

CepTor CORP  
Form 10QSB  
September 05, 2006  
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-QSB

(Mark One)

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
OF 1934

For the quarterly period ended June 30, 2006

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 333-105793

CEPTOR CORPORATION

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(Name of Small Business Issuer in Its Charter)

Delaware  
(State or Other Jurisdiction of Incorporation  
or Organization)

11-2897392  
(I.R.S. Employer Identification No.)

200 International Circle, Suite 5100  
Hunt Valley, Maryland  
(Address of Principal Executive Offices)

21030  
(Zip Code)

Issuer's Telephone Number: (410) 527-9998

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of September 1, 2006, there were 15,500,069 shares of the issuer's common equity outstanding.

Transitional Small Business Disclosure Format (Check one): Yes No

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PART I  
FINANCIAL INFORMATION

Item 1. Financial Statements.  
 CEPTOR CORPORATION  
 (A DEVELOPMENT STAGE COMPANY)  
 CONDENSED BALANCE SHEET  
 (Unaudited)

	June 30, 2006
ASSETS	
Current Assets:	
Cash and cash equivalents	\$ 2,846
Prepaid expenses and other current assets	74,545

Total current assets	77,391
Property and equipment, net	45,896
Deferred financing costs	826,799
Security deposit	18,511
TOTAL ASSETS	\$ 968,597
LIABILITIES AND STOCKHOLDERS' DEFICIENCY	
Current Liabilities:	
Accounts payable	\$ 4,427,112
Accrued expenses	813,524
Convertible notes, net of discounts of \$1,238,743	1,335,993
Total current liabilities	6,576,629
Convertible notes, net of discounts of \$1,182,434	517,566
Warrant liability	3,882,878
Conversion option liability	2,342,243
TOTAL LIABILITIES	13,319,316
Commitments and contingencies	
Stockholders' Deficiency:	
Preferred stock, \$0.0001 par value; authorized 20,000,000 shares, issued and outstanding – 221.40 shares of Series A Convertible Preferred Stock; liquidation preference – \$5,535,000	5,535,000
Common stock, \$0.0001; authorized 100,000,000 shares, issued and outstanding – 15,500,069	1,550
Deferred compensation	(335,318)
Additional paid-in capital	25,745,342
Deficit accumulated during the development stage	(43,297,293)
Total stockholders' deficiency	(12,350,719)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	\$ 968,597

(See Notes to Unaudited Condensed Financial Statements)

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CEPTOR CORPORATION  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED STATEMENTS OF OPERATIONS  
(Unaudited)

	Three-Month Period Ended		Cumulative
	June 30,		August 11, 1986
	2006	2005	(Date of Inception)
Revenues:			to
Other income	\$ —	\$ —	to June 30, 2006
Expenses:			

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Research and development	472,027	2,204,202	13,645,257
In-process research and development	—	—	5,034,309
General and administrative	497,239	510,357	11,874,098
Gain on extinguishment of debt	(387,362)	(311,281)	(698,643)
Change in fair value of derivative financial instruments	311,147	—	(3,276,566)
Interest expense	4,817,154	212,299	7,657,475
Interest income	—	(20,090)	(52,318)
Total operating expenses	5,710,205	2,595,487	34,183,612
Net loss	(5,710,205)	(2,595,487)	(34,108,263)
Deemed preferred stock dividends	—	—	(10,100,616)
Net loss available to common stockholders	\$ (5,710,205)	\$ (2,595,487)	\$ (44,208,879)
Loss per share:			
Basic and diluted	\$ (0.38)	\$ (0.24)	
Weighted-average common shares outstanding:			
Basic and diluted	14,855,983	10,962,165	

	Six-Month Period Ended June 30,	
	2006	2005
Revenues:		
Other income	\$ —	\$ —
Expenses:		
Research and development	1,043,752	2,863,235
In-process research and development	—	—
General and administrative	1,756,753	1,921,582
Gain on extinguishment of debt	(387,362)	(311,281)
Change in fair value of derivative financial instruments	(2,326,585)	—
Interest expense	5,294,640	456,877
Interest income	—	(38,820)
Total operating expenses	5,381,198	4,891,593
Net loss	(5,381,198)	(4,891,593)
Deemed preferred stock dividends	—	(9,164,500)
Net loss available to common stockholders	\$ (5,381,198)	\$ (14,056,093)
Loss per share:		
Basic and diluted	\$ (0.39)	\$ (1.29)
Weighted-average common shares outstanding:		
Basic and diluted	13,785,982	10,889,339

(See Notes to Unaudited Condensed Financial Statements)

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CEPTOR CORPORATION  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIENCY

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(Unaudited)

	Preferred Stock		Common Stock		Deferred Compensation	Additional Paid-in Capital
	Shares	Amount	Shares	Amount		
Balance, January 1, 2006	248.15	\$6,203,750	11,744,120	\$1,174	\$(322,830)	\$22,960
Common stock issued January 2006 upon conversion of preferred shares (\$2.50)	(10.00)	(250,000)	100,000	10		24
Common stock issued January 2006 upon conversion of replacement notes (\$0.375)			855,267	85		32
Common stock issued February 2006 upon conversion of preferred shares (\$2.50)	(7.00)	(175,000)	70,000	7		17
Common stock issued February 2006 upon conversion of 2005 Convertible Debentures (\$0.5795)			86,281	9		4
Common stock issued March 2006 upon conversion of preferred shares (\$2.50)	(6.75)	(168,750)	67,500	7		16
Common stock issued March 2006 upon exercise of options (\$0.359)			557,102	56		19
Expenses incurred pursuant to entering into Stock Purchase Agreement						(3)
Common stock issued March 2006 upon conversion of 2005 Convertible Debentures (\$0.3373)			148,236	15		4
Common stock issued April 2006 upon conversion of 2005 Convertible Debentures (\$0.1985)			755,735	76		14
Common stock issued May 2006 upon conversion of preferred shares (\$2.50)	(3.00)	(75,000)	30,000	3		7
Common stock issued May 2006 upon conversion of 2005 Convertible Debentures (\$0.1615)			309,598	31		4
Common stock issued May 2006 pursuant to anti-dilution provisions (\$0.20)			776,230	77		15
Incremental fair value of additional common stock issuable upon conversion of preferred shares						50
Stock option-based compensation for financial consulting services rendered					(464,466)	46
Stock option-based compensation for directors					(3,360)	
Adjustment pursuant to SFAS 123R of stock option based compensation to employees					(199,719)	19
Amortization of deferred compensation					655,057	
Net loss						
Balance, June 30, 2006	221.40	\$5,535,000	15,500,069	\$1,550	\$(335,318)	\$25,740

(See Notes to Unaudited Condensed Financial Statements)

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CEPTOR CORPORATION  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED STATEMENTS OF CASH FLOWS  
(Unaudited)

	For the Six-Month Period Ended June 30,		Cumulative August 11, 1986 (Date of Inception) to June 30, 2006
	2006	2005	
Cash Flows Used In Operating Activities:			
Net loss	\$ (5,381,198)	\$ (4,891,593)	\$ (34,108,263)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	9,535	8,665	41,025
Write-off of in-process research and development	—	—	5,034,309
Charge for stock option issued pursuant to spinoff agreement	—	—	2,082,500
Stock-based compensation to employees and directors	75,466	80,122	192,242
Stock-based compensation to nonemployees	579,591	671,875	4,802,822
Stock-based component of payment of legal fees	—	70,000	70,000
Stock-based component of litigation settlement	—	—	422,000
Gain on extinguishment of debt	(387,362)	(311,281)	(698,643)
Change in fair value of derivative financial instruments	(2,326,585)	—	(3,276,566)
Non-cash interest expense	5,170,999	412,161	7,391,194
Changes in assets and liabilities:			
Prepaid expenses and other current assets	101,240	(52,283)	(74,545)
Other assets	—	—	(18,511)
Accounts payable and accrued expenses	6,832	540,422	5,216,402
Net cash used in operating activities	(2,151,482)	(3,471,912)	(12,924,034)
Cash Flows Used In Investing Activities:			
Purchases of property and equipment	—	(9,049)	(86,921)
Cash Flows Provided By Financing Activities:			
Proceeds from issuances of common stock	200,000	6,250	1,499,516
Collections of subscriptions receivable	—	272	303
Net proceeds from issuances of preferred stock	—	7,650,457	10,448,629
Acquisition of treasury stock under put right	—	(916,450)	(1,279,125)
Acquisition of treasury stock under purchase agreement	—	(2,309,250)	(2,309,250)
Distribution to shareholders	—	—	(4,260)
Capital contributed by Xechem International, Inc.	—	—	350,310
Proceeds from issuance of debt	1,876,000	—	5,501,000

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Expense of issuance of long term debt	(355,949)	—	(843,322)
Principal payments on bridge loans	—	—	(350,000)
Net cash provided by financing activities	1,720,051	4,431,279	13,013,801
Net increase (decrease) in cash and cash equivalents	(431,431)	950,318	2,846
Cash and cash equivalents at the beginning of period	434,277	1,331,513	—
Cash and cash equivalents at the end of period	\$ 2,846	\$ 2,281,831	\$ 2,846

(See Notes to Unaudited Condensed Financial Statements)

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CEPTOR CORPORATION  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED STATEMENTS OF CASH FLOWS  
(Unaudited)

	For the Six-Month Period Ended June 30,		Cumulative August 11, 1986 (Date of Inception) to June 30, 2006
	2006	2005	
Supplemental Disclosure of Cash Flow Information:			
Deemed dividend of the beneficial conversion feature of units sold in private placement	\$ —	\$ 9,164,500	\$ 10,100,616
Issuance of 2,902,500 shares of common stock upon conversion of preferred shares	668,750	1,100,000	7,256,250
Issuance of 100,000 shares of common stock pursuant to stock plan	—	—	270,000
Issuance of 7,500 shares of common stock as compensation for past services	—	—	46,875
Issuance of 25,000 shares of common stock as compensation for financial planning	—	—	75,000
Issuance of 23,000 shares of common stock in payment of accrued legal fees	—	70,000	70,000
Capital contribution for repurchase of common stock pursuant to Stock Purchase Agreement	—	—	424,818
Issuance of 1,340,267 shares of common stock upon conversion of convertible note	320,725	—	502,600
Issuance of 1,299,850 shares of common stock upon conversion of convertible debenture	300,000	—	300,000
Issuance of 36,000 shares of common stock as debt issuance costs	—	—	90,000
	—	—	550,000

Issuance of 451,597 shares of common stock to bridge loan investors and placement agent			
Issuance of 167,610 shares up on conversion of convertible notes	—	—	209,512
Issuance of convertible notes in exchange for bridge loans and long-term debt plus accrued interest	—	—	1,111,240

(See Notes to Unaudited Condensed Financial Statements)

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NOTE 1 – BASIS OF INTERIM FINANCIAL STATEMENT PRESENTATION

The accompanying unaudited Condensed Financial Statements of CepTor Corporation have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and the instructions to Form 10-QSB. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows for all periods presented have been made. The results of operations for the three- and six-month periods ended June 30, 2006 are not necessarily indicative of the operating results that may be expected for the entire year ending December 31, 2006.

NOTE 2 – THE COMPANY

Organization

The financial statements presented are those of CepTor Corporation (the “Company”), incorporated in August 1986 in the State of Delaware.

Nature of Business and Development Stage Operations

The Company is a biopharmaceutical company engaged in the research and development of therapeutic products for neuromuscular, neurodegenerative and other diseases with a focus on orphan diseases (defined as those which affect less than 200,000 people). Since its inception, the Company has devoted its efforts and resources to the development of its receptor mediated drug-targeting platform for neuromuscular and neurodegenerative diseases, and to raising the funds necessary to continue this research.

The Company is a development stage enterprise which has a limited history of operations and has not generated any material revenues since its inception. The Company has received a limited amount of funding through grants and collaborative research efforts in connection with developing its products. The Company does not have any products that are approved for commercial distribution at the present time. As a development stage enterprise, the Company is subject to all of the risks and uncertainties that are associated with developing a new business.

NOTE 3 – LIQUIDITY AND FINANCIAL CONDITION



The Company has had difficulty securing the necessary capital to fully execute its business plan and has not been able to remain current with respect to the payment terms of all of its operating obligations. In addition, the Company has substantial convertible debt obligations with terms that require repayment during the next twelve months. During the six months ended June 30, 2006, the Company received (i) proceeds from exercises of stock options of \$200,000, (ii) \$1,625,000 from the issuance of its 2006 6% Convertible Notes (see Note 8), and (iii) unsecured advances of \$251,000. Subsequent to June 30, 2006, the Company received (i) \$950,000 from the issuance of its 2006 6% Convertible Notes (which includes the rollover of unsecured advances of \$250,000 received prior to June 30, 2006), and (ii) unsecured advances of \$335,000 (see Note 13).

The Company is continuing to seek additional capital, collaborative partners, joint ventures and strategic alliance agreements both within the United States and abroad in an effort to continue the development of its proposed products; however, there are currently no firm commitments in place for new capital nor for any prospective joint venture partners or participants with which it would enter into a strategic alliance arrangement providing additional capital. Absent additional funding from private or public equity or debt financings, collaborative or other partnering arrangements, or other sources, the Company will be unable to conduct its product development efforts as planned, and may need to curtail its development plans, cease operations or sell assets. These matters raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Primarily as the result of recording non-cash interest expense of \$5,170,999, offset by the reduction in the fair values of its derivative financial instruments of \$2,326,585, the Company recorded a net loss for the

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six-month period ended June 30, 2006 of \$5,381,198. Non-cash interest expense consisted primarily of the excess fair values of its derivative securities included in its financing transactions and amortization of deferred financing costs of those financing transactions. The Company used net cash flows in its operating activities of \$2,151,482 during the six-month period ended June 30, 2006. The Company's working capital deficiency amounted to \$6,499,238 and its development stage accumulated deficit amounted to \$43,297,293 at June 30, 2006. The Company expects to continue incurring losses for the foreseeable future due to the inherent uncertainty that is related to establishing the commercial feasibility of pharmaceutical products. The Company will require substantial additional funding to support the development of its proposed products and fund its operations while it continues its efforts to execute its business plan.

