development and testing. Results of any testing could lead to a decision to change or terminate development of a technology, in which case estimated future costs could change substantially. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing or funding by such corporate partner of development costs, the estimated development costs incurred by us could be substantially less than estimated. Additionally, research and development costs are extremely difficult to estimate for early-stage technologies due to the fact that there are generally less comprehensive data available for such technologies to determine the development activities that would be required prior to the filing of a New Drug Application, or NDA. As a result, we cannot reasonably estimate the cost and the date of completion for any technology that is not at least in Phase III clinical development due to the uncertainty regarding the number of required trials, the size of such trials and the duration of development. Even in Phase III clinical development, estimating the cost and the filing date for an NDA can be challenging due to the uncertainty regarding the number and size of the required Phase III trials. We are currently analyzing what additional expenditures may be required to complete the Phase III clinical trial program for Altropane for the diagnosis of PS and cannot reasonably estimate the cost of this Phase III clinical trial program at this time.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements which have been prepared by us in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. Our estimates include those related to marketable securities, research contracts, the fair value and classification of equity instruments, our lease accrual and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

#### ***Marketable Securities***

Our marketable securities consist exclusively of investments in United States agency bonds and corporate debt obligations. These marketable securities are adjusted to fair value on the Consolidated Balance Sheet through other comprehensive income. If a decline in the fair value of a security is considered to be other than temporary, the investment is written down to a new cost basis and the unrealized loss is removed from accumulated other comprehensive loss and recorded in the Consolidated Statements of Operations. We evaluate whether a decline in fair value is other than temporary based on factors such as the significance of the decline, the duration of time for which the decline has been in existence and our ability and intent to hold the security to maturity. To date, we have not recorded any other than temporary impairments related to our marketable securities. These marketable securities are classified as current assets because they are highly liquid and are available, as required, to meet working capital and other operating requirements.

#### ***Research Contracts***

We regularly enter into contracts with third parties to perform research and development activities on our behalf in connection with our scientific technologies. Costs incurred under these contracts are recognized ratably over the term of the contract or based on actual enrollment levels which we believe corresponds to the manner in which the work is performed. Clinical trial, contract services and other outside costs require that we make estimates of the costs incurred in a given accounting period and record accruals at period end as the third party service periods and billing terms do not always coincide with our period end. We base our estimates on our knowledge of the research and development programs, services performed for the period, past history for related activities and the expected duration of the third party service contract, where applicable.

### *Fair Value and Classification of Equity Instruments*

Historically, we have issued warrants to purchase shares of our common stock in connection with our debt and equity financings. We record each of the securities issued on a relative fair value basis up to the amount of the proceeds received. We estimate the fair value of the warrants using the Black-Scholes valuation model. The Black-Scholes valuation model is dependent on a number of variables and estimates including: interest rates; dividend yield; volatility and the expected term of the warrants. Our estimates are based on market interest rates at the date of issuance, our past history for declaring dividends, our estimated stock price volatility and the contractual term of the warrants. The value ascribed to the warrants in connection with debt offerings is considered a cost of capital and amortized to interest expense over the term of the debt.

We have, at certain times, issued preferred stock and notes, which were convertible into common stock at a discount from the common stock market price at the date of issuance. The amount of the discount associated with such conversion rights represents an incremental yield, or “beneficial conversion feature” that is recorded when the consideration allocated to the convertible security, divided by the number of common shares into which the security converts, is below the fair value of the common stock at the date of issuance of the convertible instrument.

A beneficial conversion feature associated with the preferred stock is recognized as a return to the preferred stockholders and represents a non-cash charge in the determination of net loss attributable to common stockholders. The beneficial conversion feature is recognized in full immediately if there is no redemption date for the preferred stock, or over the period of issuance through the redemption date, if applicable. A beneficial conversion feature associated with debentures, notes or other debt instruments is recognized as a discount to the debt and is amortized as additional interest expense using the effective interest method over the remaining term of the debt instrument.

### *Lease Accrual*

We are required to make significant judgments and assumptions when estimating the liability for our net ongoing obligations under our amended lease agreement relating to our former executive offices located in Boston, Massachusetts. In accordance with SFAS 146, “Accounting for Costs Associated with Exit or Disposal Activities,” we use a discounted cash-flow analysis to calculate the amount of the liability. We applied a discount rate of 15% representing our best estimate of our credit adjusted risk-free rate. The discounted cash-flow analysis is based on management’s assumptions and estimates of our ongoing lease obligations, and income from sublease rentals, including estimates of sublease timing and sublease rental terms. It is possible that our estimates and assumptions will change in the future, resulting in additional adjustments to the amount of the estimated liability, and the effect of any adjustments could be material. We review our assumptions and judgments related to the lease amendment on at least a quarterly basis, until the outcome is finalized, and make whatever modifications we believe are necessary, based on our best judgment, to reflect any changes in circumstances.

### *Stock-Based Compensation*

We account for stock-based compensation in accordance with SFAS No. 123R, “Share-Based Payment”, or SFAS 123R. SFAS 123R requires companies to measure compensation costs for all share-based awards at fair value on grant date and recognize it as expense over the requisite service period or expected performance period of the award. We estimate the fair value of stock-based awards using the Black-Scholes valuation model on the grant date. The Black-Scholes valuation model requires us to make certain assumptions and estimates concerning the expected term of the awards, the rate of return of risk-free investments, our stock price volatility, and our anticipated dividends. If any of our estimates or assumptions prove incorrect, our results could be materially affected.

## **Results of Operations**

### *Three Months Ended June 30, 2008 and 2007*

Our net loss and net loss attributable to common stockholders was \$6,114,786 during the three months ended June 30, 2008 as compared with \$5,292,749 during the three months ended June 30, 2007. Net loss attributable to common stockholders totaled \$0.29 per share for the 2008 period as compared to \$0.30 per share for the 2007 period. The increase in net loss in the 2008 period was primarily due to higher operating and interest expenses. The decrease in net loss attributable to common stockholders on a per share basis in the 2008 period was primarily due to

## Table of Contents

the increase in the weighted average common shares outstanding of approximately 3,400,000 in 2008, which was primarily the result of the conversion of certain notes payable into common stock in June 2007.

Research and development expenses were \$3,630,292 during the three months ended June 30, 2008 as compared with \$2,678,439 during the three months ended June 30, 2007. The increase in the 2008 period was primarily attributable to higher costs of approximately \$1,381,000 associated with our nerve repair program, primarily related to Cethrin clinical costs including our Phase I/IIa trial and preparations for our Phase IIb trial. The increase was partially offset by lower compensation and related costs of approximately \$267,000 primarily related to the closing of our Baltimore facility during the 2007 period. We currently anticipate that our research and development expenses will increase over the next twelve months although there may be significant fluctuations on a quarterly basis. This expected increase is primarily related to higher Cethrin and Altropane clinical costs. Our working capital constraints may limit our planned expenditures.

General and administrative expenses were \$1,958,868 during the three months ended June 30, 2008 as compared with \$2,468,669 during the three months ended June 30, 2007. The decrease in the 2008 period was primarily related to a reduction in legal and consulting costs of approximately \$425,000 primarily related to our collaboration and fundraising efforts. We currently anticipate that our general and administrative expenses will remain relatively consistent over the next twelve months although there may be significant fluctuations on a quarterly basis.

Interest expense was \$541,080 during the three months ended June 30, 2008 as compared with \$186,718 during the three months ended June 30, 2007. The increase in the 2008 period was attributable to the issuance of \$10,000,000 and \$25,000,000 in convertible promissory notes during 2008 and 2007, respectively, that bear interest at the rate of 5% per annum and the related non-cash interest expense of approximately \$158,000 related to the beneficial conversion features of the Highbridge, ISVP and March 2008 RG convertible promissory notes. The notes issued in March 2007 eliminated all outstanding principal and accrued interest due under the notes previously issued and a gain related to the forgiveness of interest of approximately \$273,000 was recorded during the 2007 period.

Investment income was \$15,454 during the three months ended June 30, 2008 as compared with \$41,077 during the three months ended June 30, 2007. The decrease in the 2008 period was primarily due to lower average cash, cash equivalent, and marketable securities balances during the 2008 period.

### *Six months ended June 30, 2008 and 2007*

Our net loss and net loss attributable to common stockholders was \$11,440,724 during the six months ended June 30, 2008 as compared with \$9,373,890 during the six months ended June 30, 2007. Net loss attributable to common stockholders totaled \$0.55 per share for both the 2008 and 2007 periods. The increase in net loss in the 2008 period was primarily due to higher operating and interest expenses. There was no change to net loss attributable to common stockholders on a per share basis as the increase in net loss was offset by an increase in weighted average common shares outstanding of approximately 3,800,000 in 2008, primarily the result of the conversion of certain notes payable into common stock during the 2007 period.

Research and development expenses were \$6,289,266 during the six months ended June 30, 2008 as compared with \$5,257,185 during the six months ended June 30, 2007. The increase in the 2008 period was primarily attributable to higher costs of approximately \$1,757,000 associated with our nerve repair program, primarily related to Cethrin clinical costs including our Phase I/IIa trial and preparations for our Phase IIb trial. The increase was partially offset by (i) a reduction in costs of approximately \$554,000 associated with our molecular imaging program primarily related to decreased Altropane clinical costs and (ii) lower compensation and related costs of approximately \$142,000 primarily associated with the closing of our Baltimore facility during the 2007 period.

General and administrative expenses were \$4,203,239 during the six months ended June 30, 2008 as compared with \$4,066,007 during the six months ended June 30, 2007. The increase in the 2008 period was primarily related to (i) higher compensation and related costs of approximately \$318,000 primarily related to increased headcount, (ii) higher commercialization and communication costs of approximately \$97,000 and (iii) higher patent and related costs of approximately \$148,000 primarily related to our nerve repair program. The increase was partially offset by reduced legal and consulting costs of approximately \$387,000 primarily related to our collaboration and fundraising efforts.

## Table of Contents

Interest expense was \$1,000,498 during the six months ended June 30, 2008 as compared with \$109,698 during the six months ended June 30, 2007. The increase in the 2008 period was attributable to the issuance of \$10,000,000 and \$25,000,000 in convertible promissory notes during 2008 and 2007, respectively, that bear interest at the rate of 5% per annum and the related non-cash interest expense of approximately \$288,000 related to the beneficial conversion features of the Highbridge, ISVP and March 2008 RG convertible promissory notes. The notes issued in March 2007 eliminated all outstanding principal and accrued interest due under the notes previously issued and a gain related to the forgiveness of interest of approximately \$273,000 was recorded during the 2007 period.

Investment income was \$52,279 during the six months ended June 30, 2008 as compared with \$59,000 during the six months ended June 30, 2007. The decrease in the 2008 period was primarily due to lower average cash, cash equivalent, and marketable securities balances during the 2008 period.

### Liquidity and Capital Resources

Net cash used for operating activities, primarily related to our net loss, totaled \$8,829,132 during the six months ended June 30, 2008 as compared to \$16,112,524 during the six months ended June 30, 2007. The decrease in cash used during 2008 is primarily related to the \$7,500,000 due under our license agreement, or Cethrin License, with BioAxone Therapeutic, Inc., or BioAxone, in 2006 and paid in March 2007. Net cash provided by investing activities totaled \$1,292,514 during the six months ended June 30, 2008 as compared to net cash used for investing activities of \$40,277 during the six months ended June 30, 2007. The change in investing activities in 2008 is primarily associated with the sale of marketable securities used to fund operations. Net cash provided by financing activities totaled \$10,002,541 during the six months ended June 30, 2008 as compared to \$17,006,102 during the six months ended June 30, 2007. The decrease in 2008 primarily reflects the decrease in convertible notes issued in 2008.

To date, we have dedicated most of our financial resources to the research and development of our product candidates, general and administrative expenses and costs related to obtaining and protecting patents. Since inception, we have primarily satisfied our working capital requirements from the sale of our securities through private placements. These private placements have included the sale and issuance of preferred stock, common stock, promissory notes and convertible debentures.

A summary of financings completed during the three years ended June 30, 2008 is as follows:

Date	Net Proceeds Raised	Securities or Debt Instrument Issued
June 2008	\$5.0 million	Convertible Promissory Notes
March 2008	\$5.0 million	Convertible Promissory Notes
August 2007	\$10.0 million	Convertible Promissory Notes
May 2007	\$6.0 million	Convertible Promissory Notes
March 2007	\$9.0 million	Convertible Promissory Notes
February 2007	\$2.0 million	Convertible Promissory Notes(1)
October 2006	\$6.0 million	Convertible Promissory Notes(1)
August 2006	\$2.0 million	Convertible Promissory Notes(1)
September 2005	\$12.8 million	Common Stock

(1) Converted to shares of our common stock in June 2007.

In the future, our working capital and capital requirements will depend on numerous factors, including the progress of our research and development activities, the level of resources that we devote to the developmental, clinical, and regulatory aspects of our technologies, and the extent to which we enter into collaborative relationships with pharmaceutical and biotechnology companies.

At June 30, 2008, we had available cash and cash equivalents of approximately \$5,399,000.

As of June 30, 2008, we have experienced total net losses since inception of approximately \$174,493,000 and stockholders' deficit of approximately \$32,581,000. For the foreseeable future, we expect to experience continuing

## Table of Contents

operating losses and negative cash flows from operations as our management executes our current business plan. The cash and cash equivalents available at June 30, 2008 will not provide sufficient working capital to meet our anticipated expenditures for the next twelve months. We believe that the cash and cash equivalents available at June 30, 2008 and our ability to control certain costs, including those related to clinical trial programs, preclinical activities, and certain general and administrative expenses will enable us to meet our anticipated cash expenditures into October 2008.

In order to continue as a going concern, we will therefore need to raise additional capital through one or more of the following: a debt financing, an equity offering, or a collaboration, merger, acquisition or other transaction with one or more pharmaceutical or biotechnology companies. We are currently engaged in fundraising efforts. There can be no assurance that we will be successful in our fundraising efforts or that additional funds will be available on acceptable terms, if at all. We also cannot be sure that we will be able to obtain additional credit from, or effect additional sales of debt or equity securities to the Purchasers. If we are unable to raise additional or sufficient capital, we will need to cease operations or reduce, cease or delay one or more of our research or development programs, adjust our current business plan and may not be able to continue as a going concern. If we violate a debt covenant or default under the Purchase Agreements, we may need to cease operations or reduce, cease or delay one or more of our research or development programs, adjust our current business plan and may not be able to continue as a going concern.

In connection with the March 2005 Financing, we agreed with the March 2005 Investors, that, subject to certain exceptions, we would not issue any shares of our common stock at a per share price less than \$2.50 without the prior consent of the March 2005 Investors holding at least a majority of the shares issued in the March 2005 Financing. On August 4, 2008, the closing price of our common stock was \$2.18. The failure to receive the requisite waiver or consent of the March 2005 Investors could have the effect of delaying or preventing the consummation of a financing by us should the price per share in such financing be set at less than \$2.50.

### Contractual Obligations and Commitments

Except as set forth below, the disclosures relating to our contractual obligations in our Annual Report on Form 10-K for the year ended December 31, 2007 have not materially changed since we filed that report.

In March 2008, we issued a convertible promissory note to Robert Gipson in the aggregate principal amount of \$5,000,000 pursuant to the March 2008 Amended Purchase Agreement. In June 2008, we issued a convertible promissory note to Robert Gipson in the aggregate principal amount of \$5,000,000 pursuant to the June 2008 Purchase Agreement. At June 30, 2008, we had borrowed \$35,000,000 in convertible promissory notes under the Purchase Agreements and owed approximately \$1,439,700 in accrued interest on those notes.

In April 2008, we entered into an option agreement with BioAxone pursuant to which we were granted an option to amend our Cethrin License, or the BioAxone Option Agreement. The BioAxone Option Agreement provides that we can exercise our option to amend certain terms of the Cethrin License until the earlier of (a) sale or issuance of shares of our capital stock, including the sale of debt that is convertible into shares of our capital stock, which results in aggregate gross proceeds of not less than \$25,000,000, and (b) October 27, 2008. If the option is exercised, we will pay a fee of \$7,000,000 to BioAxone and we will enter into an amendment to the Cethrin License.

The amendment to the Cethrin License will replace the existing \$25,000,000 in milestone payments and royalty payments with a requirement that we pay \$7,000,000 to BioAxone on or before December 31, 2009, or upon BioAxone's written request, if we assign all of our rights and interest in and to the underlying licensed intellectual property (as defined in the Cethrin License), prior to December 31, 2009. In addition, the amendment will provide that we will make royalty payments to BioAxone based on a percentage of annual net sales of certain products specified in the Cethrin License for the treatment of acute spinal cord injury equal to 4% of such net sales and 1% of such net sales for all other products specified in the Cethrin License for indications other than acute spinal cord injury, until the earlier of December 31, 2021 or the Royalty Expiration Date (as defined in the Cethrin License).

The amendment to the Cethrin License will also provide that BioAxone will grant to us a fully paid-up, irrevocable, perpetual worldwide license to the underlying licensed intellectual property, and take steps to transfer to us certain ancillary intellectual property rights related thereto. In addition, the amendment will provide that

## Table of Contents

BioAxone will release us from certain development and commercialization requirements imposed by the Cethrin License.

Our current office leases expire in 2008. In July 2008, we entered into a noncancelable operating lease agreement for new office space in Hopkinton, Massachusetts that expires in September 2011. The annual rent expense is approximately \$275,000.

### Recent Accounting Pronouncements

In February 2008, the FASB issued FASB Staff Position (“FSP”) No. 157-2, “Effective Date of FASB Statement No. 157,” (“SFAS 157-2”). This FSP delays the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). SFAS 157 will therefore be applicable to non-financial assets and liabilities for our fiscal year commencing January 1, 2009. We are currently reviewing the impact of the adoption of SFAS 157 for all non-financial assets and liabilities on our financial statements.

In May 2008, the FASB issued FSP No. APB 14-1, “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion” (“FSP APB 14-1”). FSP APB 14-1 specifies that issuers of convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) should separately account for the liability and equity components in a manner that will reflect the entity’s nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the impact that the adoption of FSP APB 14-1 will have on our financial position, results of operations and cash flow.

### Item 3 — Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes in the market risks reported in our Annual Report on Form 10-K for the year ended December 31, 2007.

We generally maintain a portfolio of cash equivalents, and short-term and long-term marketable securities in a variety of securities which can include commercial paper, certificates of deposit, money market funds and government and non-government debt securities. The fair value of these available-for-sale securities are subject to changes in market interest rates and may fall in value if market interest rates increase. Our investment portfolio includes only marketable securities with active secondary or resale markets to help insure liquidity. We have implemented policies regarding the amount and credit ratings of investments. Due to the conservative nature of these policies, we do not believe we have material exposure due to market risk. We may not have the ability to hold our fixed income investments until maturity, and therefore our future operating results or cash flows could be affected if we are required to sell investments during a period in which increases in market interest rates have adversely affected the value of our securities portfolio. For fixed rate debt, changes in interest rates generally affect the fair market value of the debt instrument, but not earnings or cash flows. We do not have an obligation to prepay any fixed rate debt prior to maturity and, therefore, interest rate risk and changes in the fair market value of fixed rate debt should not have a significant impact on earnings or cash flows until such debt is refinanced, if necessary. The terms related to our fixed rate debt are described in Note 5 to the consolidated financial statements. For variable rate debt, changes in interest rates generally do not impact the fair market value of the debt instrument, but do affect future earnings and cash flows. We did not have any variable rate debt outstanding during the six months ended June 30, 2008.