At June 30, 2006, the Company had \$4,274,736 in principal of convertible notes outstanding before discounts. The December 2004 Convertible Note in the principal amount of \$448,736, was due July 3, 2006. There has not been an agreement on amended terms and no assurance that the Company will reach agreement with the note holder on amended terms. The terms of the 2004 Convertible Note do not provide for penalties or other payments upon default, and accordingly, the Company has not accrued a penalty as of June 30, 2006. Of the remaining debt, (i) \$251,000 was repaid from proceeds of a closing under the 2006 6% Convertible Note offering subsequent to June 30, 2006, (ii) \$250,000 in principal plus accrued interest is due before December 31, 2006, (iii) \$1,625,000 in principal representing 2006 6% Convertible Notes mature in June 2007 and (iv) the balance of \$1,700,000 mature in December 2008. Currently, the Company does not have the available cash to repay these obligations as they come due and if the note holders do not elect to convert their notes at maturity, the Company will be required to raise additional capital in order to meet these obligations. The note holders holding \$1,700,000 in principal have a security interest in all the assets of the Company.

If the Company is able to secure suitable financing to continue the development of its technologies, it may incur significant expenditures as it initiates human clinical trials for Myodur and for the cost to manufacture the Company's Myodur product for use in additional clinical and other testing. For the foreseeable future, the Company's primary efforts will be on moving its lead product, Myodur, into clinical trials for Duchenne muscular dystrophy, for which the Company presently expects to initiate a phase I human clinical trial for Myodur during the first quarter of 2007. The Company, from time to time, may explore the development of other technologies. If the Company decides to develop one or more other technologies, it may require substantial additional financing which it may or may not be able to obtain. If it cannot obtain the additional financing, it may have to forego the development of the other technologies or decide to halt or delay the development of Myodur in favor of the other technologies. As resources allow, the Company may also fund other working capital needs.

The Company does not have, and does not intend to establish, its own manufacturing facilities to produce its product candidates in the foreseeable future. The Company has outsourced the manufacturing of its proposed products to contract manufacturers. As of June 30, 2006, the Company had sufficient materials required for the Company's initial human clinical trials. Furthermore, if the Company receives regulatory approval for any of its products in the United States or elsewhere, it will incur substantial expenditures to develop manufacturing, sales, and marketing capabilities and/or to subcontract or joint venture these activities with others. There can be no assurance that the Company will ever recognize revenue or profit from any such products. In addition, the Company may encounter unanticipated problems, including developmental, regulatory, manufacturing, or marketing difficulties, some of which may be beyond its ability to resolve. The Company may lack the capacity to produce its products in-house and there can be no assurances that it will be able to locate or retain suitable contract manufacturers or be able to have them produce products at satisfactory prices.

#### NOTE 4 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

##### Basis of Presentation

The Company is a development stage enterprise. Accordingly, the Company has included its cumulative statements of operations and cash flows for the period of August 11, 1986 (date of inception) to June 30, 2006 in accordance with Statement of Financial Accounting Standards ("SFAS") No. 7 "Accounting and Reporting by Development Stage Enterprises."

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The Company's net loss available to common shareholders as reported in its statement of operations for the period of August 11, 1986 (date of inception) to June 30, 2006 is \$44,208,879 whereas the deficit accumulated during its development stage as reported on its balance sheet at June 30, 2006 is \$43,297,293. The difference is a result of the acquisition of the Company by Xechem and the restatement of its assets and liabilities to fair value, which resulted in the Company's accumulated deficit, net of distributions, from inception through December 31, 2003 (the date of merger for financial reporting purposes) being reclassified to additional paid-in capital, net of a deemed dividend to the preferred shareholders.

##### Accounting for Stock-Based Compensation

Prior to January 1, 2006, the Company accounted for employee stock transactions in accordance with Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees." The Company applied the pro

forma disclosure requirements of SFAS No. 123 “Accounting for Stock-Based Compensation.”

Effective January 1, 2006, the Company adopted SFAS No. 123R “Share Based Payment.” This statement is a revision of SFAS Statement No. 123, and supersedes APB Opinion No. 25, and its related implementation guidance. SFAS 123R addresses all forms of share based payment (“SBP”) awards including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. Under SFAS 123R, SBP awards result in a cost that will be measured at fair value on the awards' grant date, based on the estimated number of awards that are expected to vest and that will result in a charge to operations. The Company adopted the modified prospective method with respect to accounting for its transition to SFAS 123(R) and recorded unrecognized compensation cost of \$407,425 as deferred compensation at January 1, 2006. Accordingly, the Company recognized expense on the statement of operations of \$37,686 and \$75,372 for the fair value of these stock options which vested during the three- and six-month periods ended June 30, 2006, respectively. The fair value of these awards was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions: risk free interest rate: 3.3% to 3.6%; expected dividend yield: 0%; expected option life: 10 years; and volatility: 108% to 123%.

For the three- and six-month periods ended June 30, 2005, the Company applied APB Opinion No. 25, “Accounting for Stock Issued to Employees.” As required under SFAS No. 148, “Accounting for Stock-based Compensation — Transition and Disclosure,” the following table presents pro-forma net loss and basic and diluted loss per share as if the fair value-based method had been applied to all awards during that period.

	Three Month Period Ended June 30, 2005	Six Month Period Ended June 30, 2005
Net loss available to common stockholders	\$ (2,595,487)	\$ (14,056,093)
Stock-based employee compensation cost, under fair value accounting	(15,485)	(28,799)
Pro-forma net loss under fair value method	\$ (2,610,972)	\$ (14,084,892)
Net loss per share – basic and diluted	\$ (0.22)	\$ (1.23)
Pro-forma net loss per share, basic and diluted	\$ (0.22)	\$ (1.24)

#### Net Loss per Share

Net loss per share is presented under SFAS No. 128 “Earnings Per Share.” Under SFAS 128, basic net loss per share is computed by dividing net loss per share available to common stockholders by the weighted average shares of common stock outstanding for the period and excludes any potential dilution. Diluted earnings per share reflect the potential dilution that would occur upon the exercise or conversion of all dilutive securities into common stock. The computation of loss per share for the three- and six-month periods ended June 30, 2006 and 2005 excludes potentially dilutive securities because their inclusion would be anti-dilutive.

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Shares of common stock issuable upon the conversion or exercise of potentially dilutive securities are as follows:

	June 30,	
	2006	2005
Convertible Notes	30,463,204	1,269,171
Warrants	20,583,232	4,239,900
Series A Preferred Stock	5,504,000	3,826,500
Options	1,971,029	607,695
Total	58,521,465	9,943,266

#### Accounting for Conversion Options Embedded in Convertible Notes and Convertible Preferred Stock

The Company accounts for conversion options embedded in convertible notes and convertible preferred stock in accordance with SFAS No. 133 “Accounting for Derivative Instruments and Hedging Activities” and EITF 00-19 “Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock”. SFAS 133 generally requires companies to bifurcate conversion options embedded in convertible notes and preferred shares from their host instruments and to account for them as free standing derivative financial instruments in accordance with EITF 00-19. SFAS 133 provides for an exception to this rule when convertible notes and mandatorily redeemable preferred shares, as host instruments, are deemed to be conventional as that term is described in the implementation guidance provided in paragraph 61 (k) of Appendix A to SFAS 133 and further clarified in EITF 05-2 “The Meaning of ‘Conventional Convertible Debt Instrument’ in Issue No. 00-19.” SFAS 133 provides for an additional exception to this rule when the economic characteristics and risks of the embedded derivative instrument are clearly and closely related to the economic characteristics and risks of the host instrument.

The Company accounts for convertible notes (deemed conventional) in accordance with the provisions of EITF 98-5 “Accounting for Convertible Securities with Beneficial Conversion Features,” and EITF 00-27 “Application of EITF 98-5 to Certain Convertible Instruments.” Accordingly, the Company records, as a discount to convertible notes, the intrinsic value of such conversion options based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their earliest date of redemption.

The Company issued \$3,875,000 in principal of various convertible notes with embedded conversion options accounted for as free standing derivative financial instruments in accordance with SFAS 133 and EITF 00-19 and on the dates of issuance recorded liabilities for conversion options of \$2,701,192. The fair value of these embedded conversion options were estimated at the date of issuance using the Black-Scholes option pricing model with the following assumptions: risk free interest rate: 3.3% to 5.1%; expected dividend yield: 0%; expected option life: one year to 3 years; and volatility: 130% to 173%. The accounting guidance instructs that the conversion options are a derivative liability and are marked to market for each reporting period. During the three- and six-month periods ended June 30, 2006, the Company recognized an expense of \$408,235 for the increase in fair value and a gain of \$165,825 for the decrease in fair value, respectively, of the derivative financial instruments. The fair value of these embedded conversion options were estimated at June 30, 2006 using the Black-Scholes option pricing model with the following assumptions: risk free interest rate: 5.1%; expected dividend yield: 0%; expected option life: 3 years; and volatility: 184%.

The Company also determined that the conversion option embedded in its Series A Preferred stock is not a free-standing derivative in accordance with the implementation guidance provided in paragraph 61 (l) of Appendix A to SFAS 133.

#### Accounting for Warrants and Freestanding Derivative Financial Instruments

The Company accounts for the issuance of common stock purchase warrants and other freestanding derivative financial instruments in accordance with the provisions of EITF 00-19. Based on the provisions of EITF 00-19, the Company classifies as equity any contracts that (i) require physical settlement or

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net-share settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

The terms of the Company's December 2005 Convertible Debentures (see Note 8) provide for a conversion price in certain situations based on a floating conversion price which results in an indeterminable number of shares of common stock potentially issued upon conversion. Under accounting guidance provided by EITF 00-19, as of December 31, 2005, the Company had liabilities of \$3,130,957 representing the fair value of warrants to purchase approximately 6.0 million shares of common stock which had been granted to non-employees for services rendered or as components of other financing instruments. The Company recorded additional liabilities for the fair value of warrants granted during the six-month period ended June 30, 2006 in the aggregate of \$2,912,681. The fair value of these awards was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions: risk free interest rate: 4.7% to 5.1%; expected dividend yield: 0%; expected option life: 2 years to 5 years; and volatility: 164% to 184%.

The accounting guidance instructs that the warrants are a derivative liability and are marked to market for each reporting period. During the three- and six-month periods ended June 30, 2006, the Company recognized a gain of \$97,088 and \$2,160,760, respectively, for the decrease in fair value of the derivative financial instruments. The fair value of these awards was estimated at June 30, 2006 using the Black-Scholes option pricing model with the following assumptions: risk free interest rate: 5.1%; expected dividend yield: 0%; expected option life: 1.4 years to 4.9 years; and volatility: 184%.

## Recently Issued Accounting Pronouncements

In February 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 155, which is an amendment of SFAS No. 133 and 140. This Statement: a) permits fair value re-measurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, b) clarifies which interest-only strip and principal-only strip are not subject to the requirements of SFAS 133, c) establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, d) clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives, e) amends SFAS 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. This Statement is effective for financial statements for fiscal years beginning after September 15, 2006. Earlier adoption of this Statement is permitted as of the beginning of an entity's fiscal year, provided the entity has not yet issued any financial statements for that fiscal year. The Company is evaluating if this Statement will have an impact on the financial statements of the Company.

In March 2006, the FASB issued SFAS No. 156, which amends FASB Statement No. 140. This Statement establishes, among other things, the accounting for all separately recognized servicing assets and servicing liabilities. This Statement amends SFAS 140 to require that all separately recognized servicing assets and servicing liabilities be initially measured at fair value, if practicable. This Statement permits, but does not require, the subsequent measurement of separately recognized servicing assets and servicing liabilities at fair value. An entity that uses derivative instruments to mitigate the risks inherent in servicing assets and servicing liabilities is required to account for those derivative instruments at fair value. Under this Statement, an entity can elect subsequent fair value measurement to account for its separately recognized servicing assets and servicing liabilities. By electing that option, an entity may simplify its accounting because this Statement permits income statement recognition of the potential offsetting changes in fair value of those servicing assets and servicing liabilities and derivative instruments in the same accounting period. This Statement is effective for financial statements for fiscal years beginning after September 15, 2006. Earlier adoption of this Statement is permitted as of the beginning of an entity's fiscal year, provided the entity has not yet issued any financial statements for that fiscal year. The Company believes this Statement will not have an impact on the financial statements of the Company once adopted.

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NOTE 5 – PREPAID EXPENSES

Prepaid expense consists primarily of unamortized premiums paid to carriers for insurance policies.

NOTE 6 – DEFERRED FINANCING COSTS

The Company capitalizes the costs and expenses incurred in entering into its debt obligations which is then amortized over the term of the debt. During the year ended December 31, 2005, the Company incurred \$104,408 in deferred financing costs associated with its December 2005 Convertible Debentures offering. During the three-month period ended June 30, 2006, the Company incurred \$807,045 in deferred financing costs associated with its 2006 6% Convertible Notes offering. During the three- and six-month periods ended June 30, 2006, the Company amortized \$75,954 and \$84,654 of deferred financing costs, respectively, to non-cash interest expense.

NOTE 7 – ACCRUED EXPENSES

Accrued expenses at June 30, 2006 are as follows:

Financial investor relations fees	\$ 188,278
Interest on convertible notes	176,241
Clinical development expenses	139,521
Professional advisory fees	135,000
Liquidating damages	97,500
Miscellaneous	76,984
Total	\$ 813,524

In connection with the sale of Series A Preferred Stock in a private placement, pursuant to the placement agent agreement, the Company had agreed to spend up to 3% of the gross proceeds from its private placement on financial

investor relations activities, all of which was accrued as "Financial Investor Relations Fees" and charged to additional paid-in capital upon each closing of the private placement.

## NOTE 8 – CONVERTIBLE NOTES

### Convertible Promissory Notes

Pursuant to an offer dated October 22, 2004 as amended November 15, 2004 made to the holders of certain convertible notes, the Company issued \$901,728 of convertible notes due December 8, 2005 in exchange for convertible notes in the principal amount of \$825,000 plus accrued interest of \$76,728 (the "December 2004 Convertible Notes").

The December 2004 Convertible Notes were convertible into shares of the Company's common stock at \$1.25 per share in amounts equal to the outstanding principal cancelled, plus accrued interest at 10% through the date of conversion. In April 2005, the Company renegotiated certain terms of the December 2004 Convertible Notes to extend the maturity date until July 3, 2006 and in exchange the Company (1) increased the contractual interest rate effective December 8, 2005 to 12%, (2) reduced the conversion rate from \$1.25 to \$0.75 per share and (3) eliminated the Company's right to call the December 2004 Convertible Notes (the "Amended December 2004 Convertible Notes").

On December 9, 2005, the Company amended a portion of the convertible promissory note that was payable to Harbor Trust dated December 9, 2004, in the principal amount of \$452,991 by reducing the conversion price to \$0.375 from \$0.75 per share (the "Amended December 2005 Harbor Note"). The affect of this modification was insignificant since approximately 50% of the note was converted in December 2005 and the remainder was converted in January 2006. The Amended December 2005 Harbor Note bears interest at the rate of 10% per year through December 8, 2005 and 12% per year thereafter. The Amended December 2005 Harbor Note was fully converted on January 27, 2006.

The remaining December 2004 Convertible Note in the principal amount of \$448,736 which was due July 3, 2006, is currently being renegotiated to amend the maturity date or conversion terms. There has

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not been an agreement on amended terms and no assurance the Company will reach agreement with the note holder. The terms of the December 2004 Convertible Note do not provide for penalties or other payments upon default, and accordingly, the Company has not accrued any as of June 30, 2006. The conversion price was adjusted to \$0.15 from \$0.75 pursuant to the 2006 6% Convertible Note offering which commenced June 1, 2006 (see below).

As of June 30, 2006, the principal amount of \$448,736 remains outstanding under the December 2004 Convertible Note.

### 2005 Harbor Note

On December 9, 2005, the Company issued a convertible promissory note (the "2005 Harbor Note") in the principal amount of \$250,000 which bears interest at the rate of 6% per year. All unpaid principal and interest under the 2005 Harbor Note will be due and payable on December 9, 2006. The 2005 Harbor Note is convertible, in whole or in part, at any time, into common stock at an adjusted conversion price of \$0.15 per share (adjusted pursuant to the 2006 6% Convertible Note offering commenced on June 1, 2006, see below), subject to certain limitations on conversion as set

forth in the 2005 Harbor Note, including where the resulting number of shares converted on a cumulative basis, would exceed 19.99% of the total number of shares of common stock outstanding and, subject to a conversion price adjustment in the event the Company offers or sells an option not pursuant to an approved stock plan to acquire common stock at a price per share less than the conversion price. The conversion option featured in this note is being accounted for as a free standing derivative financial instrument in accordance with SFAS 133 and EITF 00-19. The fair value of the conversion option amounted to \$182,883 at June 30, 2006.

As of June 30, 2006, the principal amount of \$250,000 remains outstanding under the 2005 Harbor Note.

#### 2005 Convertible Debentures

On December 9, 2005, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with Cornell Capital Partners, LP ("Cornell Capital") pursuant to which Cornell Capital has purchased, in a private placement, secured convertible debentures in the aggregate principal amount of \$2,000,000 (the "2005 Convertible Debentures"), which bear interest at the rate of 8% per year. Pursuant to the Securities Purchase Agreement, the Company issued a 2005 Convertible Debenture in the principal amount of \$1,000,000 on each of December 9, 2005 and December 28, 2005. Each 2005 Convertible Debenture has a three-year maturity from the date of issuance and was subject to earlier conversion or redemption pursuant to its terms.

Cornell Capital has the right to convert a portion or all of the outstanding principal and interest under the 2005 Convertible Debentures into shares of common stock at a conversion price per share equal to the lesser of \$0.9765 (105% of the closing bid price of the common stock on December 8, 2005) (the "Fixed Price") or (ii) 95% of the lowest closing bid price of the common stock for the twenty trading days immediately preceding the conversion date (the "Floating Price" and together with the Fixed Price, the "Conversion Price"), subject to adjustment as provided in the 2005 Convertible Debentures; provided, that any such conversion based on the Floating Price will generally be limited to \$150,000 of principal outstanding under the 2005 Convertible Debentures in any thirty day period; and further provided, that Cornell Capital may not convert the 2005 Convertible Debentures into shares of common stock if such conversion would result in Cornell Capital, together with its affiliates, beneficially owning in excess of 4.9% of the then issued and outstanding shares of common stock. The Conversion Price and number of shares of common stock issuable upon conversion of the 2005 Convertible Debentures is subject to certain exceptions and adjustment for stock splits and combinations and other dilutive events.

Subject to the terms and condition of the 2005 Convertible Debentures, the Company had the right at any time upon three business days notice to redeem the 2005 Convertible Debentures, in whole or in part. If the closing bid price of the common stock, is less than the Fixed Price at the time of the redemption, the Company is obligated to pay, in addition to the principal and accrued interest being redeemed, a redemption premium of 8% of the principal amount being redeemed (the "Redemption Amount"). If the closing bid price is greater than the Fixed Price, the Company may redeem up to 50% of the principal

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amount at the Redemption Amount and the remaining 50% at the greater of the (x) Redemption Amount or (y) the market value of the common stock. In addition, Cornell Capital will receive a three-year warrant to purchase 25,000 shares of common stock for every \$100,000 redeemed by the Company, on a pro rata basis, at an exercise price per share of \$0.9765 (the "Redemption Warrant").



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If an Event of Default (as such term is defined in the 2005 Convertible Debentures) occurs, any principal and accrued interest outstanding will become immediately due and payable, in cash or common stock, at Cornell Capital's election.

Pursuant to the Securities Purchase Agreement, on December 9, 2005, the Company issued to Cornell Capital a warrant to purchase 1,000,000 shares of common stock at an exercise price per share of \$1.023 (110% of the closing bid price of the common stock on December 8, 2005) and (ii) 268,817 shares of common stock, and (iii) on each of December 9, 2005 and December 28, 2005, the Company made a cash payment to an affiliate of Cornell Capital of \$80,000 for expenses incurred in connection with the transaction.

### Assignment of 2005 Convertible Debentures

On June 29, 2006, the Company entered into an assignment agreement ("Assignment Agreement") by and between Cornell Capital, The Longview Fund, LP ("Longview"), Alpha Capital Aktiengesellschaft ("Alpha"), Ellis International Ltd. ("Ellis") and Momona Capital Corp. ("Momona") (each an "Assignee") which provides for, among other things, the assignment of the unpaid and unconverted amounts outstanding under each of the 2005 Convertible Debentures to the Assignees in the amounts listed in the Assignment Agreement. The aggregate unpaid and unconverted principal amount of \$1,700,000 under the 2005 Convertible Debentures was assigned. The aggregate purchase price paid by the Assignees was \$1,914,180, of which \$1,836,000 is being paid for principal (which includes the Redemption Amount) and \$78,180 represents accrued interest.

The Company now owes in the principal amounts of \$700,000 and \$400,000 to Longview and \$300,000, \$200,000 and \$100,000 to Alpha, Ellis and Momona, respectively, in proportion to their assignment from Cornell Capital. All of the terms and conditions remain unchanged in the 2005 Convertible Debentures except that the Assignment Agreement provides that the Company may not redeem the 2005 Convertible Debentures, in whole or in part.

Pursuant to the Securities Purchase Agreement, the Company granted a security interest in all of its assets to Cornell Capital to secure its obligations under the 2005 Convertible Debentures, which security interest will be transferred to the Assignees pursuant to the Assignment Agreement.

As of June 30, 2006, \$1,700,000 of principal of the 2005 Convertible Debentures remains outstanding.

### 2006 6% Convertible Notes

On May 26, 2006, the Company entered into a placement agency agreement with Brookshire Securities Corporation for a private offering of one-year 6% convertible notes in an aggregate principal amount of up to \$6,000,000 (the "2006 6% Convertible Notes").

The Company is offering the 2006 6% Convertible Notes on a "best efforts" basis only to "accredited investors" (as defined in Rule 501 (a) of Regulation D under Section 4(2) of the Securities Act of 1933, as amended) by offer letter dated May 25, 2006 (the "Offer Letter"), which sets forth the terms and conditions of the offering. The Company will offer the 2006 6% Convertible Notes until August 30, 2006, unless extended.

The 2006 6% Convertible Notes are payable one year after the date of funding, or earlier upon acceleration following the occurrence of an "Event of Default", as defined in the 2006 6% Convertible Notes. Interest on the 2006 6% Convertible Notes will accrue from the date of issue at 6% per annum, or 12 % per annum upon the occurrence of an Event of Default.

The Company may repurchase the 2006 6% Convertible Notes for 200% of their principal amount, plus accrued interest, on or before September 30, 2006, upon 30 days' prior written notice. The Company must

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repurchase the 2006 6% Convertible Notes at 200% of their principal amount, plus accrued interest, if on or before September 30, 2006, the Company announces a sale or merger of the company or its assets, which is completed within six months.

The principal of, and accrued interest on, the 2006 6% Convertible Notes is convertible into shares of common stock, at the option of the holders of the 2006 6% Convertible Notes, at an initial conversion price per share of \$0.15, subject to adjustment for certain issuances or events that will result in dilution (the "Fixed Conversion Price"). If the 2006 6% Convertible Notes have not been fully converted or repurchased for 200% of their principal amount by September 30, 2006, then commencing on October 1, 2006, the conversion price will be the lesser of (i) the Fixed Conversion Price and (ii) 90% of the lowest closing price (or, if no closing price is available, the average of closing bid and asked prices) of the Company's common stock for the 20 trading days immediately preceding the date on which a notice of conversion is delivered (the "Floating Conversion Price").

Purchasers of 2006 6% Convertible Notes who have not previously purchased shares of the Company's Series A Convertible Preferred Stock, par value \$0.0001 per share (the "Preferred Stock") will receive, without additional consideration, five-year warrants to purchase a number of additional shares of common stock equal to 100% of the number of shares that the purchaser may initially acquire upon conversion of the 2006 6% Convertible Notes, at an initial exercise price of \$0.30 per share, subject to adjustment for certain issuances and events that will result in dilution.

Purchasers of 2006 6% Convertible Notes who purchased shares of Preferred Stock, will be issued a number of additional shares of common stock upon conversion of the Preferred Stock, based upon the principal amount of 2006 6% Convertible Notes purchased relative to the total purchase price of the shares of Preferred Stock purchased, which will effectively reduce the per share conversion price of the Preferred Stock so that it is the same as the conversion price per share of the 2006 6% Convertible Notes, or to the extent purchasers have converted shares of Preferred Stock, but not sold the common stock received upon conversion, the Company will issue a number of additional shares of common stock that will provide equivalent value, in each case without additional consideration. The Company will issue warrants to purchase a number of additional shares of common stock at \$0.15 that will provide equivalent value, to those purchasers of 2006 6% Convertible Notes who have sold or otherwise disposed of shares of common stock received upon conversion of Preferred Stock. If the Company redeems the 2006 6% Convertible Notes but does not redeem the Preferred Stock by September 30, 2006, then commencing on October 1, 2006, the conversion price of outstanding shares of Preferred Stock of purchasers of the 2006 6% Convertible Notes will be reduced to the lesser of the Fixed Conversion Price and the Floating Conversion Price, to the extent of the total purchase price paid by the purchaser for the 2006 6% Convertible Notes bears in relation to the total purchase price paid for the Preferred Stock. The Company also will reduce to \$0.30 the per share exercise price of warrants purchasers of the 2006 6% Convertible Notes received with their purchase of Preferred Stock, to the extent of the principal amount of 2006 6% Convertible Notes purchased relative to the total purchase price for the shares of Preferred Stock, subject to the Company's right, after the registration statement referred to below has become effective, to force the exercise of those warrants on 20 days' notice by offering to purchase those warrants for a nominal price if the closing price per share of the common stock exceeds \$0.45 for ten consecutive trading days.

The Company has agreed to file a registration statement to register for resale the shares of common stock that purchasers of 2006 6% Convertible Notes may acquire upon conversion of the 2006 6% Convertible Notes or exercise of the warrants, as well as any additional shares of common stock which may be issued as part of the offering. If the Company fails to file a registration statement for the resale of these shares by August 21, 2006, or the registration statement is not effective by the 150th day after the Initial Closing on June 1, 2006, the Company will be obligated to

pay purchasers of the 2006 6% Convertible Notes liquidated damages in an amount equal to 2% of the principal amount of the 2006 6% Convertible Notes for each month, or portion of a month, for which the Company fails to timely file the registration statement or until the registration statement becomes effective, but in no event may the liquidated damages exceed 18% of the principal amount of the 2006 6% Convertible Notes. At June 30, 2006, the Company has accrued \$97,500 as estimated liquidated damages, which represents the damages which would be due with a potential delay of three months in the filing of its registration statement.

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As a condition to their purchase of the 2006 6% Convertible Notes, purchasers have agreed that they will not sell, transfer or otherwise dispose of any securities of the Company prior to the 150th day after June 1, 2006, except that the restrictive period applicable to shares of common stock that were acquired, or may be acquired, upon conversion of shares of Preferred Stock held by the purchaser, expired on August 20, 2006 to the extent of the total purchase price paid by the purchaser for 2006 6% Convertible Notes bears in relation to the total purchase price paid for the Preferred Stock.

Pursuant to the terms of the subscription agreement for the 2006 6% Convertible Note offering, the proceeds of the offering, after payment of sales commissions and other fees and expenses, are to be disbursed to the Company from escrow for use as working capital in monthly installments, to the extent available, as follows: \$540,000 on June 1, 2006, \$820,000 by June 10, 2006, \$590,000 by July 10, 2006, \$440,000 by August 10, 2006, \$270,000 by September 10, 2006, and up to \$500,000 by the 10th day of each succeeding calendar month until fully funded.

The Company will pay a cash fee equal to 10% of the gross proceeds from the sale of the 2006 6% Convertible Notes for purchasers obtained through the assistance of the placement agent, a portion of which may be reallocated to other registered broker-dealers participating in the offering, and reimburse the placement agent for \$15,000 of its legal expenses. The Company also will issue to the placement agent, or its designee(s), at each closing, a five-year warrant to purchase such number of shares of common stock at an exercise price of \$0.15 per share equal to 10% of such number of shares of common stock into which the 2006 6% Convertible Notes sold through the placement agent at such closing are convertible. In addition, the Company has agreed to reduce to \$0.30 the per share exercise price of warrants to purchase shares of common stock issued to the placement agent previously, as placement agent for our Preferred Stock.