### Item 4T — Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2008. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information

## Table of Contents

required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2008, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## Part II — Other Information

### Item 1A — Risk Factors

Statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not based on historical fact are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections, and the beliefs and assumptions of our management including, without limitation, our expectations regarding our product candidates, including the success and timing of our preclinical, clinical and development programs, the submission of regulatory filings and proposed partnering arrangements, collaboration, merger, acquisition and fund raising efforts, results of operations, selling, general and administrative expenses, research and development expenses and the sufficiency of our cash for future operations. Forward-looking statements may be identified by the use of forward-looking terminology such as “may,” “could,” “will,” “expect,” “estimate,” “anticipate,” “continue,” or similar terms, variations of such terms or the negative of those terms.

We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.

#### Risks Related to our Financial Results and Need for Additional Financing

***WE ARE A DEVELOPMENT STAGE COMPANY. WE HAVE INCURRED LOSSES FROM OUR OPERATIONS SINCE INCEPTION AND ANTICIPATE LOSSES FOR THE FORESEEABLE FUTURE. WE WILL NOT BE ABLE TO ACHIEVE PROFITABILITY UNLESS WE OBTAIN REGULATORY APPROVAL AND MARKET ACCEPTANCE OF OUR PRODUCT CANDIDATES. WE WILL NEED SUBSTANTIAL ADDITIONAL FUNDING IN ORDER TO CONTINUE OUR BUSINESS AND OPERATIONS. IF WE ARE UNABLE TO SECURE SUCH FUNDING ON ACCEPTABLE TERMS, WE WILL NEED TO CEASE OPERATIONS, SIGNIFICANTLY REDUCE, DELAY OR CEASE ONE OR MORE OF OUR RESEARCH OR DEVELOPMENT PROGRAMS, OR SURRENDER RIGHTS TO SOME OR ALL OF OUR TECHNOLOGIES. IF WE VIOLATE A DEBT COVENANT OR DEFAULT UNDER OUR DEBT AGREEMENTS, WE MAY NEED TO CEASE OPERATIONS OR REDUCE, CEASE OR DELAY ONE OR MORE OF OUR RESEARCH OR DEVELOPMENT PROGRAMS, ADJUST OUR CURRENT BUSINESS PLAN AND MAY NOT BE ABLE TO CONTINUE AS A GOING CONCERN.***

Biotechnology companies that have no approved products or other sources of revenue are generally referred to as development stage companies. We have never generated revenues from product sales and we do not currently expect to generate revenues from product sales for at least the next three years. If we do generate revenues and operating profits in the future, our ability to continue to do so in the long term could be affected by the introduction of competitors' products and other market factors. We expect to incur significant operating losses for at least the next three years. The level of our operating losses may increase in the future if more of our product candidates begin human clinical trials. We will never generate revenues or achieve profitability unless we obtain regulatory approval and market acceptance of our product candidates. This will require us to be successful in a range of challenging

## Table of Contents

activities, including clinical trial stages of development, obtaining regulatory approval for our product candidates, and manufacturing, marketing and selling them. We may never succeed in these activities, and may never generate revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We require significant funds to conduct research and development activities, including preclinical studies and clinical trials of our technologies, and to commercialize our product candidates. Because the successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to develop and commercialize them. Our funding requirements depend on many factors, including:

- The scope, rate of progress and cost of our clinical trials and other research and development activities;
- Future clinical trial results;
- The terms and timing of any collaborative, licensing and other arrangements that we may establish;
- The cost and timing of regulatory approvals and of establishing sales, marketing and distribution capabilities;
- The cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- The cost of obtaining and maintaining licenses to use patented technologies;
- The effect of competing technological and market developments; and
- The cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights and other patent-related costs, including litigation costs and the results of such litigation.

Until such time, if ever, as we can generate substantial revenue from product sales or through collaborative arrangements with third parties, we will need to raise additional capital. To date, we have experienced negative cash flows from operations and have funded our operations primarily from equity and debt financings.

As of June 30, 2008, we have experienced total net losses since inception of approximately \$174,493,000 and stockholders' deficit of approximately \$32,581,000. For the foreseeable future, we expect to experience continuing operating losses and negative cash flows from operations as our management executes our current business plan. The cash and cash equivalents available at June 30, 2008 will not provide sufficient working capital to meet our anticipated expenditures for the next twelve months. We believe that the cash and cash equivalents available at June 30, 2008 and our ability to control certain costs, including those related to clinical trial programs, preclinical activities, and certain general and administrative expenses will enable us to meet our anticipated cash expenditures into October 2008.

In order to continue as a going concern, we will therefore need to raise additional capital through one or more of the following: a debt financing, an equity offering, or a collaboration, merger, acquisition or other transaction with one or more pharmaceutical or biotechnology companies. We are currently engaged in fundraising efforts. There can be no assurance that we will be successful in our fundraising efforts or that additional funds will be available on acceptable terms, if at all. We also cannot be sure that we will be able to obtain additional credit from, or effect additional sales of debt or equity securities to the Purchasers. If we are unable to raise additional or sufficient capital, we will need to cease operations or reduce, cease or delay one or more of our research or development programs, adjust our current business plan and may not be able to continue as a going concern. If we violate a debt covenant or default under the Purchase Agreements, we may need to cease operations or reduce, cease or delay one or more of our research or development programs, adjust our current business plan and may not be able to continue as a going concern.

In connection with the March 2005 Financing, we agreed with the March 2005 Investors that, subject to certain exceptions, we would not issue any shares of our common stock at a per share price less than \$2.50 without the prior consent of the March 2005 Investors holding at least a majority of the shares issued in the March 2005 Financing.

## Table of Contents

On August 4, 2008, the closing price of our common stock was \$2.18. The failure to receive the requisite waiver or consent of the March 2005 Investors could have the effect of delaying or preventing the consummation of a financing by us should the price per share in such financing be set at less than \$2.50.

Alternatively, to secure funds, we may be required to enter financing arrangements with others that may require us to surrender rights to some or all of our technologies or grant licenses on terms that are not favorable to us. If the results of our current or future clinical trials are not favorable, it may negatively affect our ability to raise additional funds. If we are successful in obtaining additional equity and/or debt financing, the terms of such financing will have the effect of diluting the holdings and the rights of our stockholders. Estimates about how much funding will be required are based on a number of assumptions, all of which are subject to change based on the results and progress of our research and development activities. If we are unable to raise additional capital we will need to reduce, cease or delay one or more of our research or development programs and adjust our current business plan.

Our ability to continue development of our clinical programs, including the development of Cethrin and the Altropane molecular imaging agent, and our preclinical programs will be affected by the availability of financial resources to fund each program. Financial considerations may cause us to modify planned development activities for one or more of our programs, and we may decide to suspend development of one or more programs until we are able to secure additional working capital. If we are not able to raise additional capital, we will not have sufficient funds to complete the clinical trial programs for Cethrin or the Altropane molecular imaging agent.

### ***OUR ESTIMATES OF OUR LIABILITY UNDER OUR BOSTON, MASSACHUSETTS LEASE MAY CHANGE.***

Our lease in Boston, Massachusetts expires in 2012. We have entered into two sublease agreements covering all 6,600 square feet under this lease through the date of expiration. In determining our obligations under the lease that we do not expect to occupy, we have made certain assumptions for the discounted estimated cash flows related to the rental payments that our subtenants have agreed to pay. We may be required to change our estimates in the future as a result of, among other things, the default of one or both of our subtenants with respect to their payment obligations. Any such adjustments to the estimate of liability could be material.

## Risks Related to Commercialization

### ***OUR SUCCESS DEPENDS ON OUR ABILITY TO SUCCESSFULLY DEVELOP OUR PRODUCT CANDIDATES INTO COMMERCIAL PRODUCTS.***

To date, we have not marketed, distributed or sold any products and, with the exception of Cethrin and the Altropane molecular imaging agent, all of our technologies and early-stage product candidates are in preclinical development. The success of our business depends primarily upon our ability to successfully develop and commercialize our product candidates. Successful research and product development in the biotechnology industry is highly uncertain, and very few research and development projects produce a commercial product. In the biotechnology industry, it has been estimated that less than five percent of the technologies for which research and development efforts are initiated ultimately result in an approved product. If we are unable to successfully commercialize Cethrin or the Altropane molecular imaging agent or any of our other product candidates, our business would be materially harmed.

### ***EVEN IF WE RECEIVE APPROVAL TO MARKET OUR DRUG CANDIDATES, THE MARKET MAY NOT BE RECEPTIVE TO OUR DRUG CANDIDATES UPON THEIR COMMERCIAL INTRODUCTION, WHICH COULD PREVENT US FROM SUCCESSFULLY COMMERCIALIZING OUR PRODUCTS AND FROM BEING PROFITABLE.***

Even if our drug candidates are successfully developed, our success and growth will also depend upon the acceptance of these drug candidates by physicians and third-party payors. Acceptance of our product development candidates will be a function of our products being clinically useful, being cost effective and demonstrating superior diagnostic or therapeutic effect with an acceptable side effect profile as compared to existing or future treatments. In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance

## Table of Contents

over time. Factors that we believe will materially affect market acceptance of our drug candidates under development include:

- The timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;
- The safety, efficacy and ease of administration of our products;
- The competitive pricing of our products;
- The success of our education and marketing programs;
- The sales and marketing efforts of competitors; and
- The availability and amount of government and third-party payor reimbursement.