The Harbor Trust, has agreed to a pledge of its 2005 Harbor Note dated December 9, 2005 issued in the name of The Harbor Trust in the principal amount of \$250,000 to secure a non-recourse obligation to increase the return to purchasers of Preferred Stock to the extent required to protect investors from a loss on their investment to the extent of such collateral, measured on the earlier of May 20, 2007 or the date on which all the 2006 6% Convertible Notes offered have been sold or otherwise disposed of, including by conversion. Such protection is to be available only to 2006 6% Convertible Note purchasers who did not acquire Preferred Stock from the Company directly and to persons who acquired Preferred Stock directly (or are current holders) and who elect not to have any adjustment made with respect to their Preferred Stock holdings as previously described (i.e., who elect to receive the benefit of the yield enhancement in lieu of the conversion adjustments). In consideration for the agreements made by The Harbor Trust, at each closing the Company will (i) pay The Harbor Trust a yield enhancement incentive fee equal to 10% of the aggregate gross proceeds of the 2006 6% Convertible Notes receiving the benefit of such protection (the "Yield Protected Notes"), plus (ii) issue to The Harbor Trust, for nominal consideration, five-year warrants to purchase, for the principal amount thereof, (A) 2006 6% Convertible Notes having a principal amount equal to 10% of the principal amount of the Yield Protected Notes sold in the Offering, and (B) five-year warrants to purchase a number of shares

of common stock equal to 10% of the shares of common stock that purchasers of the Yield Protected Notes sold in the offering may acquire upon exercise of the warrants they received with the purchase of the Yield Protected Notes, at an exercise price of \$0.30 per share. In no event will the total yield enhancement incentive fee, plus the placement agent fee, paid by the Company exceed 10% of the gross proceeds of the offering.

On June 1, 2006 and June 15, 2006, the Company sold an aggregate principal amount of \$1,500,000, and \$125,000 of 2006 6% Convertible Notes. To those purchasers who had not previously purchased the Company's Preferred Stock, the Company issued five-year warrants to purchase an aggregate of 6,500,000 and 833,333 shares of common stock, respectively, at an initial exercise price of \$0.30 per share. To those purchasers who had previously purchased the Company's Preferred Stock, the Company will issue upon the conversion of their Preferred Stock, 3,290,000 additional shares of common stock to those purchasers on June 1, 2006 who had previously purchased Preferred Stock and adjust the exercise price on the warrants they received when they purchased the Preferred Stock to purchase 105,000 shares of common stock to \$0.30.

Of the \$1,100,000 in principal purchased by those investors who had not previously purchased the Company's Preferred Stock, the Company recognized a debt discount of \$755,237 at date of issuance

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based on an allocation of the proceeds based on relative fair values of the 2006 6% Convertible Notes, the warrants and the conversion option, as determined by the Black-Scholes option pricing model. Since the Company is required to account for its derivative financial instruments as liabilities (see Note 4), the Company recorded the full fair values of the warrants and the conversion options at date of issuance of the 2006 6% Convertible Notes of \$1,239,700 and \$1,169,960, respectively, as liabilities and charged non-cash interest expense. The fair value of these awards was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions: risk free interest rate: 5.1%; expected dividend yield: 0%; expected option life: 3 years to 5 years; and volatility: 173%. The Company marks to market these derivative financial instruments at each reporting date.

Of the \$525,000 in principal purchased by those investors who had previously purchased the Company's Preferred Stock, the Company recognized a debt discount of \$525,000 at date of issuance based on the (i) fair values of the conversion option, (ii) the incremental increase in fair value of the additional shares of common stock to be issued upon conversion of the Preferred Stock and (iii) the change in fair value of the underlying warrants associated with the Preferred Stock due to the change in exercise price, as determined by the Black-Scholes option pricing model. Since the Company is required to account for its derivative financial instruments as liabilities (see Note 4), the Company recorded the incremental fair value of the Preferred Stock warrants and the full fair value conversion options at date of issuance of the 2006 6% Convertible Notes of \$4,872 and \$558,390, respectively, as liabilities and charged the excess to non-cash interest expense. The fair value of these awards was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions: risk free interest rate: 5.1%; expected dividend yield: 0%; expected option life: 2 years to 3 years; and volatility: 173%. The Company marks to market these derivative financial instruments at each reporting date. In addition, the Company charged non-cash interest expense and credited equity for the incremental increase in fair value of the additional shares of common stock issuable upon conversion of the Preferred Stock.

Adjustments to Outstanding Convertible Securities and Other Rights to Purchase Common Stock Resulting from 2006 6% Convertible Notes Offering

Pursuant to the terms of the 2006 6% Convertible Note offering, the conversion prices on certain convertible securities were adjusted to the conversion price of the 2006 6% Convertible Notes.

The December 2004 Convertible Note and the 2005 Harbor Note in the principal amount of \$448,736 and \$250,000, respectively and with adjusted conversion prices of \$0.75 per share and \$0.375 per share, respectively, will adjust their conversion prices to \$0.15 per share. As a result of this adjustment, the Company anticipates that it will issue an additional 2,794,804 and 1,501,667 shares, respectively, assuming conversion at maturity.

The Company evaluated the revision in the December 2004 Convertible Note to determine whether the reduction in the conversion price resulted in the issuance of a substantially different debt instrument. The Company determined that after giving effect to the substantial increase in the fair value of the beneficial conversion feature that resulted from reducing the conversion price, it had issued a substantially different debt instrument which resulted in a constructive extinguishment of the original debt instrument. Accordingly, the Company recorded a gain on the extinguishment of debt in the amounts of \$387,362 for the December 2005 Convertible Note that is included in the accompanying statement of operations for the three- and six-month periods ended June 30, 2006.

Since the incremental fair value of the Company's common stock which would be issued upon conversion, as determined by the Black-Scholes option pricing model, was in the aggregate greater than the principal balance of individual notes, the Company recorded an original issuance discount equal to the fair value of this beneficial conversion feature, limited to the principal balance of the notes. This debt discount is being amortized as non-cash interest expense over the remaining term of the December 2004 Convertible Note. During the three- and six-month periods ended June 30, 2006, the Company amortized an aggregate of \$426,667 of the debt discount which is included in interest expense in the accompanying statement of operations. Assumptions relating to the estimated fair value of the beneficial conversion features, are as follows: risk-free interest rate of 5.1%; expected dividend yield zero percent; expected option life of 1.5 years; and current volatility of 165.4%.

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The 2005 Convertible Debentures in the principal of \$1,700,000 plus accrued interest, with a Fixed Conversion Price (as that term is defined in the 2005 Convertible Debentures) of \$0.9765, adjusted to a Fixed Conversion Price of \$0.15. In addition, the exercise price of the warrants issued to Cornell Capital, for the purchase of 1,000,000 shares of common stock at \$1.023 per share has been reduced to \$0.15 per share. As the terms of 2005 Convertible Debentures provide for a lower of Fixed Conversion Price or Floating Conversion Price (as both terms are defined in the 2005 Convertible Debentures) at conversion, the number of shares of Common Stock issuable upon conversion is indeterminate.

Certain options granted pursuant to our 2004 Incentive Stock Plan and certain shares of common stock issued upon exercise of those options, contain anti-dilution provisions which provide for a reduction of the exercise price if the Company sells common stock or issues convertible securities at a per share price less than their exercise price of \$0.359 (fair market value on the date of grant). As a result of the anti-dilution provision, the Company issued an additional 776,231 shares of common stock and increased the remaining unexercised option by an additional 776,230 shares of common stock issuable upon exercise to the optionees.

## NOTE 9 – EQUITY TRANSACTIONS

During the six-month period ended June 30, 2006, the Company issued the following securities.

#### Common Stock Issued Upon Conversion of Series A Preferred Stock

During the six-month period ended June 30, 2006, the Company issued 267,500 shares of common stock upon conversion of 26.75 shares of Series A Preferred Stock.

#### Shares Issued Upon Exercise of Options Pursuant to 2004 Incentive Stock Plan

In March 2006, the Company issued fully-vested, five-year options to purchase an aggregate of 1,114,206 shares of its common stock at \$0.359 per share pursuant to the 2004 Incentive Stock Plan, to two financial consultants for services previously provided, of which options were exercised as to an aggregate of 557,102 shares of common stock for proceeds to the Company of \$200,000. Pursuant to anti-dilution provisions contained in the option agreements, the Company issued an additional 776,230 shares of common stock during May 2006 in connection with executing the term sheet for the 2006 6% Convertible Note offering.

#### Conversion of Amended December 2004 Convertible Note

In January 2006, the holder of the Company's Amended December 2004 Convertible Note elected to convert the remaining principal balance plus accrued interest of \$320,725 into 855,267 shares of common stock at a conversion price of \$0.375 per share.

#### Conversion of December 2005 Convertible Debenture

During the six-month period ended June 30, 2006, a holder of the Company's December 2005 Convertible Debentures elected to convert a portion of its aggregate principal balance of \$300,000 into 1,299,850 shares of common stock at a conversion price pursuant to the terms of the December 2005 Convertible Debentures.

#### Insufficient Authorized but Unissued Shares of Common Stock

On May 9, 2006, the Board of Directors authorized an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of capital stock from 120,000,000 shares to 270,000,000 shares, of which 250,000,000 shares would be designated as common stock and 20,000,000 shares would be designated as Series A Preferred Stock. Unless the proposed amendment is approved by the stockholders, the Company will not be able to satisfy its obligations in the agreements relating to those securities. If the stockholders do not approve the amendment, the Company will be in default of its obligations under those agreements, and the holders of those securities may accelerate payment of the Company's obligations, obtain liquidated damages under certain of those agreements and pursue other legal remedies against the Company that could severely limit its ability to continue operations.

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#### NOTE 10 – STOCK BASED COMPENSATION

The Company, since its inception has granted non-qualified stock options to various employees and non-employees at the discretion of the Board of Directors under its 2004 Incentive Stock Plan and its 2006 Incentive Stock Plan (the "Plans"). Both Plans have substantially the same terms. Substantially all options granted to date have exercise prices equal to the fair value of the underlying common stock at the date of grant and terms ranging from three to ten years.

Vesting periods range from fully vested at the date of grant to four years.

The fair value of all awards is estimated at the date of grant using the Black-Scholes option pricing model. Assumptions relating to the estimated fair value of stock options that the Company granted prior to January 1, 2006 that were previously accounted for and recorded under the intrinsic value method prescribed under APB 25 are described in Note 3. Pursuant to SFAS 123R, the Company recognized expense on the statement of operations of \$37,686 and \$75,372 for the fair value of those stock options granted prior to January 1, 2006 and which vested during the three- and six-month periods ended June 30, 2006, respectively.

During March 2006, the Company granted stock options to acquire an aggregate of 1,514,206 shares of common stock to three consultants. The option agreements for two of the consultants contained anti-dilution protection of the exercise price and the number of shares issuable upon conversion in the event the Company issued common stock at a price less than the exercise price contained in their option. Each option was exercisable at a price of \$0.359 per share for a period of up to five years from issuance. All of these options were fully vested and non forfeitable on their date of issuance. The Company charged the estimated fair value of \$579,591 to compensation expense during the six-month period ended June 30, 2006 with respect to these options. Assumptions relating to the estimated fair value of these stock options (as determined by the Black-Scholes option pricing model), which the Company accounted for in accordance with SFAS 123(R) and EITF 96-18, are as follows: risk-free interest rate of 4.7%; expected dividend yield zero percent; expected option life of 5 years; and current volatility of 129.6%.

Pursuant to the 2006 6% Convertible Note offering commencing in May 2006, the options for the two consultants who had the anti-dilution protection were adjusted for the dilutive effect of the offering. The two consultants were issued an aggregate of 776,230 additional shares of common stock of which the fair value of \$155,246 was charged to non-cash interest expense as a component of the 2006 6% Convertible Note Offering. In addition, they were granted an additional option, pursuant to the 2006 Incentive Stock Plan, to acquire an aggregate of 776,230 shares of common stock at an exercise price of \$0.15 per share, of which the fair value (as determined by the Black-Scholes option pricing model) of \$158,144 was charged to non-cash interest expense as a component of the 2006 6% Convertible Note offering. Assumptions related to the estimated fair value of the stock options at the date of adjustment, which the Company accounted for in accordance with SFAS 123R and EITF-96-18 were: risk free interest rate: 5.1%; expected dividend yield: 0%; expected option life: 5 years; and volatility: 173%. The exercise price on their remaining unexercised options was adjusted to \$0.15 per share.

During June 2006, the Company granted stock options to acquire an aggregate of 16,000 shares of common stock to three directors of the Company. Each option was exercisable at a price of \$0.21 per share for a period of up to ten years from issuance. All of these options vest over three years and were non forfeitable on their date of issuance. The fair value of these options (as determined by the Black-Scholes option pricing model) was \$3,360 and the Company amortized \$94 to compensation expense during the six-month period ended June 30, 2006 with respect to these options. Assumptions relating to the estimated fair value of these stock options, which the Company accounted for in accordance with SFAS 123(R) and EITF 96-18 are as follows: risk-free interest rate of 5.1%; expected dividend yield zero percent; expected option life of 10 years; and current volatility of 220.3%.

The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. The Company has not paid dividends to date and does not expect to pay dividends in the foreseeable future due to its substantial accumulated deficit and limited capital resources. Accordingly, expected dividends yields are zero. Historical cancellations and forfeitures of stock options are insignificant. The Company will adjust its assumptions relating to its expectations of future vesting and terms of options at such times that

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additional data indicates that changes in these assumptions are necessary. Expected volatility is principally based on the historical volatility of the Company's stock.

A summary of option activity for the six months ended June 30, 2006 is as follows:

Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2006	646,695	\$ 3.08		
Granted	3,082,666	\$ 0.18		
Exercised	1,333,332	\$ 0.15		
Forfeited or expired	425,000	\$ 2.45		
Outstanding at June 30, 2006	1,971,029	\$ 0.66	4.6 years	\$ 66,667
Exercisable at June 30, 2006	1,864,883	\$ 0.54	4.4 years	\$ 66,667

The weighted-average grant-date fair value of options granted during the six-month period ended June 30, 2006 and 2005 amounted to \$0.25 and \$4.67, respectively.

As of June 30, 2006, the Company has \$332,052 of unrecognized compensation cost related to non-vested share-based compensation arrangements, which represents the fair value of stock options that the Company accounted for under APB 25 through December 31, 2005. These costs are expected to be recognized over a weighted-average period of 3.3 years.

## NOTE 11 – ADOPTION OF SHAREHOLDER RIGHTS PLAN

At its February 2006 board meeting, the directors of the Company unanimously approved the adoption of a shareholder rights plan pursuant to which the Company issued one preferred share purchase right for each share of the Company's common stock held by shareholders of record as of the close of business on March 7, 2006. Each right will entitle the holder to purchase one one-hundredth of a share of Series B Preferred Stock at an exercise price of \$168. These preferred shares are structured so that the value of one one-hundredth of a preferred share will approximate the value of one share of the Company's common stock. The purpose of the plan is to protect the long-term value of the Company for its shareholders and to protect shareholders from various abusive takeover tactics, including attempts to acquire control of the Company at an inadequate price. The plan is designed to give the Company's Board of Directors sufficient time to study and respond to an unsolicited takeover attempt. Adoption of the plan was unanimously approved by the Company's directors

The terms of the plan provide for the Company's shareholders of record at the close of business on March 7, 2006 to receive one right for each outstanding common share held. In general, the rights will become exercisable if a person or group acquires 15% or more of the Company's common stock or announces a tender offer or exchange offer for 15% or more of the Company's common stock. Depending on the circumstances, the effect of the exercise of rights will vary. When the rights initially become exercisable, as described above, each holder of a right will be allowed to purchase one one-hundredth of a share of a newly created series of the Company's preferred shares at an exercise price of \$168. However, if a person acquires 15% or more of the Company's common stock in a transaction that was not approved by the Board of Directors, each right would instead entitle the holder (other than such an acquiring person)



to purchase common stock at 50% of the market price of the Company's common stock at that time.

The rights will expire on March 6, 2016. The Company may redeem the rights for \$0.0001 each at any time until the tenth business day following public announcement that a person or group has acquired 15% or more of its outstanding common stock.

#### NOTE 12 – ADOPTION OF 2006 INCENTIVE STOCK PLAN

The 2006 Incentive Stock Plan was approved by the Company's Board of Directors at its February 2006 meeting. The Company intends to submit the 2006 Incentive Stock Plan for approval of its stockholders within 12 months of the effective date of the Plan. The purpose of the 2006 Incentive Stock Plan is to

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provide an incentive to retain in the employ of and as directors, officers, consultants, advisors and employees of the Company, persons of training, experience and ability, to attract new directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage the sense of proprietorship and to stimulate the active interest of such persons into the development and financial success of the Company. Under the 2006 Incentive Stock Plan, the Company is authorized to issue incentive stock options intended to qualify under Section 422 of the Code, non-qualified stock options, and restricted stock. The 2006 Incentive Stock Plan is administered by the Board of Directors or the Compensation Committee. The Company reserved 2,730,090 shares of common stock for issuance under the 2006 Incentive Stock Plan. Options to acquire 776,230 shares of common stock at \$0.15 per share were issued to two financial consultants upon initiation of the 2006 6% Convertible Note offering pursuant to anti-dilution provisions contained in the initial grant of options to these two consultants (see Note 10).

#### NOTE 13 – SUBSEQUENT EVENTS

##### Offering of 2006 6% Convertible Notes

On July 18, 2006, the Company sold an aggregate principal amount of \$950,000 of 2006 6% Convertible Notes and issued five-year warrants to purchase an aggregate of 4,833,333 shares of common stock at an initial exercise price of \$0.30 per share. Pursuant to the terms of the 2006 6% Convertible Notes, the Company will issue 1,410,000 additional shares of common stock to those purchasers who had previously purchased Preferred Stock and adjust the exercise price on the warrants they received when they purchased the Preferred Stock to purchase 45,000 shares of common stock to \$0.30.

##### Unsecured Advances

Subsequent to June 30, 2006, the Company received in the aggregate, \$335,000 in unsecured advances. These advances carry an interest rate of 6% and will be repaid out of the next closing under the 2006 6% Convertible Note offering.

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Item 2. Management's Discussion and Analysis or Plan of Operation.

The following discussion of our plan of operations should be read in conjunction with our financial statements and notes thereto appearing elsewhere in this document.

### Overview

We are a development-stage biopharmaceutical company focusing on the development of proprietary, cell-targeted therapeutic products for the treatment of neuromuscular and neurodegenerative diseases. Our goal is to increase the quality and quantity of life of people suffering with these diseases. Primary efforts are currently being focused on moving our lead product into phase I clinical trials for Duchenne muscular dystrophy. Even though our broad platform technology may include the development of products for multiple sclerosis, amyotrophic lateral sclerosis and chronic inflammatory demyelinating polyneuropathy, from time to time we may explore the development of other technologies.

### Capital Resources and Cash Requirements

We have had difficulty in securing the necessary capital to fully execute our business plan and have not been able to remain current with respect to the payment terms of all of our operating obligations. In addition, we have substantial convertible debt obligations with terms that require repayment during the next twelve months. During the six months ended June 30, 2006, we received (i) proceeds from exercises of stock options of \$200,000, (ii) \$1,625,000 from the issuance of 2006 6% Convertible Notes (see Note 8), and (iii) unsecured advances of \$251,000. Subsequent to June 30, 2006, we received (i) \$950,000 from the issuance of 2006 6% Convertible Notes (which includes the rollover of the unsecured advances of \$250,000 received prior to June 30, 2006), and (ii) unsecured advances of \$335,000 (see Note 13).

We are continuing to seek additional capital, collaborative partners, joint ventures and strategic alliance agreements both within the United States and abroad in an effort to continue the development of our proposed products; however, there are currently no firm commitments in place for new capital nor for any prospective joint venture partners or participants with which we would enter into a strategic alliance arrangement providing additional capital. Absent additional funding from private or public equity or debt financings, collaborative or other partnering arrangements, or other sources, we will be unable to conduct our product development efforts as planned, and may need to curtail our development plans, cease operations or sell assets. These matters raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Primarily as the result of recording non-cash interest expense of \$5,170,999, offset by the reduction in the fair values of derivative financial instruments of \$2,326,585, we recorded a net loss for the six-month period ended June 30, 2006 of \$5,381,198. Non-cash interest expense consisted primarily of the excess fair values of derivative securities included in our financing transactions and amortization of deferred financing costs of those financing transactions. We used net cash flows in operating activities of \$2,151,482 during the six-month period ended June 30, 2006. Our working capital deficiency amounted to \$6,499,238 and our development stage accumulated deficit amounted to \$43,297,293 at June 30, 2006. We expect to continue incurring losses for the foreseeable future due to the inherent uncertainty that is related to establishing the commercial feasibility of pharmaceutical products. We will require substantial additional funding to support the development of our proposed products and fund our operations while we continue our efforts to execute our business plan.

At June 30, 2006, we had \$4,274,736 in principal of convertible notes outstanding before discounts. The December 2004 Convertible Note in the principal amount of \$448,736, was due July 3, 2006. There has not been an agreement

on amended terms and no assurance that we will reach agreement with the note holder on amended terms. The terms of the 2004 Convertible Note do not provide for penalties or other payments upon default, and accordingly, we have not accrued a penalty as of June 30, 2006. Of the remaining debt, (i) \$251,000 was repaid from proceeds of a closing under the 2006 6% Convertible Note offering subsequent to June 30, 2006, (ii) \$250,000 in principal plus accrued interest is due before December 31, 2006, (iii) \$1,625,000 in principal representing 2006 6% Convertible Notes mature in

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June 2007 and (iv) the balance of \$1,700,000 mature in December 2008. Currently, we do not have the available cash to repay these obligations as they come due and if the note holders do not elect to convert their notes at maturity, we will be required to raise additional capital in order to meet these obligations. The note holders holding \$1,700,000 in principal have a security interest in all of our assets.

If we are able to secure suitable financing to continue the development of our technologies, we may incur significant expenditures as we initiate human clinical trials for Myodur and for the cost to manufacture our Myodur product for use in additional clinical and other testing. For the foreseeable future, our primary efforts will be on moving our lead product, Myodur, into clinical trials for Duchenne muscular dystrophy as we presently expect to initiate a phase I human clinical trial for Myodur during the first quarter of 2007. From time to time, we may explore the development of other technologies. If we decide to develop one or more other technologies, we may require substantial additional financing which we may or may not be able to obtain. If we cannot obtain additional financing, we may have to forego the development of the other technologies or may decide to halt or delay development of Myodur in favor of the other technologies. As resources allow, we may also fund other working capital needs.

We do not have, and do not intend to establish, our own manufacturing facilities to produce our product candidates in the foreseeable future. We have outsourced the manufacturing of our proposed products to contract manufacturers. As of June 30, 2006, we had sufficient materials required for the initial human clinical trials. Further, if we receive regulatory approval for any of our products in the United States or elsewhere, we will incur substantial expenditures to develop manufacturing, sales, and marketing capabilities and/or to subcontract or joint venture these activities with others. There can be no assurance that we will ever recognize revenue or profit from any such products. In addition, we may encounter unanticipated problems, including developmental, regulatory, manufacturing, or marketing difficulties, some of which may be beyond our ability to resolve. We may lack the capacity to produce our products in-house and there can be no assurances that we will be able to locate or retain suitable contract manufacturers or be able to have them produce products at satisfactory prices.

## Research, Development and Manufacturing

Currently, our primary efforts are raising capital and moving our lead product into phase I clinical trials for Duchenne muscular dystrophy. During the three- and six-month periods ended June 30, 2006 we have been focusing our efforts on responding to the FDA questions received after submission of our investigational drug application in January 2006. Subsequent to June 30, 2006, we have continued this response preparation and currently anticipate submitting our response to the FDA before the end of the third quarter of 2006.

If we are successful in raising capital, we plan to use any available cash to continue the development of our technologies, which currently is primarily focused on preparing for and executing our phase I human clinical trial for Myodur, if approved by the FDA. As resources permit, we may also fund other development of Myodur or any of our

other technologies. We presently expect to initiate human clinical trials in early 2007.

We currently rely on third party contract research organizations, service providers, and suppliers for support in research and development and pre-clinical, toxicology and clinical testing. In addition, we do not have, and do not intend to establish, our own manufacturing facilities to produce our product candidates in the near or mid-term. We outsource the manufacturing of our proposed product, Myodur, to contract manufacturers. As of June 30, 2006, we had sufficient materials required for our initial human clinical trials. We do not have sufficient capital to purchase all the materials necessary to complete our long-term toxicology studies or to complete all of our human clinical trials in order to file for approval to market our proposed product, Myodur.

#### Off Balance Sheet Arrangements

Currently, we do not have any off balance sheet arrangements which would require disclosure in our financial statements.

#### Employees

As of September 1, 2006, we had seven employees, all of whom are full-time employees, one of whom focuses on and coordinates our research program, four that focus on and coordinate clinical and

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regulatory strategy and operations, and two in management, finance, and administration. Three of our employees have doctorate and/or M.D. degrees. As our current business strategy is primarily to coordinate research, clinical development, and manufacturing activities by third parties, we do not anticipate hiring a significant number of additional employees over the next twelve months.

#### Properties

We currently lease our executive offices in Hunt Valley, Maryland consisting of approximately 5,200 square feet for approximately \$7,200 per month. This lease expires on December 31, 2006 and we are currently negotiating a twelve-month extension. We believe this should provide sufficient space for our clinical, regulatory and other administrative functions during the remaining term of the lease. We are currently evaluating our needs for laboratory space. If financing is available, we may secure laboratory facilities for our own internal research activities. We are currently conducting research in various third party commercial and academic settings, and we plan to continue this practice and expand our use of third-party research organizations and facilities to meet specific needs.

#### CAUTIONARY STATEMENTS AND RISK FACTORS

The risks noted below and elsewhere in this report and in other documents e file with the SEC are risks and uncertainties that could cause our actual results to differ materially from the results contemplated by the forward-looking statements contained in this report and other public statements we make.

#### Risks Related to Our Company

IF WE CANNOT OBTAIN ADDITIONAL FUNDS WHEN NEEDED, OR ACHIEVE PROFITABILITY WE MAY NOT BE ABLE TO CONTINUE AS A GOING CONCERN.

Absent additional funding from private or public equity or debt financings, collaborative or other partnering arrangements, or other sources, we will be unable to conduct our product development efforts as planned, and we may need to curtail our development plans, cease operations or sell assets.

WE HAVE A LIMITED OPERATING HISTORY WITH SIGNIFICANT LOSSES AND EXPECT LOSSES TO CONTINUE FOR THE FORESEEABLE FUTURE.

We have yet to establish any history of profitable operations. At June 30, 2006, we had an accumulated deficit of \$43,297,293. Our revenues have not been sufficient to sustain our operations. We expect that our revenues will not be sufficient to sustain our operations for the foreseeable future. Our profitability will require the successful commercialization of our proposed products. No assurances can be given when, or if, this will occur or that we will ever be profitable.

Our ability to obtain additional funding will determine our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

EVEN WITH THE PROCEEDS FROM THE 2006 6% CONVERTIBLE NOTES, WE WILL REQUIRE ADDITIONAL FUNDING WHICH WILL BE SIGNIFICANT AND WE MAY HAVE DIFFICULTY RAISING NEEDED CAPITAL IN THE FUTURE BECAUSE OF OUR LIMITED OPERATING HISTORY AND BUSINESS RISKS ASSOCIATED WITH OUR COMPANY.

We currently do not generate any revenue from our proposed products and revenue from grants and collaborative agreements may not be sufficient to meet our future capital requirements. We do not know when, or if, this will change.

We have expended substantial funds in research, development and contract manufacturing and will continue to expend substantial funds in contract manufacturing, research, development and pre-clinical testing and clinical trials of our drug delivery technology and compounds. We will require substantial additional funds to conduct research and development, establish and conduct clinical and pre-clinical trials, obtain required regulatory approvals and clearances, establish clinical and, if our products are subsequently considered candidates for FDA approval, commercial scale manufacturing arrangements,

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and provide for the marketing and distribution of our products. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable or are not available on terms deemed acceptable by management, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs or product or marketing efforts which may materially harm our business, financial condition, and results of operations. Our long term capital requirements are expected to depend on many factors, including:

- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;

- progress with pre-clinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drugs;
- costs involved in establishing manufacturing capabilities for clinical trial and commercial quantities of our drugs;
- competing technological and market developments;
- market acceptance of our products;
- costs for recruiting and retaining management, employees, and consultants; and
- costs for training physicians.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through the exercise of warrants, equity, or debt financings, collaborative arrangements with corporate partners, or other sources. Any such equity financing may be dilutive to existing stockholders and debt financing, if available, may involve restrictive covenants that would limit how we conduct our business or finance our operations, or otherwise have a material effect on our current or future business prospects. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves. If adequate funds are not available, we may be required to significantly reduce, refocus, or delay our development efforts with regard to our drug delivery technology, compounds, and drugs.