If our products do not achieve market acceptance, we will not be able to generate sufficient revenues from product sales to maintain or grow our business.

### ***ACQUISITIONS PRESENT MANY RISKS, AND WE MAY NOT REALIZE THE ANTICIPATED FINANCIAL AND STRATEGIC GOALS FOR ANY SUCH TRANSACTIONS.***

We may in the future acquire complementary companies, products and technologies. Such acquisitions involve a number of risks, including:

- We may find that the acquired company or assets do not further our business strategy, or that we overpaid for the company or assets, or that economic conditions change, all of which may generate a future impairment charge;
- We may have difficulty integrating the operations and personnel of the acquired business, and may have difficulty retaining the key personnel of the acquired business;
- We may have difficulty incorporating the acquired technologies;
- We may encounter technical difficulties or failures with the performance of the acquired technologies or drug products or may experience unfavorable results in the clinical studies related to such technologies or products;
- We may face product liability risks associated with the sale of the acquired company's products;
- Our ongoing business and management's attention may be disrupted or diverted by transition or integration issues and the complexity of managing diverse locations;
- We may have difficulty maintaining uniform standards, internal controls, procedures and policies across locations;
- The acquisition may result in litigation from terminated employees or third-parties; and
- We may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

These factors could have a material adverse effect on our business, results of operations and financial condition or cash flows, particularly in the case of a larger acquisition or multiple acquisitions in a short period of time. From time to time, we may enter into negotiations for acquisitions that are not ultimately consummated. Such negotiations could result in significant diversion of management time, as well as out-of-pocket costs.

The consideration paid in connection with an acquisition also affects our financial results. If we were to proceed with one or more significant acquisitions in which the consideration included cash, we could be required to use a substantial portion of our available cash to consummate any acquisition. To the extent we issue shares of stock or other rights to purchase stock, including options or other rights, existing stockholders may be diluted and earnings per share may decrease. In addition, acquisitions may result in the incurrence of debt, large one-time write-offs (such as acquired in-process research and development costs) and restructuring charges. They may also result in goodwill and other intangible assets that are subject to impairment tests, which could result in future impairment charges.

### Risks Related to Regulation

#### ***IF OUR PRECLINICAL TESTING AND CLINICAL TRIALS ARE NOT SUCCESSFUL, WE WILL NOT OBTAIN REGULATORY APPROVAL FOR COMMERCIAL SALE OF OUR PRODUCT CANDIDATES.***

We will be required to demonstrate, through preclinical testing and clinical trials, that our product candidates are safe and effective before we can obtain regulatory approval for the commercial sale of our product candidates. Preclinical testing and clinical trials are lengthy and expensive and the historical rate of failure for product candidates is high. Product candidates that appear promising in the early phases of development, such as in preclinical study or in early human clinical trials, may fail to demonstrate safety and efficacy in clinical trials.

Except for Cethrin and the Altropane molecular imaging agent, we have not yet received Investigational New Drug, or IND, approval from the Food and Drug Administration, or FDA, for our other product candidates which will be required before we can begin clinical trials in the United States. We may not submit INDs for our product candidates if we are unable to accumulate the necessary preclinical data for the filing of an IND. The FDA may request additional preclinical data before allowing us to commence clinical trials. The FDA or other applicable regulatory authorities may suspend clinical trials of a drug candidate at any time if we or they believe the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons. Adverse side effects of a drug candidate on subjects or patients in a clinical trial could result in the FDA or foreign regulatory authorities refusing to approve a particular drug candidate for any or all indications of use.

We have met with the FDA, Health Canada, the European Medicines Agency, and with regulatory authorities in selected European countries to review the Phase I/IIa results and our Cethrin clinical development plan, including our planned Phase IIb trial. Our preliminary planning for the Phase IIb trial of Cethrin called for us to enroll up to 100 subjects in 80 sites worldwide. Ongoing inputs, including the results to date in the Phase I/IIa trial, discussions with the regulatory authorities and our expert advisors, now indicate that a placebo-controlled trial to demonstrate the potential efficacy of Cethrin can be accomplished with fewer patients and sites, and provide us with results from the trial approximately a year earlier. We are now planning to initiate a randomized, double-blind, placebo-controlled, Phase IIb trial in subjects with acute cervical SCI in the first quarter of 2009 at sites across North America.

After a series of discussions with the FDA and our expert advisors, the POET-2 program was designed as a two-part Phase III program using the optimized Altropane image acquisition protocol. The first part of the program was initiated in December 2007 in a multi-center clinical study in subjects to acquire the set of Altropane images which will be used to train the expert readers, as is the customary process for clinical trials of molecular imaging agents. The second part involves two concurrent, replicate, multi-center Phase III trials. These two concurrent trials, the final design of which is under discussion with the FDA, will be initiated once final agreement on the design of the trials is reached with the FDA.

There is no assurance that the results obtained to date and/or any further work completed in the future will be sufficient to achieve the approvability of Cethrin or the Altropane molecular imaging agent.

Clinical trials require sufficient patient enrollment which is a function of many factors, including the size of the potential patient population, the nature of the protocol, the availability of existing treatments for the indicated disease and the eligibility criteria for enrolling in the clinical trial. Delays or difficulties in completing patient enrollment can result in increased costs and longer development times.

## Table of Contents

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or regulatory authorities to delay or suspend those trials, or delay the analysis of data from our completed or ongoing clinical trials. Any of the following could delay the initiation or the completion of our ongoing and planned clinical trials:

- Ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- Delays in enrolling patients and volunteers into clinical trials;
- Lower than anticipated retention rate of patients and volunteers in clinical trials;
- Negative or inconclusive results of clinical trials or adverse medical events during a clinical trial could cause a clinical trial to be repeated or a program to be terminated, even if other studies or trials related to the program are successful;
- Insufficient supply or deficient quality of drug candidate materials or other materials necessary for the conduct of our clinical trials;
- Serious and unexpected drug-related side-effects experienced by participants in our clinical trials; or
- The placement of a clinical trial on hold.

***OUR PRODUCT CANDIDATES ARE SUBJECT TO RIGOROUS REGULATORY REVIEW AND, EVEN IF APPROVED, REMAIN SUBJECT TO EXTENSIVE REGULATION.***

Our technologies and product candidates must undergo a rigorous regulatory approval process which includes extensive preclinical and clinical testing to demonstrate safety and efficacy before any resulting product can be marketed. Our research and development activities are regulated by a number of government authorities in the United States and other countries, including the FDA pursuant to the Federal Food, Drug, and Cosmetic Act. The clinical trial and regulatory approval process usually requires many years and substantial cost. To date, neither the FDA nor any of its international equivalents has approved any of our product candidates for marketing.

The FDA regulates drugs in the United States, including their testing, manufacturing and marketing. Data obtained from testing is subject to varying interpretations which can delay, limit or prevent FDA approval. The FDA has stringent laboratory and manufacturing standards which must be complied with before we can test our product candidates in people or make them commercially available. Examples of these standards include Good Laboratory Practices and current Good Manufacturing Practices, or cGMP. Our compliance with these standards is subject to initial certification by independent inspectors and continuing audits thereafter. In addition, manufacturers of our product candidates are subject to the FDA's cGMP regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers. If any of these third-party manufacturers fail to perform as required, this could impair our ability to deliver our products on a timely basis or cause delays in our clinical trials and applications for regulatory approval.

Obtaining FDA approval to sell our product candidates is time-consuming and expensive. The FDA usually takes at least 12 to 18 months to review an NDA which must be submitted before the FDA will consider granting approval to sell a product. If the FDA requests additional information, it may take even longer for the FDA to make a decision especially if the additional information that they request requires us to complete additional studies. We may encounter similar delays in foreign countries. After reviewing any NDA we submit, the FDA or its foreign equivalents may decide not to approve our products. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing our product candidates.

Other risks associated with the regulatory approval process include:

- Regulatory approvals may impose significant limitations on the uses for which any approved products may be marketed;
- Any marketed product and its manufacturer are subject to periodic reviews and audits, and any discovery of previously unrecognized problems with a product or manufacturer could result in suspension or limitation of approvals;

## Table of Contents

- Changes in existing regulatory requirements, or the enactment of additional regulations or statutes, could prevent or affect the timing of our ability to achieve regulatory compliance. Federal and state laws, regulations and policies may be changed with possible retroactive effect, and how these rules actually operate can depend heavily on administrative policies and interpretation over which we have no control, and we may possess inadequate experience to assess their full impact upon our business; and
- The approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials.

***OUR PRODUCTS COULD BE SUBJECT TO RESTRICTIONS OR WITHDRAWAL FROM THE MARKET AND WE MAY BE SUBJECT TO PENALTIES IF WE FAIL TO COMPLY WITH REGULATORY REQUIREMENTS, OR IF WE EXPERIENCE UNANTICIPATED PROBLEMS WITH OUR PRODUCTS, WHEN AND IF ANY OF THEM ARE APPROVED.***

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. The manufacturer and the manufacturing facilities we use to make any of our product candidates will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer or facility, including withdrawal of the product from the market. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in:

- Restrictions on such products, manufacturers or manufacturing processes;
- Warning letters;
- Withdrawal of the products from the market;
- Refusal to approve pending applications or supplements to approved applications that we submit;
- Recall;
- Fines;
- Suspension or withdrawal of regulatory approvals;
- Refusal to permit the import or export of our products;
- Product seizure; and
- Injunctions or the imposition of civil or criminal penalties.