**OUR FINANCIAL CONDITION AND THE RESTRICTIVE COVENANTS CONTAINED IN OUR OUTSTANDING DEBT MAY LIMIT OUR ABILITY TO BORROW ADDITIONAL FUNDS OR TO RAISE ADDITIONAL EQUITY AS MAY BE REQUIRED TO FUND OUR FUTURE OPERATIONS.**

The terms of our outstanding notes may limit our ability, without the note holders' consent, to, among other things:

- enter into certain transactions;
- create additional liens on our assets;
- issue preferred stock or common stock at certain discounts below market prices; or
- merge or consolidate with other entities and could adversely affect our liquidity and our ability to attract additional funding as required.

**WE MAY NOT BE ABLE TO PAY OUR DEBT AND OTHER OBLIGATIONS AND OUR ASSETS MAY BE SEIZED AS A RESULT.**

At June 30, 2006, we had \$4,274,736 in principal of convertible notes outstanding before discounts. The December 2004 Convertible Note in the principal amount of \$448,736, was due July 3, 2006. There has not been an agreement on amended terms and no assurance that we will reach agreement with the note holder

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on amended terms. The terms of the 2004 Convertible Note do not provide for penalties or other payments upon default, and accordingly, we have not accrued a penalty as of June 30, 2006. Of the remaining debt, (i) \$251,000 was repaid from proceeds of a closing under the 2006 6% Convertible Note offering subsequent to June 30, 2006, (ii) \$250,000 in principal plus accrued interest is due before December 31, 2006, (iii) \$1,625,000 in principal representing

2006 6% Convertible Notes, mature in June 2007 and (iv) the balance of \$1,700,000 mature in December 2008. Currently, we do not have the available cash to repay these obligations as they come due and if the note holders do not elect to convert their notes at maturity, we will be required to raise additional capital in order to meet these obligations, which we may not be able to do. If we raise additional funds to repay the notes by selling equity securities, the relative equity ownership of our existing investors could be diluted and new investors could obtain terms more favorable than previous investors.

The note holders holding \$1,700,000 in principal have a security interest in all of our assets.

**OUR OBLIGATIONS UNDER THE 2005 CONVERTIBLE DEBENTURES ARE SECURED BY ALL OF OUR ASSETS.**

Our obligations under the 2005 Convertible Debentures are secured by all of our assets. As a result, if we default under the terms of the 2005 Convertible Debentures or related agreements, including our failure to issue shares of common stock upon conversion by the debenture holder, our failure to timely file a registration statement or have such registration statement declared effective, our breach of any covenant, representation or warranty in the Securities Purchase Agreement or 2005 Convertible Debentures or the commencement of a bankruptcy, insolvency, reorganization or liquidation proceeding against us could require the early repayment of the 2005 Convertible Debentures, if the default is not cured within the specified grace period. In addition, the debenture holders could foreclose their security interest and liquidate some or all of our assets and we could cease to operate. Any such issuance of shares upon conversion could cause a significant drop in the price of our stock and significant dilution to our stockholders.

**THE FAILURE TO COMPLETE DEVELOPMENT OF OUR TECHNOLOGY, OBTAIN GOVERNMENT APPROVALS, INCLUDING REQUIRED FDA APPROVALS, OR TO COMPLY WITH ONGOING GOVERNMENTAL REGULATIONS COULD DELAY OR LIMIT INTRODUCTION OF PROPOSED PRODUCTS AND RESULT IN FAILURE TO ACHIEVE REVENUES OR MAINTAIN OUR ONGOING BUSINESS.**

Our research and development activities and the manufacture and marketing of our intended products are subject to extensive regulation for safety, efficacy, and quality by numerous government authorities in the United States and abroad. Before receiving FDA clearance to market our proposed products, we will have to demonstrate that our products are safe and effective on the patient population and for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act ("FDCA") and other federal, state, and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution, and promotion of drugs and medical devices. As a result, clinical trials and regulatory approval can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial, and other resources.

In order to be commercially viable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market, and distribute our technologies. For each drug utilized with our drug delivery technology, and for Myodur and Neurodur, we must successfully meet a number of critical developmental milestones, including:

- demonstrate benefit from delivery of each specific drug through our drug delivery technology;
- demonstrate through pre-clinical and clinical trials that our drug delivery technology and patient specific therapy is safe and effective;
- establish a viable Good Manufacturing Process capable of potential scale-up.

The time frame necessary to achieve these developmental milestones may be long and uncertain, and we may not successfully complete these milestones for any of our intended products in development.

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In addition to the risks previously discussed, our technology is subject to additional developmental risks which include the following:

- the uncertainties arising from the rapidly growing scientific aspects of drug delivery, therapies, and potential treatments;
- uncertainties arising as a result of the broad array of potential treatments related to nerve and muscle injury and disease; and
- anticipated expense and time believed to be associated with the development and regulatory approval of treatments for nerve and muscle injury and disease.

In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a product it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because our clinical investigators do not follow the FDA's requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are halted by the FDA, we would not be able to achieve any revenue from such product, as it is illegal to sell any drug or medical device in the United States for human consumption without FDA approval, and many foreign countries are influenced in granting their own required approvals by the FDA.

**DATA OBTAINED FROM CLINICAL TRIALS IS SUSCEPTIBLE TO VARYING INTERPRETATIONS, WHICH COULD DELAY, LIMIT OR PREVENT REGULATORY CLEARANCES.**

Data already obtained, or in the future obtained, from pre-clinical studies and clinical trials (as of the date of this Report no clinical trials of our technology have been undertaken) do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical and clinical data is susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of a potential drug, resulting in delays to commercialization, and could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing. Even after approval, further studies could result in withdrawal of FDA and other regulatory approvals and voluntary or involuntary withdrawal of products from the market.

We may encounter delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of development, clinical trials and FDA regulatory review. We may encounter similar delays in foreign countries. Sales of our products outside the U.S. would be subject to foreign regulatory approvals that vary from country to country. The time required to obtain approvals from foreign countries may be shorter or longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. We may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis, or they may not cover the uses that we request.

In the future, we may select drugs for “molecular binding” using our drug delivery technology which may contain controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture,



use, sale, importation and distribution. For such drugs containing controlled substances, we and any suppliers, manufacturers, contractors, customers and distributors may be required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation and distribution of controlled substances. These regulations are extensive and include regulations governing manufacturing, labeling, packaging, testing, dispensing, prescription, and procurement quotas, record keeping, reporting, handling, shipment, and disposal. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our drugs containing controlled substances and

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subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of drugs containing controlled substances.

**OUR DRUGS OR TECHNOLOGY MAY NOT GAIN FDA APPROVAL IN CLINICAL TRIALS OR BE EFFECTIVE AS A THERAPEUTIC AGENT WHICH COULD AFFECT OUR FUTURE PROFITABILITY AND PROSPECTS.**

In order to obtain regulatory approvals, we must demonstrate that the procedure is safe and effective for use in humans and functions as a therapeutic against the effects of injury or disease. To date, we have not conducted any human pilot study pursuant to Institutional Review Board oversight in anticipation of our initial FDA submission for patient-specific or other therapy. Further, we have conducted only sporadic and limited animal studies to observe the effects of our drugs and have not subjected our drugs or technologies to all of the rigorous testing standards that would be acceptable for publication in scientific peer review journals.

We may not be able to demonstrate that any potential drug or technology, including Myodur or Neurodur, although appearing promising in pre-clinical and animal observations, is safe or effective in advanced clinical trials that involve human patients. We are also not able to assure that the results of the tests already conducted and which we intend to repeat will be consistent with our prior observations or support our applications for regulatory approval. As a result, our drug and technology research program may be curtailed, redirected or eliminated at any time.

The diseases and illnesses to which our drugs and technologies are directed are very complex and may be prone to genetic mutations. These mutations may prove resistant to currently approved therapeutics or our drugs or technologies. Even if we gain regulatory approval there may develop resistance to our treatment. This could have a material adverse effect on our business, financial condition, and results of operations.

**WE HAVE ACCUMULATED DEFICITS IN THE RESEARCH AND DEVELOPMENT OF OUR TECHNOLOGY AND THERE IS NO GUARANTEE THAT WE WILL EVER GENERATE REVENUE OR BECOME PROFITABLE EVEN IF ONE OR MORE OF OUR DRUGS ARE APPROVED FOR COMMERCIALIZATION.**

Since our inception in 1986, we have incurred operating losses. As of June 30, 2006, our accumulated deficit amounted to \$43,297,293. In addition, we expect to continue incurring operating losses for the foreseeable future as we continue to develop our products which will cause us to incur substantial research and development and clinical trials costs. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market, and sell our proposed products. Development, including the cost of contract manufacturing of our proposed

products for pre-clinical testing and human clinical trials is extremely costly and requires significant investment. In the absence of additional financing we may not be able to continue our development activities. In addition, we may choose to license the rights to particular drugs or other technology. License fees may increase our costs.

We have not generated any revenue from the commercial sale of our proposed products or any drugs and do not expect to receive such revenue in the near future. Our primary activity to date has been research and development of our technology. All revenues to date are from grants, both public and private, and collaborative agreements. We cannot be certain as to when or whether to anticipate commercializing and marketing our proposed products in development, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the foreseeable future.

**WE HAVE RELIED SOLELY ON THIRD-PARTY RESEARCH INSTITUTIONS FOR ALL OF OUR RESEARCH AND DEVELOPMENT, WHICH COULD BE MATERIALLY DELAYED SHOULD WE LOSE ACCESS TO THOSE FACILITIES.**

We currently have no research and development facilities of our own. We are entirely dependent on third parties to use their facilities to conduct research and development. To date, we have primarily relied on third-party research institutions for this purpose including the Health Science Center at Downstate Medical Center and Stony Brook University. Our inability to have continued access to these facilities to

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conduct research and development may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technology and products.

We currently maintain a good working relationship with our third-party research institutions. Although we are evaluating various facilities in which to establish our laboratories, should we be required to relocate on short notice, we do not currently have an alternate facility where we could relocate our research activities. The cost and time to establish or locate an alternative research and development facility to develop our technology will be substantial and may delay gaining FDA approval and commercializing our products.

**WE ARE DEPENDENT ON OUR COLLABORATIVE AGREEMENTS FOR THE DEVELOPMENT OF OUR TECHNOLOGIES AND BUSINESS DEVELOPMENT WHICH EXPOSES US TO THE RISK OF RELIANCE ON THE VIABILITY OF THIRD PARTIES.**

In conducting our research and development activities, we rely and expect in the future to rely upon numerous collaborative agreements with universities, governmental agencies, charitable foundations, manufacturers, contract research organizations, and corporate partners. The loss of or failure to perform under any of these arrangements, by any of these entities, may substantially disrupt or delay our research and development activities including our anticipated clinical trials.

**WE ARE EXPOSED TO PRODUCT LIABILITY, CLINICAL AND PRE-CLINICAL LIABILITY RISKS WHICH COULD PLACE A SUBSTANTIAL FINANCIAL BURDEN UPON US SHOULD WE BE SUED, BECAUSE WE DO NOT CURRENTLY HAVE PRODUCT LIABILITY INSURANCE ABOVE AND BEYOND OUR GENERAL INSURANCE COVERAGE.**

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We cannot assure that such potential claims will not be asserted against us. In addition, the use in our clinical trials of pharmaceutical products that we may develop and the subsequent sale of these products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition, and results of operations.

All of our pre-clinical trials have been and all of our proposed clinical and pre-clinical trials are anticipated to be conducted by collaborators and third party contractors. We do not currently have any product liability insurance or other liability insurance relating to clinical trials or any products or compounds. We intend to seek insurance against such risks before we initiate clinical trials or before our product sales are commenced. We cannot assure that we will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against our potential liabilities. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our drug delivery technology. A product liability claim could also significantly harm our reputation and delay market acceptance of our intended products. Furthermore, our current and potential partners with whom we have collaborative agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have a net worth sufficient to satisfy any product liability claims. Product liability claims or other claims related to our intended products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. Claims or losses in excess of any product liability insurance coverage that may be obtained by us could have a material adverse effect on our business, financial condition, and results of operations.

**OUR LIMITED OPERATING HISTORY MAKES EVALUATING OUR BUSINESS MORE DIFFICULT, AND THEREFORE, INVESTORS HAVE LIMITED INFORMATION UPON WHICH TO RELY.**

An investor can only evaluate our business based on a limited operating history. While we were organized in 1986, our current level of activity and operations only recently began following our acquisition by

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Xechem and subsequent closing on our financing during the period December 2004 through February 2005. Our operations will continue to change and our costs will increase dramatically as we evolve from primarily a technology holding company to a capitalized company with employees and internal operations. Since inception, we have engaged primarily in research and development, relied to a great extent on third-party efforts, sought avenues for licensing technology, sought grants, raised capital, and recruited scientific and management personnel external to us. We have not generated any meaningful revenue to date, and have no royalty revenue or products ready for use and in the marketplace. This limited history may not be adequate to enable an investor to fully assess our ability to develop our technologies and proposed products, obtain FDA approval, and achieve market acceptance of our proposed products, and respond to competition, or conduct such affairs as are presently contemplated.

**FUTURE SALES OF OUR COMMON STOCK RECEIVED UPON CONVERSION BY OUR NOTE HOLDERS MAY ADVERSELY AFFECT OUR STOCK PRICE AND OUR ABILITY TO RAISE FUNDS IN NEW STOCK OFFERINGS.**

The sale of shares issued upon conversion of our convertible notes by the note holders will have a dilutive impact on our stockholders. Currently, all convertible debt is convertible into common stock at \$0.15 per share. Substantially all of this debt has anti-dilution provisions that in the event we issue shares of common stock at less than \$0.15 per share, the conversion price will adjust to the lower price. Therefore, the number of shares issuable to the note holders upon conversion may be substantially greater. The note holders may sell such shares in the market immediately, which could cause our stock price to decline. In addition, the interest on the convertible notes may be payable, at the option of the note holder, in shares of our common stock in lieu of cash, which could have a further dilutive impact on our stockholders and could cause our stock price to decline.