***FAILURE TO OBTAIN REGULATORY APPROVAL IN FOREIGN JURISDICTIONS WOULD PREVENT US FROM MARKETING OUR PRODUCTS ABROAD.***

Although we have not initiated any marketing efforts in foreign jurisdictions, we intend in the future to market our products outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not

obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or approval by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

***FOREIGN GOVERNMENTS TEND TO IMPOSE STRICT PRICE CONTROLS WHICH MAY ADVERSELY AFFECT OUR REVENUES, IF ANY.***

The pricing of prescription pharmaceuticals is subject to governmental control in some foreign countries. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

**Risks Related to our Intellectual Property**

***IF WE ARE UNABLE TO SECURE ADEQUATE PATENT PROTECTION FOR OUR TECHNOLOGIES, THEN WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY AS A BIOTECHNOLOGY COMPANY.***

At the present time, we do not have patent protection for all uses of our technologies. There is significant competition in the field of CNS diseases, our primary scientific area of research and development. Our competitors may seek patent protection for their technologies, and such patent applications or rights might conflict with the patent protection that we are seeking for our technologies. If we do not obtain patent protection for our technologies, or if others obtain patent rights that block our ability to develop and market our technologies, our business prospects may be significantly and negatively affected. Further, even if patents can be obtained, these patents may not provide us with any competitive advantage if our competitors have stronger patent positions or if their product candidates work better in clinical trials than our product candidates. Our patents may also be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products.

Our patent strategy is to obtain broad patent protection, in the United States and in major developed countries, for our technologies and their related medical indications. Risks associated with protecting our patent and proprietary rights include the following:

- Our ability to protect our technologies could be delayed or negatively affected if the United States Patent and Trademark Office, or USPTO, requires additional experimental evidence that our technologies work;
- Our competitors may develop similar technologies or products, or duplicate any technology developed by us;
- Our competitors may develop products which are similar to ours but which do not infringe our patents or products;
- Our competitors may successfully challenge one or more of our patents in an interference or litigation proceeding;
- Our technologies may infringe the patents or rights of other parties who may decide not to grant a license to us. We may have to change our products or processes, pay licensing fees or stop certain activities because of the patent rights of third parties which could cause additional unexpected costs and delays;
- Patent law in the fields of healthcare and biotechnology is still evolving and future changes in such laws might conflict with our existing and future patent rights, or the rights of others;

## Table of Contents

- Our collaborators, employees and consultants may breach the confidentiality agreements that we enter into to protect our trade secrets and proprietary know-how. We may not have adequate remedies for such breach; and
- There may be disputes as to the ownership of technological information developed by consultants, scientific advisors or other third parties which may not be resolved in our favor.

***WE IN-LICENSE A SIGNIFICANT PORTION OF OUR INTELLECTUAL PROPERTY AND IF WE FAIL TO COMPLY WITH OUR OBLIGATIONS UNDER ANY OF THE RELATED AGREEMENTS, WE COULD LOSE LICENSE RIGHTS THAT ARE NECESSARY TO DEVELOP OUR PRODUCT CANDIDATES.***

We have entered into license agreements with BioAxone, Harvard University and its affiliated hospitals, or Harvard and its Affiliates, and Children's Medical Center Corporation, or CMCC, that give us rights to intellectual property that is necessary for our business. These license arrangements impose various development, royalty and other obligations on us. If we breach these obligations and fail to cure such breach in a timely manner, these exclusive licenses could be converted to non-exclusive licenses or the agreements could be terminated, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology. In particular, the development of our nerve repair program is highly dependent upon Cethrin which we licensed from BioAxone. If we are unable to meet our obligations in the time period specified in the Cethrin License, including achieving the development and clinical milestones, obtaining a commercial agreement for the delivery of Cethrin and the out-license of Cethrin development in Japan, our business could be materially harmed.

In order to continue to expand our business we may need to acquire additional product candidates including those in clinical development through in-licensing that we believe will be a strategic fit with us. We may not be able to in-license suitable product candidates at an acceptable price or at all. Engaging in any in-license will incur a variety of costs, and we may never realize the anticipated benefits of any such in-license.

***IF WE BECOME INVOLVED IN PATENT LITIGATION OR OTHER PROCEEDINGS RELATED TO A DETERMINATION OF RIGHTS, WE COULD INCUR SUBSTANTIAL COSTS AND EXPENSES, SUBSTANTIAL LIABILITY FOR DAMAGES OR BE REQUIRED TO STOP OUR PRODUCT DEVELOPMENT AND COMMERCIALIZATION EFFORTS.***

A third party may sue us for infringing its patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of third-party proprietary rights. In addition, a third party may claim that we have improperly obtained or used its confidential or proprietary information. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared against us by the USPTO, regarding intellectual property rights with respect to our products and technology. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. We might be required to redesign the formulation of a product candidate so that it does not infringe, which may not be possible or could require substantial funds and time. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if we are unable to enter into license agreements that are acceptable to us.

Moreover, we expect that a number of our collaborations will provide that royalties payable to us for licenses to our intellectual property may be offset by amounts paid by our collaborators to third parties who have competing or superior intellectual property positions in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations.

***CONFIDENTIALITY AGREEMENTS WITH EMPLOYEES AND OTHERS MAY NOT ADEQUATELY PREVENT DISCLOSURE OF TRADE SECRETS AND OTHER PROPRIETARY INFORMATION.***

In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers, and other advisors. These agreements may be breached, may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

**Risks Related to our Dependence on Third Parties**

***IF ANY COLLABORATOR TERMINATES OR FAILS TO PERFORM ITS OR THEIR OBLIGATIONS UNDER AGREEMENTS WITH US, THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATES COULD BE DELAYED OR TERMINATED.***

We are dependent on expert advisors and our collaborations with research and development service providers. Our business could be adversely affected if any collaborator terminates its collaboration agreement with us or fails to perform its obligations under that agreement. Most biotechnology and pharmaceutical companies have established internal research and development programs, including their own facilities and employees which are under their direct control. By contrast, we have limited internal research capability and have elected to outsource substantially all of our research and development, preclinical and clinical activities. As a result, we are dependent upon our network of expert advisors and our collaborations with other research and development service providers for the development of our technologies and product candidates. These expert advisors are not our employees but provide us with important information and knowledge that may enhance our product development strategies and plans. Our collaborations with research and development service providers are important for the testing and evaluation of our technologies, in both the preclinical and clinical stages.

Many of our expert advisors are employed by, or have their own collaborative relationship with Harvard and its Affiliates or CMCC. A summary of the key scientific, research and development professionals with whom we work, and a composite of their professional background and affiliations is as follows:

- Larry I. Benowitz, Ph.D., Director, Laboratories for Neuroscience Research in Neurosurgery, Children's Hospital, Boston; Associate Professor of Neurosurgery, Harvard Medical School.
- Joseph R. Bianchine, M.D., Ph.D., F.A.C.P., F.A.C.C.P., Scientific Advisory Board Member, Alseres Pharmaceuticals, Inc.; former Senior Scientific Advisor, Schwarz Pharma AG.
- Zhigang He, Ph.D., BM, Research Associate, Department of Neurology, Children's Hospital Boston; Associate Professor of Neurology, Department of Neurology, Harvard Medical School.
- Robert S. Langer, Jr., Sc.D., Director, Alseres Pharmaceuticals, Inc., Institute Professor of Chemical and Biomedical Engineering, Massachusetts Institute of Technology.
- Peter Meltzer, Ph.D., President, Organix, Inc., Woburn, MA.

Dr. Benowitz, Dr. Bianchine, Dr. He, and Dr. Langer provide scientific consultative services resulting in total payments of approximately \$125,000 per year. Dr. Benowitz and Dr. He provide scientific consultative services primarily related to our nerve repair program. Dr. Bianchine provides scientific consultative services primarily

## Table of Contents

related to our nerve repair and neurodegenerative disease programs. Dr. Langer provides consultative services primarily related to scientific and business services.

We do not have a consulting agreement with Dr. Meltzer but do enter into research and development contracts from time to time with Organix, Inc., of which Dr. Meltzer is president.

Our significant collaborations include:

- Children's Hospital in Boston, Massachusetts where certain of our collaborating scientists perform their research efforts;
- Harvard Medical School in Boston, Massachusetts where certain of our collaborating scientists perform their research efforts;
- MDS Nordion in Vancouver, British Columbia which manufactures the Altropane molecular imaging agent; and
- Organix, Inc. in Woburn, Massachusetts which provides non-radioactive Altropane for FDA mandated studies and synthesizes our compounds for the treatment of PD and for axon regeneration.

We generally have a number of collaborations with research and development service providers ongoing at any point in time. These agreements generally cover a specific project or study, are usually for a duration between one month to one year, and expire upon completion of the project. Under these agreements, we are sometimes required to make an initial payment upon execution of the agreement with the remaining payments based upon the completion of certain specified milestones such as completion of a study or delivery of a report.

We cannot control the amount and timing of resources our advisors and collaborators devote to our programs or technologies. Our advisors and collaborators may have employment commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. If any of our advisors or collaborators were to breach or terminate their agreement with us or otherwise fail to conduct their activities successfully and in a timely manner, the preclinical or clinical development or commercialization of our technologies and product candidates or our research programs could be delayed or terminated. Any such delay or termination could have a material adverse effect on our business, financial condition or results of operations.

Disputes may arise in the future with respect to the ownership of rights to any technology developed with our advisors or collaborators. These and other possible disagreements could lead to delays in the collaborative research, development or commercialization of our technologies, or could require or result in litigation to resolve. Any such event could have a material adverse effect on our business, financial condition or results of operations.

Our advisors and collaborators sign agreements that provide for confidentiality of our proprietary information. Nonetheless, they may not maintain the confidentiality of our technology and other confidential information in connection with every advisory or collaboration arrangement, and any unauthorized dissemination of our confidential information could have a material adverse effect on our business, financial condition or results of operations.

***IF WE ARE UNABLE TO MAINTAIN OUR KEY WORKING RELATIONSHIPS WITH OUR LICENSORS, INCLUDING BIOAXONE, HARVARD AND ITS AFFILIATES AND CMCC, WE MAY NOT BE SUCCESSFUL SINCE SUBSTANTIALLY ALL OF OUR CURRENT TECHNOLOGIES WERE LICENSED FROM SUCH LICENSORS.***

We maintain relationships with our licensors, including BioAxone, Harvard and its Affiliates, and CMCC. Substantially all of our technologies were licensed from these licensors. Under the terms of our license agreements with BioAxone, Harvard and its Affiliates and CMCC, we acquired the exclusive, worldwide license to make, use, and sell the technology covered by each respective agreement. Among other things, the technologies licensed under these agreements include:

## Table of Contents

- Cethrin compositions and methods of use;
- Altoprane molecular imaging agent compositions and methods of use;
- Technetium-based molecular imaging agent compositions and methods of use;
- Inosine methods of use; and
- DAT blocker compositions and methods of use.

Generally, each of these license agreements is effective until the last patent licensed relating to the technology expires or a fixed and determined date. The patents on Cethrin expire beginning in 2022. The patents on the Altoprane molecular imaging agent expire beginning in 2013. The patents on the technetium-based molecular imaging agents expire beginning in 2017. The patents for Inosine expire beginning in 2017. The patents for our DAT blockers expire beginning in 2012.

We are required to make certain payments under our license agreements with our licensors which generally include:

- An initial licensing fee payment upon the execution of the agreement and annual license maintenance fee;
- Reimbursement payments for all patent related costs incurred by the licensor, including fees associated with the filing of continuation-in-part patent applications;
- Milestone payments as licensed technology progresses through each stage of development (filing of IND, completion of one or more clinical stages and submission and approval of an NDA); and
- Royalty payments on the sales of any products based on the licensed technology.

In December 2006, we entered into the Cethrin License pursuant to which we were granted an exclusive, worldwide license to develop and commercialize specified compounds including, but not limited to, Cethrin as further defined in the Cethrin License. The Cethrin License calls for us to conduct development and commercialization activities of Cethrin, to pay certain pre-commercialization milestones and on-going royalties on sales of Cethrin when and if approved for marketing. The Cethrin License includes a development plan with discrete development milestones which, if not met, could result in additional payments to BioAxone and/or loss of some or all of our license rights. Under the Cethrin License, we paid \$10,000,000 in up-front payments. We also agreed to pay BioAxone up to \$25,000,000 upon the achievement of certain milestone events and royalties based on 10-12% of the worldwide net sales of licensed products, subject to specified minimums, in each calendar year until either the expiration of a valid claim covering a licensed product or a certain time period after the launch of a licensed product, in each case applicable to the specific country. If we fail to launch a licensed product within twelve months of obtaining marketing approval for such product in the United States, at least two specified European countries or Japan, BioAxone may terminate our rights under the Cethrin License in whole or in part in the United States, the European Union or Japan.

In April 2008, we entered into the BioAxone Option Agreement. There can be no assurance that we will exercise our rights under the BioAxone Option Agreement and amend the Cethrin License.

We have entered into license agreements, or the CMCC Licenses, with CMCC to acquire the exclusive worldwide rights to certain axon regeneration technologies. The CMCC Licenses provide for future milestone payments of up to an aggregate of approximately \$425,000 for each product candidate upon achievement of certain regulatory milestones. Additionally, we entered into two sponsored research agreements with CMCC which provide for a total of \$550,000 in annual expenditures through May 2009.

We have entered into license agreements, or the Harvard License Agreements, with Harvard and its Affiliates to acquire the exclusive worldwide rights to certain technologies within our molecular imaging and neurodegenerative disease programs. The Harvard License Agreements obligate us to pay up to an aggregate of approximately

## Table of Contents

\$2,520,000 in milestone payments in the future. The future milestone payments are generally payable only upon achievement of certain regulatory milestones.

Our license agreements with Harvard and its Affiliates and CMCC generally provide for royalty payments equal to specified percentages of product sales, annual license maintenance fees and continuing patent prosecution costs.

We have entered into sponsored research agreements with certain key collaborators, including CMCC. Under these agreements, we provide funding so that the sponsored scientists can continue their research efforts. These payments are generally made in equal quarterly installments over the term of the agreements which are usually for one to three years.

Universities and other not-for-profit research institutions are becoming increasingly aware of the commercial value of their findings and are becoming more active in seeking patent protection and licensing arrangements to collect royalties for the use of technology that they have developed. The loss of our relationship with one or more of our key licensors could adversely affect our ongoing development programs and could make it more costly and difficult for us to obtain the licensing rights to new scientific discoveries.

***IF WE ARE UNABLE TO ESTABLISH, MAINTAIN AND RELY ON NEW COLLABORATIVE RELATIONSHIPS, THEN WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND COMMERCIALIZE OUR TECHNOLOGIES.***

To date, our operations have primarily focused on the preclinical development of most of our technologies, as well as conducting clinical trials for certain of our technologies. We currently expect that the continued development of our technologies will result in the initiation of additional clinical trials. We expect that these developments will require us to establish, maintain and rely on new collaborative relationships in order to successfully develop and commercialize our technologies. We face significant competition in seeking appropriate collaborators. Collaboration arrangements are complex to negotiate and time consuming to document. We may not be successful in our efforts to establish additional collaborations or other alternative arrangements, and the terms of any such collaboration or alternative arrangement may not be favorable to us. There is no certainty that:

- We will be able to enter into such collaborations on economically feasible and otherwise acceptable terms and conditions;
- Such collaborations will not require us to undertake substantial additional obligations or require us to devote additional resources beyond those we have identified at present;
- Any of our collaborators will not breach or terminate their agreements with us or otherwise fail to conduct their activities on time, thereby delaying the development or commercialization of the technology for which the parties are collaborating; and
- The parties will not dispute the ownership rights to any technologies developed under such collaborations.

***IF ONE OF OUR COLLABORATORS WERE TO CHANGE ITS STRATEGY OR THE FOCUS OF ITS DEVELOPMENT AND COMMERCIALIZATION EFFORTS WITH RESPECT TO OUR RELATIONSHIP, THE SUCCESS OF OUR PRODUCT CANDIDATES AND OUR OPERATIONS COULD BE ADVERSELY AFFECTED.***

There are a number of factors external to us that may change our collaborators' strategy or focus with respect to our relationship with them, including:

- The amount and timing of resources that our collaborators may devote to the product candidates;
- Our collaborators may experience financial difficulties;
- We may be required to relinquish important rights such as marketing and distribution rights;

## Table of Contents

- Should a collaborator fail to develop or commercialize one of our product candidates, we may not receive any future milestone payments and will not receive any royalties for the product candidate;
- Business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- A collaborator may not devote sufficient time and resources to any collaboration with us, which could prevent us from realizing the potential commercial benefits of that collaboration;
- A collaborator may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the business and financial communities; and
- A collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

If any of these occur, the development and commercialization of one or more drug candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own.

### Risks Related to Competition

#### ***WE ARE ENGAGED IN HIGHLY COMPETITIVE INDUSTRIES DOMINATED BY LARGER, MORE EXPERIENCED AND BETTER CAPITALIZED COMPANIES.***

The biotechnology and pharmaceutical industries are highly competitive, rapidly changing, and are dominated by larger, more experienced and better capitalized companies. Such greater experience and financial strength may enable them to bring their products to market sooner than us, thereby gaining the competitive advantage of being the first to market. Research on the causes of, and possible treatments for, diseases for which we are trying to develop therapeutic or diagnostic products are developing rapidly and there is a potential for extensive technological innovation in relatively short periods of time. Factors affecting our ability to successfully manage the technological changes occurring in the biotechnology and pharmaceutical industries, as well as our ability to successfully compete, include:

- Many of our potential competitors in the field of CNS research have significantly greater experience than we do in completing preclinical and clinical testing of new pharmaceutical products, the manufacturing and commercialization process, and obtaining FDA and other regulatory approvals of products;
- Many of our potential competitors have products that have been approved or are in late stages of development;
- Many of our potential competitors may develop products or other novel technologies that are more effective, safer or less costly than any that we are developing;
- Many of our potential competitors have collaborative arrangements in our target markets with leading companies and research institutions;
- The timing and scope of regulatory approvals for these products;
- The availability and amount of third-party reimbursement;
- The strength of our patent position;
- Many of our potential competitors are in a stronger financial position than us, and are thus better able to finance the significant cost of developing, manufacturing and selling new products; and

- Companies with established positions and prior experience in the pharmaceutical industry may be better able to develop and market products for the treatment of those diseases for which we are trying to develop products.

To our knowledge, there is presently no approved therapeutic focused on the nerve repair of CNS disorders resulting from traumas, such as SCI. We are aware of other companies who are developing therapeutics to treat the CNS disorders resulting from SCI. These companies have significantly greater infrastructure and financial resources than us and if they were to be able to obtain marketing approval for their products it could significantly adversely affect our competitive position. Given the challenges of achieving functional recovery in severe CNS disorders, we believe some of these competitors are developing devices or drugs that could potentially be used in conjunction with the therapeutics we are developing.

To our knowledge, there is presently no approved diagnostic in the United States for PD and other movement disorders. To our knowledge, there is only one company, GE Healthcare (formerly Nycomed/Amersham), that has marketed a diagnostic imaging agent for PD, DaTSCAN. To date, GE Healthcare has obtained marketing approval only in certain countries in Europe. To our knowledge, GE Healthcare is not presently seeking approval of DaTSCAN in the United States. GE Healthcare has significantly greater infrastructure and financial resources than us, and their decision to seek approval in the United States could significantly adversely affect our competitive position. Their established market presence, and greater financial strength in the European market may make it difficult for us to successfully market Altropane in Europe.