**ACCEPTANCE OF OUR PRODUCTS IN THE MARKETPLACE IS UNCERTAIN AND FAILURE TO ACHIEVE MARKET ACCEPTANCE WILL PREVENT OR DELAY OUR ABILITY TO GENERATE REVENUES.**

Our future financial performance will depend, in part, upon the introduction and customer acceptance of our proposed products. Even if approved for marketing by the necessary regulatory authorities, our products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration of the advantages, safety and efficacy of our technologies;
- pricing and reimbursement policies of government and third party payors such as insurance companies, health maintenance organizations and other health plan administrators;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our intended products; and
- our ability to market our products.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize, or recommend any of our products. If we are unable to obtain regulatory approval, commercialize, and market our proposed products when planned, we may not achieve any market acceptance or generate revenue.

**WE MAY FACE LITIGATION FROM THIRD PARTIES THAT CLAIM OUR PRODUCTS INFRINGE ON THEIR INTELLECTUAL PROPERTY RIGHTS, PARTICULARLY BECAUSE THERE IS SUBSTANTIAL UNCERTAINTY ABOUT THE VALIDITY AND BREADTH OF MEDICAL PATENTS.**

We may be exposed to future litigation by third parties based on claims that our technologies, products, or activities infringe the intellectual property rights of others or that we have the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us, whether or not

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valid, could result in substantial costs, could place a significant strain on our financial and managerial resources, and could harm our reputation. Most of our license agreements would likely require that we pay the costs associated with defending this type of litigation. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling, incorporating or using any of our technologies and/or products that incorporate the challenged intellectual property, which would adversely affect our future revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our products, which would be costly and time consuming.

We have not engaged in discussions, received any communications, nor do we have any reason to believe that any third party is challenging or has the proper legal authority to challenge our intellectual property rights or those of the actual patent holders, other than a letter received during August 2004 from counsel to a company named Ceptyr Corporation alleging infringement of trademarks issued to Ceptyr with respect to our name CepTor. In light of our formation and use of the name CepTor in commerce many years prior to the formation of Ceptyr and issuance of their trademark, we believe the demand to cease and desist from future infringement to be substantially without merit. No further communication has been received since mid-2004.

**IF WE ARE UNABLE TO ADEQUATELY PROTECT OR ENFORCE OUR RIGHTS TO INTELLECTUAL PROPERTY OR SECURE RIGHTS TO THIRD PARTY PATENTS, WE MAY LOSE VALUABLE RIGHTS, EXPERIENCE REDUCED MARKET SHARE, ASSUMING ANY, OR INCUR COSTLY LITIGATION TO PROTECT SUCH RIGHTS.**

Our ability to obtain licenses to third-party patents, maintain trade secret protection, and operate without infringing the proprietary rights of others will be important to our commercialization of any products under development. Therefore, any disruption in access to the technology could substantially delay the development of our technology.

The patent positions of biotechnology and pharmaceutical companies, including ours, which also involve licensing agreements, are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications and any issued and licensed patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. Our competitors may also independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent patents issued or licensed to us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

We also rely upon trade secrets, technical know how, and continuing technological innovation to develop and maintain our competitive position. We generally require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment of inventions agreements. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached and we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know how, and other non patented technology.

Although our trade secrets and technical know how are important, our continued access to the patents is a significant factor in the development and commercialization of our drug delivery technology. Aside from the general body of scientific knowledge from other drug delivery processes and technology, we believe these patents, based upon our current scientific data, are the only intellectual property necessary to develop our short-term plans for our current drug delivery system using our proposed Myodur, Neurodur

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and other drugs. We do not believe that we are or will be violating any other patents in developing our technology although we anticipate seeking a license from Sigma-Tau in order to employ a manufacturing method useful for large scale manufacturing of Myodur.

We may have to resort to litigation to protect our rights for certain intellectual property, or to determine their scope, validity, or enforceability. Enforcing or defending our rights is expensive, could cause diversion of our resources, and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

We currently depend and will continue to depend heavily on third parties for support in research and development and clinical and pre-clinical testing. Under certain circumstances, others may acquire certain rights in newly developed intellectual property developed in conjunction with us.

Research and development and clinical trials involve a complex process, and these third parties' facilities may not be sufficient. Inadequate facilities could delay clinical trials of our drugs and result in delays in regulatory approval and commercialization of our drugs, either of which would materially harm our business. We may, if adequate funding is obtained, decide to establish an independent facility to replace or supplement those facilities. To date, we have not identified the location, negotiated leases or equipment purchases, and, accordingly, we are subject to various uncertainties and risks that may be associated with the potential establishment of a new facility.

We may rely on third party contract research organizations, service providers, and suppliers to support development and clinical testing of our products. Failure of any of these contractors to provide the required services in a timely manner or on reasonable commercial terms could materially delay the development and approval of our products, increase our expenses, and materially harm our business, financial condition, and results of operations.

**KEY COMPONENTS OF OUR TECHNOLOGIES MAY BE PROVIDED BY SOLE OR LIMITED NUMBERS OF SUPPLIERS, AND SUPPLY SHORTAGES OR LOSS OF THESE SUPPLIERS COULD RESULT IN INTERRUPTIONS IN SUPPLY OR INCREASED COSTS.**

Certain components used in our research and development activities such as leupeptin, carnitine and taurine compounds, are currently purchased or manufactured for us from a single or a limited number of outside sources. The reliance on a sole or limited number of suppliers could result in:

- potential delays associated with research and development and clinical and pre-clinical trials due to an inability to timely obtain a single or limited source component;
- potential inability to timely obtain an adequate supply of required components; and
- potential of reduced control over pricing, quality, and timely delivery.

We do not have long-term agreements with any of our suppliers, and therefore the supply of a particular component could be terminated without penalty to the supplier. Any interruption in the supply of components could cause us to seek alternative sources of supply or manufacture these components internally. If the supply of any components is interrupted, components from alternative suppliers may not be available in sufficient volumes within required timeframes, if at all, to meet our needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing, or cause us to lose sales, incur additional costs, delay new product introductions, or harm our reputation. Further, components from a new supplier may not be identical to those provided by the original supplier. Such differences if they exist could affect product formulations or the safety and effect of our products that are being developed and delay regulatory approvals.

WE HAVE LIMITED MANUFACTURING EXPERIENCE AND ONCE OUR PRODUCTS ARE APPROVED, IF AT ALL, WE MAY NOT BE ABLE TO MANUFACTURE SUFFICIENT QUANTITIES AT AN ACCEPTABLE COST.

Our products remain in the research and development and pre-clinical trial phase of commercialization. Once our products are approved for commercial sale, if at all, we will need to establish the capability to commercially manufacture our products in accordance with FDA and other regulatory requirements. We

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have limited experience in establishing, supervising, and conducting commercial manufacturing. If we fail to adequately establish, supervise, and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products. We do not presently own manufacturing facilities necessary to provide clinical or commercial quantities of our intended products.

We presently plan to rely on third party contractors to manufacture part or all of our products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanic shut downs, employee strikes, or any other unforeseeable acts that may delay production.

DUE TO OUR LIMITED MARKETING, SALES, AND DISTRIBUTION EXPERIENCE, WE MAY BE UNSUCCESSFUL IN OUR EFFORTS TO SELL OUR PRODUCTS, ENTER INTO RELATIONSHIPS WITH THIRD PARTIES, OR DEVELOP A DIRECT SALES ORGANIZATION.

We have yet had to establish any marketing, sales, or distribution capabilities for our proposed products. Until such time as our products are further along in the regulatory process, we will not devote any meaningful time or resources to this effort. At the appropriate time, we intend to enter into agreements with third parties to sell our products or we may develop our own sales and marketing force. We may be unable to establish or maintain third party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors who may exist after our introduction of products, if any.

If we do not enter into relationships with third parties for the sales and marketing of our products, we will need to develop our own sales and marketing capabilities. We have limited experience in developing, training, or managing a sales force. If we choose to establish a direct sales force, we may incur substantial additional expenses in developing, training, and managing such an organization. We may be unable to build a sales force on a cost effective basis or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all, and may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our products;
- cease operations with little or no notice; or
- offer, design, manufacture, or promote competing products.

If we fail to develop sales, marketing, and distribution channels, we would experience delays in product sales and incur increased costs, which would harm our financial results.

IF WE ARE UNABLE TO CONVINCE PHYSICIANS AS TO THE BENEFITS OF OUR INTENDED PRODUCTS, WE MAY INCUR DELAYS OR ADDITIONAL EXPENSE IN OUR ATTEMPT TO ESTABLISH MARKET ACCEPTANCE.

Broad use of our drug delivery technology may require physicians to be informed regarding our intended products and the intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this physician education process may adversely affect market acceptance of our products. We may be unable to timely educate physicians regarding our intended products in sufficient numbers to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our products is created, if at all.

THE MARKET FOR OUR PRODUCTS IS RAPIDLY CHANGING AND COMPETITIVE, AND NEW MECHANISMS, TECHNOLOGIES, NEW THERAPEUTICS, NEW DRUGS, AND NEW TREATMENTS WHICH MAY BE DEVELOPED BY OTHERS COULD IMPAIR OUR ABILITY TO MAINTAIN AND GROW OUR BUSINESS AND REMAIN COMPETITIVE.

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The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and intended products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing, and other resources.

We are a start-up development stage enterprise that prior to early 2005 has operated in all material respects only as a virtual company with no day-to-day business management, operating as a vehicle to hold certain technology for possible future exploration, and have been and will continue to be engaged in the development of novel untested drug delivery and therapeutic technologies. As a result, our resources are limited and we may experience management, operational, or technical challenges inherent in such activities and novel technologies. Other companies, which may become competitors, have developed or are in the process of developing technologies that could now be, or in the future become, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our technology. Our competitors may develop drug delivery technologies and drugs that are safer, more effective, or less costly than our intended products and, therefore, present a serious competitive threat to us. The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our products even if commercialized. Many of our targeted diseases and conditions can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies and products to receive widespread acceptance if commercialized.



WE MAY NOT BE SUCCESSFUL IN OBTAINING ORPHAN DRUG STATUS FOR CERTAIN OF OUR PRODUCTS OR, IF THAT STATUS IS OBTAINED, FULLY ENJOYING THE BENEFITS OF ORPHAN DRUG STATUS.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition generally affecting fewer than 200,000 people in the United States. We may not be successful in receiving orphan drug status for certain of our products. Orphan drug designation must be requested before submitting a NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are publicized by the FDA. Under current law, orphan drug status is conferred upon the first company to receive FDA approval to market the designated drug for the designated indication. Orphan drug status also grants marketing exclusivity in the United States for a period of seven years following approval of the NDA, subject to limitations. Orphan drug designation does not provide any advantage in, or shorten the duration of, the FDA regulatory approval process. Although obtaining FDA approval to market a product with orphan drug status can be advantageous, the scope of protection or the level of marketing exclusivity that is currently afforded by orphan drug status and marketing approval may not remain in effect in the future.

Our business strategy involves obtaining orphan drug designation for certain of the products we have under development. We have been granted orphan drug designation for our proposed product for muscular dystrophy. We do not know whether any of our other products will receive an orphan drug designation. Orphan drug designation does not prevent other manufacturers from attempting to develop similar drugs for the designated indication or from obtaining the approval of an NDA for their drug prior to the approval of our NDA application. If another sponsor's NDA for a competing drug in the same indication is approved first, that sponsor is entitled to exclusive marketing rights if that sponsor has received orphan drug designation for its drug. In that case, the FDA would refrain from approving an application by us to market our competing product for seven years, subject to limitations. Competing products may receive orphan drug designations and FDA marketing approval before the products under development by us may receive orphan drug designation.

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NDA approval for a drug with an orphan drug designation does not prevent the FDA from approving the same drug for a different indication, or a molecular variation of the same drug for the same indication. Because doctors are not restricted by the FDA from prescribing an approved drug for uses not approved by the FDA, it is also possible that another company's drug could be prescribed for indications for which products developed by us have received orphan drug designation and NDA approval. The prescribing of approved drugs for alternative uses, commonly referred to as "off label" sales, could adversely affect the marketing potential of products that have received an orphan drug designation and NDA approval. In addition, NDA approval of a drug with an orphan drug designation does not provide any marketing exclusivity in foreign markets.

The possible amendment of the Orphan Drug Act by the U.S. Congress has been the subject of frequent discussion. Although no significant changes to the Orphan Drug Act have been made for a number of years, members of Congress have from time to time proposed legislation that would limit the application of the Orphan Drug Act. The precise scope of protection that may be afforded by orphan drug designation and marketing approval may be subject to change in the future.

IF USERS OF OUR PRODUCTS ARE UNABLE TO OBTAIN ADEQUATE REIMBURSEMENT FROM THIRD PARTY PAYORS, OR IF NEW RESTRICTIVE LEGISLATION IS ADOPTED, MARKET ACCEPTANCE OF

**OUR PRODUCTS MAY BE LIMITED AND WE MAY NOT ACHIEVE ANTICIPATED REVENUES.**

The continuing efforts of government and insurance companies, health maintenance organizations, and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners, and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals, and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition, and results of operations.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third party payors are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

**OUR BUSINESS INVOLVES ENVIRONMENTAL RISKS RELATED TO HANDLING REGULATED SUBSTANCES THAT COULD SEVERELY AFFECT OUR ABILITY TO CONDUCT RESEARCH AND DEVELOPMENT OF OUR DRUG DELIVERY TECHNOLOGY.**

In connection with our research and development activities and manufacture of materials and drugs, we are subject to federal, states and local laws, rules, regulations, and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling, and disposal of certain materials, biological specimens, and wastes. Although we believe that we have complied with the applicable laws, regulations, and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development may in the future involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and narcotics. Although we believe that our safety procedures for storing, handling, and disposing of such materials will comply with the standards prescribed by state and federal regulations, we cannot completely

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eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

**WE DEPEND UPON KEY PERSONNEL WHO MAY TERMINATE THEIR EMPLOYMENT WITH US AT ANY TIME, AND WE WILL NEED TO HIRE ADDITIONAL QUALIFIED PERSONNEL WHICH MAY BE UNAVAILABLE DUE TO THE NECESSITY OF UNIQUE SKILLS AND RESOURCES.**

Our success will depend to a significant degree upon the continued services of key management, including William H. Pursley (age 52) and Norman W. Barton (age 58). We maintain directors and officers insurance for our directors and

executive officers. Our success will depend on the ability to attract and retain highly skilled personnel. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all. Management and other employees may voluntarily terminate their employment at any time. The loss of the services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. Additionally, failure to attract and retain highly qualified management personnel would damage our business prospects.