***IF WE ARE UNABLE TO COMPETE EFFECTIVELY, OUR PRODUCT CANDIDATES MAY BE RENDERED NONCOMPETITIVE OR OBSOLETE.***

Our competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protection, than we are able to. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, the likelihood that our product candidates will achieve initial market acceptance, and our ability to generate meaningful revenues from our product candidates. Even if our product candidates achieve initial market acceptance, competitive products may render our products obsolete, noncompetitive or uneconomical. If our product candidates are rendered obsolete, we may not be able to recover the expenses of developing and commercializing those product candidates.

***IF THIRD-PARTY PAYORS DO NOT ADEQUATELY REIMBURSE OUR CUSTOMERS FOR ANY OF OUR PRODUCTS THAT ARE APPROVED FOR MARKETING, THEY MIGHT NOT BE ACCEPTED BY PHYSICIANS AND PATIENTS OR PURCHASED OR USED, AND OUR REVENUES AND PROFITS WILL NOT DEVELOP OR INCREASE.***

Substantially all biotechnology products are distributed to patients by physicians and hospitals, and in most cases, such patients rely on insurance coverage and reimbursement to pay for some or all of the cost of the product. In recent years, the continuing efforts of government and third party payors to contain or reduce health care costs have limited, and in certain cases prevented, physicians and patients from receiving insurance coverage and reimbursement for medical products, especially newer technologies. We believe that the efforts of governments and third-party payors to contain or reduce the cost of healthcare will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. Obtaining reimbursement approval for a product from each governmental or other third-party payor is a time-consuming and costly process that could require us to provide to each prospective payor scientific, clinical and cost-effectiveness data for the use of our products. If we succeed in bringing any of our product candidates to market and third-party payors determine that the product is eligible for coverage; the third-party payors may nonetheless establish and maintain price levels insufficient for us to realize a sufficient return on our investment in product development. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases.

Our ability to generate adequate revenues and operating profits could be adversely affected if such limitations or restrictions are placed on the sale of our products. Specific risks associated with medical insurance coverage and reimbursement include:

- Significant uncertainty exists as to the reimbursement status of newly approved health care products;

## Table of Contents

- Third-party payors are increasingly challenging the prices charged for medical products and services;
- Adequate insurance coverage and reimbursement may not be available to allow us to charge prices for products which are adequate for us to realize an appropriate return on our development costs. If adequate coverage and reimbursement are not provided for use of our products, the market acceptance of these products will be negatively affected;
- Health maintenance organizations and other managed care companies may seek to negotiate substantial volume discounts for the sale of our products to their members thereby reducing our profit margins; and
- In recent years, bills proposing comprehensive health care reform have been introduced in Congress that would potentially limit pharmaceutical prices and establish mandatory or voluntary refunds. It is uncertain if any legislative proposals will be adopted and how federal, state or private payors for health care goods and services will respond to any health care reforms.

U.S. drug prices may be further constrained by possible Congressional action regarding drug reimportation into the United States. Some proposed legislation would allow the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs are sold at a lower price. Some governmental authorities in the U.S. are pursuing lawsuits to obtain expanded reimportation authority. Such legislation, regulations, or judicial decisions could reduce the prices we receive for any products that we may develop, negatively affecting our revenues and prospects for profitability. Even without legislation authorizing reimportation, increasing numbers of patients have been purchasing prescription drugs from Canadian and other non-United States sources, which has reduced the price received by pharmaceutical companies for their products.

The Centers for Medicare and Medicaid Services, or CMS, the agency within the Department of Health and Human Services that administers Medicare and that is responsible for setting Medicare reimbursement payment rates and coverage policies for any product candidates that we commercialize, has authority to decline to cover particular drugs if it determines that they are not “reasonable and necessary” for Medicare beneficiaries or to cover them at lower rates to reflect budgetary constraints or to match previously approved reimbursement rates for products that CMS considers to be therapeutically comparable. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both Medicare and other third-party payors may have sufficient market power to demand significant price reductions.

Moreover, marketing and promotion arrangements in the pharmaceutical industry are heavily regulated by CMS, and many marketing and promotional practices that are common in other industries are prohibited or restricted. These restrictions are often ambiguous and subject to conflicting interpretations, but carry severe administrative, civil, and criminal penalties for noncompliance. It may be costly for us to implement internal controls to facilitate compliance by our sales and marketing personnel.

As a result of the trend towards managed healthcare in the United States, as well as legislative proposals to constrain the growth of federal healthcare program expenditures, third-party payors are increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage and the level of reimbursement of new drug products. Consequently, significant uncertainty exists as to the reimbursement status of newly approved healthcare products.

### ***MEDICARE PRESCRIPTION DRUG COVERAGE LEGISLATION AND FUTURE LEGISLATIVE OR REGULATORY REFORM OF THE HEALTH CARE SYSTEM MAY AFFECT OUR ABILITY TO SELL OUR PRODUCT CANDIDATES PROFITABLY.***

A number of legislative and regulatory proposals to change the healthcare system in the United States and other major healthcare markets have been proposed in recent years. In addition, ongoing initiatives in the United States have exerted and will continue to exert pressure on drug pricing. In some foreign countries, particularly countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. Significant changes in the healthcare system in the United States or elsewhere, including changes resulting from the implementation of the Medicare prescription drug coverage legislation and adverse trends in third-party

reimbursement programs, could limit our ability to raise capital and successfully commercialize our product candidates.

In particular, the Medicare Prescription Drug Improvement and Modernization Act of 2003 established a new Medicare prescription drug benefit. The prescription drug program and future amendments or regulatory interpretations of the legislation could affect the prices we are able to charge for any products we develop and sell for use by Medicare beneficiaries and could also cause third-party payors other than the federal government, including the states under the Medicaid program, to discontinue coverage for any products we develop or to lower reimbursement amounts that they pay. The legislation changed the methodology used to calculate reimbursement for drugs that are administered in physicians' offices in a manner intended to reduce the amount that is subject to reimbursement. In addition, the Medicare prescription drug benefit program that took effect in January 2006 directed the Secretary of Health and Human Services to contract with procurement organizations to purchase physician-administered drugs from manufacturers and provided physicians with the option to obtain drugs through these organizations as an alternative to purchasing from manufacturers, which some physicians may find advantageous. Because we have not received marketing approval or established a price for any product, it is difficult to predict how this new legislation will affect us, but the legislation generally is expected to constrain or reduce reimbursement for certain types of drugs.

Further federal, state and foreign healthcare proposals and reforms are likely. While we cannot predict the legislative or regulatory proposals that will be adopted or what effect those proposals may have on our business, including the future reimbursement status of any of our product candidates, the announcement or adoption of such proposals could have an adverse effect on potential revenues from product candidates that we may successfully develop.

***WE HAVE NO MANUFACTURING CAPACITY AND LIMITED MARKETING INFRASTRUCTURE AND EXPECT TO BE HEAVILY DEPENDENT UPON THIRD PARTIES TO MANUFACTURE AND MARKET APPROVED PRODUCTS.***

We currently have no manufacturing facilities for either clinical trial or commercial quantities of any of our product candidates and currently have no plans to obtain additional facilities. To date, we have obtained the limited quantities of drug product required for preclinical and clinical trials from contract manufacturing companies. We intend to continue using contract manufacturing arrangements with experienced firms for the supply of material for both clinical trials and any eventual commercial sale.

We will depend upon third parties to produce and deliver products in accordance with all FDA and other governmental regulations. We may not be able to contract with manufacturers who can fulfill our requirements for quality, quantity and timeliness, or be able to find substitute manufacturers, if necessary. The failure by any third party to perform their obligations in a timely fashion and in accordance with the applicable regulations may delay clinical trials, the commercialization of products, and the ability to supply product for sale. In addition, any change in manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

Under our Cethrin License, we acquired cGMP Cethrin that we are planning to use in our Phase IIb trial. In June 2007, we entered into an agreement with a cGMP manufacturer to produce more cGMP Cethrin for use in our future clinical development. We do not presently have arrangements with any other suppliers in the event this supplier is unable to manufacture Cethrin for us. We could encounter a significant delay before another supplier could manufacture Cethrin for us due to the time required to establish a cGMP manufacturing process for Cethrin. We are aware that our current supplier may have cGMP compliance issues. If our current supplier is unable or unwilling to satisfy FDA or other regulatory requirements, it could delay clinical trials, regulatory submissions and commercialization of Cethrin, delay or prevent us from achieving development milestones under the Cethrin License or result in the termination of development of Cethrin, adversely affecting our revenues and product development timetable, which in turn could adversely affect our business and our stock price.

MDS Nordion has supplied Altropane to us since 2001. We are highly dependent upon MDS Nordion. Under the terms of our agreement, which currently expires on December 31, 2008, MDS Nordion manufactures the Altropane molecular imaging agent for our clinical trials. We do not presently have arrangements with any other suppliers in the event that MDS Nordion is unable to manufacture Altropane for us. We could encounter a significant delay before another supplier could manufacture Altropane for us due to the time required to establish a cGMP manufacturing process for Altropane. We hope to sign an extension with MDS Nordion before December 31, 2008 but there can be no assurance that we will be able to or that the terms will be acceptable. We do not have a manufacturing agreement relating to the commercial production of Altropane with MDS Nordion or any other manufacturer. We can provide no assurances that such an agreement will be executed on acceptable terms.

We currently have a limited marketing infrastructure. In order to earn a profit on any future product, we will be required to invest in the necessary sales and marketing infrastructure or enter into collaborations with third parties with respect to executing sales and marketing activities. We may encounter difficulty in negotiating sales and marketing collaborations with third parties on favorable terms for us. Most of the companies who can provide such services are financially stronger and more experienced in selling pharmaceutical products than we are. As a result, they may be in a position to negotiate an arrangement that is more favorable to them. We could experience significant delays in marketing any of our products if we are required to internally develop a sales and marketing organization or establish collaborations with a partner. There are risks involved with establishing our own sales and marketing capabilities. We have no experience in performing such activities and could incur significant costs in developing such a capability.

***USE OF THIRD PARTY MANUFACTURERS MAY INCREASE THE RISK THAT WE WILL NOT HAVE ADEQUATE SUPPLIES OF OUR PRODUCT CANDIDATES.***

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including:

- Reliance on the third party for regulatory compliance and quality assurance;
- The possible breach of the manufacturing agreement by the third party; and
- The possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

If we are not able to obtain adequate supplies of our product candidates and any approved products, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we successfully develop may compete with product candidates and products of third parties for access to manufacturing facilities. Our contract manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards. We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. We do not control compliance by our contract manufacturers with these regulations and standards. Failure of our third party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and products.

### **Risks Related to Employees and Growth**

***IF WE ARE UNABLE TO RETAIN OUR KEY PERSONNEL AND/OR RECRUIT ADDITIONAL KEY PERSONNEL IN THE FUTURE, THEN WE MAY NOT BE ABLE TO OPERATE EFFECTIVELY.***

Our success depends significantly upon our ability to attract, retain and motivate highly qualified scientific and management personnel who are able to formulate, implement and maintain the operations of a biotechnology company such as ours. We consider retaining Peter Savas, our Chairman and Chief Executive Officer, Mark Pykett, our President and Chief Operating Officer, Kenneth L. Rice, Jr., our Executive Vice President Finance and Administration and Chief Financial Officer and Frank Bobe, our Executive Vice President and Chief Business Officer to be key to our efforts to develop and commercialize our product candidates. The loss of the service of any of these key executives may significantly delay or prevent the achievement of product development and other business objectives. We have entered into employment and non-compete agreements with Messrs. Savas, Pykett, Rice and Bobe. We do not presently carry key person life insurance on any of our scientific or management personnel.

We currently outsource most of our research and development, preclinical and clinical activities. If we decide to increase our internal research and development capabilities for any of our technologies, we may need to hire additional key management and scientific personnel to assist the limited number of employees that we currently employ. There is significant competition for such personnel from other companies, research and academic institutions, government entities and other organizations. If we fail to attract such personnel, it could have a significant negative effect on our ability to develop our technologies.

### Risks Related to our Stock

#### ***OUR STOCK PRICE MAY CONTINUE TO BE VOLATILE AND CAN BE AFFECTED BY FACTORS UNRELATED TO OUR BUSINESS AND OPERATING PERFORMANCE.***

The market price of our common stock may fluctuate significantly in response to factors that are beyond our control. The stock market in general periodically experiences significant price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in significant fluctuations in the price of our common stock, which could cause a decline in the value of your investment. The market price of our common stock may be influenced by many factors, including:

- Announcements of technological innovations or new commercial products by our competitors or us;
- Announcements in the scientific and research community;
- Developments concerning proprietary rights, including patents;
- Delay or failure in initiating, conducting, completing or analyzing clinical trials or problems relating to the design, conduct or results of these trials;
- Announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- Developments concerning our collaborations;
- Publicity regarding actual or potential medical results relating to products under development by our competitors or us;
- Failure of any of our product candidates to achieve commercial success;
- Our ability to manufacture products to commercial standards;
- Conditions and publicity regarding the life sciences industry generally;
- Regulatory developments in the United States and foreign countries;
- Changes in the structure of health care payment systems;
- Period-to-period fluctuations in our financial results or those of companies that are perceived to be similar to us;
- Departure of our key personnel;
- Future sales of our common stock;
- Investors' perceptions of us, our products, the economy and general market conditions;

## Table of Contents

- Differences in actual financial results versus financial estimates by securities analysts and changes in those estimates; and
- Litigation.

### Item 2 — Unregistered Sales of Equity Securities and Use of Proceeds

On June 25, 2008, we entered into the June 2008 Purchase Agreement with Robert Gipson pursuant to which we could borrow up to \$5,000,000. In June 2008, we issued a convertible promissory note to Robert Gipson in the aggregate principal amount of \$5,000,000 pursuant to the June 2008 Purchase Agreement.

The cumulative \$35,000,000 borrowed by us under the March 2008 Amended Purchase Agreement and the June 2008 Purchase Agreement bears interest at the rate of 5% per annum and may be converted, at the option of the Purchasers, into (i) shares of our common stock at a conversion price per share of \$2.50, (ii) the right to receive future royalty payments related to our molecular imaging products (including Altropane and Fluoratec) in amounts equal to 2% of our pre-commercial revenue related to such products plus 0.5% of future net sales of such products for each \$1,000,000 of outstanding principal and interest that a Purchaser elects to convert into future payments, or (iii) a combination of (i) and (ii). Any outstanding notes that are not converted into our common stock or into the right to receive future payments will become due and payable by the earlier of December 31, 2010 or the date on which a Purchaser declares an event of default (as defined in the March 2008 Amended Purchase Agreement). However, each Purchaser is prohibited from effecting a conversion if at the time of such conversion the common stock issuable to such Purchaser, when taken together with all shares of common stock then held or otherwise beneficially owned by such Purchaser exceeds 19.9%, or 9.99% for Highbridge and ISVP of the total number of issued and outstanding shares of our common stock immediately prior to such conversion unless and until our stockholders approve the conversion of all of the shares of common stock issuable thereunder.

The convertible promissory notes were offered and sold pursuant to the March 2008 Amended Purchase Agreement and June 2008 Purchase Agreement to selected institutional investors and other accredited investors without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws.

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

We held our Annual Meeting of Stockholders on June 12, 2008.

There were present at the Annual Meeting in person or by proxy stockholders holding an aggregate of 15,916,290 shares of common stock. The results of the vote taken at the Annual Meeting with respect to the election of the director nominees were as follows:

Nominees	For	Withheld
Peter G. Savas	15,787,966	128,324
Henry Brem	15,788,864	127,426
Gary E. Frashier	15,720,349	195,941
William L.S. Guinness	15,781,374	134,916
Robert S. Langer Jr.	15,689,946	226,344
Michael J. Mullen	15,781,388	134,902
John T. Preston	15,788,751	127,539

In addition, a vote of the stockholders was taken at the Annual Meeting with respect to the proposal to ratify the selection by the Audit Committee of the appointment of McGladrey & Pullen, LLP as our independent registered public accounting firm for the year ending December 31, 2008. Of the shares voted, 15,814,493 shares voted in favor of such proposal, 53,446 shares were voted against such proposal and 48,350 shares abstained from voting.

## Table of Contents

### Item 6 — Exhibits

- 10.1 Option Agreement, dated May 2, 2008, by and between the Company and BioAxone Therapeutic Inc. (Incorporated by reference to the Current Report on Form 8-K filed on May 6, 2008)
- 10.2 Convertible Promissory Note Purchase Agreement, by and between the Company and Robert Gipson, dated June 25, 2008 (Incorporated by reference to the Current Report on Form 8-K filed on June 20, 2008)
- 31.1 Principal Executive Officer—Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Principal Financial Officer—Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Principal Executive Officer—Certification pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Principal Financial Officer—Certification pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**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.

ALSERES PHARMACEUTICALS, INC  
(Registrant)

DATE: August 14, 2008

/s/ PETER G. SAVAS

\_\_\_\_\_  
**Peter G. Savas**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

DATE: August 14, 2008

/s/ KENNETH L. RICE, JR.

\_\_\_\_\_  
**Kenneth L. Rice, Jr.**  
**Executive Vice President Finance and**  
**Administration And Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

## Table of Contents

### Exhibits

- 10.1 Option Agreement, dated May 2, 2008, by and between the Company and BioAxone Therapeutic Inc. (Incorporated by reference to the Current Report on Form 8-K filed on May 6, 2008)
- 10.2 Convertible Promissory Note Purchase Agreement, by and between the Company and Robert Gipson, dated June 25, 2008 (Incorporated by reference to the Current Report on Form 8-K filed on June 20, 2008)
- 31.1 Principal Executive Officer–Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Principal Financial Officer–Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Principal Executive Officer–Certification pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Principal Financial Officer–Certification pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**CERTIFICATIONS**

I, Peter G. Savas, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alseres 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. The registrant's other certifying officer and I are 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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us 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 our 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 our 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. The registrant's other certifying officer and I have disclosed, based on our 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.

DATE: August 14, 2008

/s/ PETER G. SAVAS  
\_\_\_\_\_  
**Peter G. Savas**  
**Chief Executive Officer**

**CERTIFICATIONS**

I, Kenneth L. Rice, Jr., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alseres 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. The registrant's other certifying officer and I are 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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us 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 our 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 our 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. The registrant's other certifying officer and I have disclosed, based on our 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.

DATE: August 14, 2008

/s/ KENNETH L. RICE, JR.

---

**Kenneth L. Rice, Jr.**  
**Executive Vice President Finance and**  
**Administration and Chief**  
**Financial Officer**

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

In connection with the Quarterly Report of Alseres Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2008 as filed with the Securities and Exchange Commission (the "Report"), I, Peter G. Savas, 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:

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

/s/ PETER G. SAVAS

---

**Peter G. Savas**  
**Chief Executive Officer**

Date: August 14, 2008

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

In connection with the Quarterly Report of Alseres Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2008 as filed with the Securities and Exchange Commission (the "Report"), I, Kenneth L. Rice, Jr., Chief Financial 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:

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

/s/ KENNETH L. RICE, JR.

---

**Kenneth L. Rice, Jr.**  
**Executive Vice President Finance and  
Administration and Chief Financial Officer**

Date: August 14, 2008