#### Risks Related to Our Common Stock

##### INSUFFICIENT AUTHORIZED BUT UNISSUED SHARES OF COMMON STOCK

As of September 1, 2006, we had outstanding 15,500,069 shares of common stock. We are authorized to issue 100,000,000 shares of Common Stock.

We do not have sufficient authorized but unissued shares to reserve shares that we may be required to issue upon conversion of the convertible notes, the Series A Preferred Stock and the warrants and other securities issued or modified in connection with the offering of the 2006 6% Convertible Notes.

On May 9, 2006, the Board of Directors authorized an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of the Company's capital stock from 120,000,000 shares to 270,000,000 shares, of which 250,000,000 shares would be designated as Common Stock and 20,000,000 shares would be designated as Series A Preferred Stock. Unless the proposed amendment is approved by our stockholders, we will not be able to satisfy our obligations in the agreements relating to those securities. If stockholders do not approve the amendment, we will be in default of our obligations under those agreements, and the holders of those securities may accelerate payment of our obligations, obtain liquidated damages under certain of those agreements and pursue other legal remedies against us that could severely limit our ability to continue operations.

Our Board of Directors believes that it is advisable and in the best interests of our company to have available additional authorized but unissued shares of Common Stock in an amount adequate to provide for our present and future needs. The increase in authorized common stock will provide us with a sufficient number of shares to fulfill our obligations under existing contractual commitments under the financing agreements. The issuance of these shares will dilute the equity interests of existing stockholders and may have a negative effect on the market price of our common stock. Additional shares also will be available for issuance from time to time by us in the discretion of the Board of Directors without further stockholder action, except as may be required under applicable law. These shares may be issued for any proper corporate purpose including, without limitation: acquiring other businesses in exchange for shares of common stock; entering into collaborative arrangements with other companies in which common stock or the right to acquire common stock are part of the consideration; facilitation of broader ownership of common stock by effecting a stock split or issuing a stock dividend; raising capital through the sale of common stock or securities convertible into, or exercisable or exchangeable for, shares of common stock; and attracting and retaining valuable employees by the issuance of additional stock options or restricted stock.

The issuance of the additional shares of common stock could have the effect of diluting earnings per share and book value per share, which could adversely affect our existing stockholders. Issuing additional shares

of common stock may also have the effect of delaying or preventing a change of control of our company. Our authorized but unissued common stock could be issued in one or more transactions that would make more difficult or costly, a takeover of our Company.

**WE HAVE RAISED SUBSTANTIAL AMOUNTS OF CAPITAL IN PRIVATE PLACEMENTS FROM TIME TO TIME.**

The securities offered in such private placements were not registered under the Securities Act or any state “blue sky” law in reliance upon exemptions from such registration requirements. Such exemptions are highly technical in nature and if we inadvertently failed to comply with the requirements of any of such exemptive provisions, investors would have the right to rescind their purchase of our securities or sue for damages. If one or more investors were to successfully seek such rescission or prevail in any such suit, we could face severe financial demands that could materially and adversely affect our financial position. Financings that may be available to us under current market conditions frequently involve sales at prices below the prices at which our Common Stock currently is reported on the OTC Bulletin Board or exchange on which our Common Stock may in the future, be listed, as well as the issuance of warrants or convertible securities at a discount to market price.

**INVESTORS IN OUR SECURITIES MAY SUFFER DILUTION.**

The issuance of shares of our common stock, or shares of our common stock underlying warrants, options or preferred stock or convertible debentures or notes will dilute the equity interest of existing stockholders who do not have anti-dilution rights and could have a significant adverse effect on the market price of our common stock. The sale of our common stock acquired at a discount could have a negative impact on the market price of our common stock and could increase the volatility in the market price of our common stock. In addition, we may seek additional financing which may result in the issuance of additional shares of our common stock and/or rights to acquire additional shares of our common stock. The issuance of our common stock in connection with such financing may result in substantial dilution to the existing holders of our common stock who do not have anti-dilution rights. Those additional issuances of our common stock would result in a reduction of an existing holder's percentage interest in our company.

**OUR COMMON STOCK IS THINLY TRADED, SO YOU MAY BE UNABLE TO SELL AT OR NEAR ASK PRICES OR AT ALL IF YOU NEED TO SELL YOUR SHARES TO RAISE MONEY OR OTHERWISE DESIRE TO LIQUIDATE YOUR SHARES.**

Our common stock historically been sporadically or “thinly-traded” on the OTC Bulletin Board, meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. As of August 25, 2006, our average trading volume per day for the past three months was approximately 55,697 shares a day with a high of 668,700 shares traded and a low of no shares traded. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they may tend to be risk-averse and may be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. There can be no assurance that a broader or more active public trading market for our common stock will develop or be sustained, or that current trading levels will be sustained.

**HISTORICALLY, OUR COMMON STOCK HAS EXPERIENCED SIGNIFICANT PRICE FLUCTUATIONS.**

There can be no assurance that the market price for our common stock will remain at its current level and a decrease in the market price could result in substantial losses for investors. The market price of our common stock may be

significantly affected by one or more of the following factors:

- announcements or press releases relating to the bio-pharmaceutical sector or to our own business or prospects;

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- regulatory, legislative, or other developments affecting us or the healthcare industry generally;
- conversion of our preferred stock and convertible debt into common stock at conversion rates based on then current market prices or discounts to market prices of our Common Stock, and exercise of options and warrants at below current market prices;
- sales by those financing our company through convertible securities of the underlying common stock of which have been registered with the SEC and may be sold into the public market immediately upon conversion; and
- market conditions specific to bio-pharmaceutical companies, the healthcare industry and general market conditions.

IN ADDITION, IN RECENT YEARS THE STOCK MARKET HAS EXPERIENCED SIGNIFICANT PRICE AND VOLUME FLUCTUATIONS.

These fluctuations, which are often unrelated to the operating performance of specific companies, have had a substantial effect on the market price for many healthcare and life science related technology companies. Factors such as those cited above, as well as other factors that may be unrelated to our operating performance, may adversely affect the price of our common stock.

WE HAVE NOT HAD EARNINGS, BUT IF EARNINGS WERE AVAILABLE, IT IS OUR GENERAL POLICY TO RETAIN ANY EARNINGS FOR USE IN OUR OPERATIONS.

We do not anticipate paying any cash dividends on our common stock or Series A Preferred Stock in the foreseeable future despite the recent reduction of the federal income tax rate on dividends. Any payment of cash dividends on our common stock or Series A Preferred Stock in the future will be dependent upon our financial condition, results of operations, current and anticipated cash requirements, preferred rights of holders of preferred stock, restrictive covenants in debt or other instruments or agreements, plans for expansion, as well as other factors that our board of directors deems relevant. We anticipate that any future financing agreements may restrict or prohibit the payment of dividends without prior consent.

CERTAIN PROVISIONS OF DELAWARE CORPORATE LAWS AND OTHER PROVISIONS THAT MAY HAVE CERTAIN ANTI-TAKEOVER EFFECTS.

The anti-takeover provisions of the Delaware General Corporation Law (“DGCL”) may have the effect of discouraging a future takeover attempt which individual common stockholders or Series A Preferred stockholders may deem to be in their best interests or in which stockholders may receive a substantial premium for their shares over then-current market prices. We are subject to such anti-takeover provisions which could prohibit or delay a merger or other takeover or change of control and may discourage attempts by other companies to acquire us. Stockholders who might desire to participate in such a transaction may not have an opportunity to do so.

Following the reincorporation merger, which became effective on January 31, 2005, our certificate of incorporation and by-laws were amended and provide additional provisions applicable to a Delaware corporation, including Section

203 of the DGCL “Business Combinations With Interested Stockholders” which, in general, restricts a corporation organized under the laws of Delaware from certain business combinations for a period of three years with an “interested” stockholder (generally, 15% ownership) without approval of the board of directors. In addition, our by-laws contain provisions providing for advance notice of certain stockholder actions, such as the nomination of directors and stockholder proposals.

#### OUR BOARD OF DIRECTORS HAS ADOPTED A STOCKHOLDER RIGHTS PLAN.

Our stockholder rights plan may prevent a change in control or sale of our company in a manner or on terms not previously approved by our board of directors.

A stockholder rights plan, in general, is a right granted as a dividend to existing stockholders as of a record date as a defensive mechanism to prevent unwanted takeovers and are triggered upon the announcement that a party has acquired a specified percentage or more of the outstanding voting stock of a company without approval by the company's board of directors.

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#### THERE MAY BE A LIMITED PUBLIC MARKET FOR OUR SECURITIES; WE MAY FAIL TO QUALIFY FOR LISTING.

Although we intend to apply for listing of our common stock on either the AMEX, NASDAQ or other registered stock exchange, there can be no assurance if and when initial listing criteria could be met or if such application would be granted, or that the trading of our common stock will be sustained. In the event that our common stock fails to qualify for initial or continued listing on a registered stock exchange or for initial or continued inclusion in the NASDAQ system, trading, if any, in our common stock, would then continue to be conducted on the NASD's “Electronic Bulletin Board” in the over-the-counter market and in what are commonly referred to as “pink sheets.” As a result, an investor may find it more difficult to dispose of, or to obtain accurate quotations as to the market value of our common stock, and our common stock would become substantially less attractive for margin loans, for investment by financial institutions, as consideration in future capital raising transactions or other purposes. We do not presently satisfy the listing criteria for the NASDAQ or AMEX markets.

Trading of our common Stock may be subject to penny stock rules under the Exchange Act. Unless exempt, for any transaction involving a penny stock, the regulations require broker-dealers making a market in our common stock to provide risk disclosure to their customers including regarding the risks associated with our common stock, the suitability for the customer of an investment in our common stock, the duties of the broker-dealer to the customer, information regarding prices for our common stock and any compensation the broker-dealer would receive. The application of these rules may result in fewer market makers in our common stock. Our common stock is presently subject to the rules on penny stocks, and the liquidity of the common stock could be materially adversely affected so long as we remain subject to such rule.

#### COMPLIANCE WITH CHANGING REGULATION OF CORPORATE GOVERNANCE AND PUBLIC DISCLOSURE MAY RESULT IN ADDITIONAL EXPENSES.

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and, in the event we are

approved for listing on either NASDAQ or a registered exchange, NASDAQ and stock exchange rules, will require an increased amount of management attention and external resources. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Item 3. Controls and Procedures.

EVALUATION OF OUR DISCLOSURE CONTROLS AND INTERNAL CONTROLS

As of the end of the period covered by this Report, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Securities Exchange Act of 1934 Rule 13-d-15 (e) and 15d-15(e)). Based upon that evaluation and management's assessment of the potential effects of the material weakness described below, our Chief Executive Officer and Chief Financial Officer, concluded that as of the end of the period covered by this Report, our disclosure controls and procedures were effective to enable us to record, process, summarize and report information required to be included in our periodic SEC filings within the required time period.

DISCLOSURE CONTROLS AND INTERNAL CONTROLS

Disclosure controls are procedures that are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, such as this Report, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls are also designed with the objective of ensuring that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Internal controls are procedures which are designed with the objective of providing reasonable assurance

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that our transactions are properly authorized, recorded, and reported and our assets are safeguarded against unauthorized or improper use, and to permit the preparation of our financial statements in conformity with generally accepted accounting principles.

Our company is not an "accelerated filer" (as defined in the Exchange Act) and is not required to deliver management's report on control over our financial reporting until our fiscal year ended December 31, 2006. Nevertheless, we consider the effectiveness of our internal controls over financial reporting as part of the quarterly evaluations of our procedures. In connection therewith, we reported, for the year ended December 31, 2005, that we identified certain matters that we believed constituted material weaknesses (as such term is defined under the Public Company Accounting Oversight Board Auditing Standard No. 2) in our internal controls over financial reporting. The first such material weakness related to our ability to ensure that the accounting for our equity-based transactions is accurate and complete and the second related to our limited segregation of duties.

With respect to the first material weakness, during the year ended December 31, 2005, we adopted a policy of having our Chief Financial Officer review all of our agreements to ensure that we identify the applicable accounting treatments to evaluate any areas that may involve the application of highly specialized accounting principles including, but not necessarily limited to, complex equity transactions. In circumstances where we may become (or

contemplate becoming) a party to transactions that would involve the application of accounting principles in which our expertise is limited, we would engage the services of outside specialists, if necessary. At the current time however, we believe that we have gained substantially greater experience in these areas and that our procedures would enable us to resolve such issues within time frames needed to comply with our reporting obligations.

With respect to the second material weakness, which relates to our segregation of duties, we have re-evaluated our procedures and believe that due to our small number of employees (most of whom have limited or no access to Company assets and/or records that would affect our financial reporting) that our risks of either material misstatement or misappropriation of assets is minimal. In addition, substantially all of our general and administrative expenses and scientific research expenditures are reviewed and approved by employees who are knowledgeable of those matters. To date our procedures have also enabled us to comply with our financial reporting obligations within the time frames required by the SEC. Although we believe our risks with respect to this matter are minimal, we still acknowledge that it would be beneficial for the Company to segregate certain procedures to a greater number of employees. We believe that our limited segregation of duties still constitutes a material deficiency in our system. However, we currently have limited financial resources and do not believe that at this time, it would be prudent for us to further constrain our liquidity by allocating resources to hiring additional employees as a corrective measure. We believe that the costs we would incur to increase our staff (solely for this purpose) exceed the potential reduction in risk. Our senior management team is monitoring this situation to determine if these circumstances change. If the situation changes and sufficient capital is secured, it is our intention to increase staffing within our general accounting and financial functions.

Other than our adoption of a policy of having our Chief Financial Officer evaluate all proposed agreements for the purpose of identifying any applicable accounting matters, particularly those that may involve accounting for equity transactions, there have been no changes in our internal controls over financial reporting during our most recent fiscal year that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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### PART II OTHER INFORMATION

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

During the period covered by this Report, we have not issued unregistered securities which have not been ‘‘previously reported’’ as defined in Rule 12b-2 of the Exchange Act, except;

On May 3, 2006, we issued additional options to purchase 388,115 shares of our common stock at \$0.15 per share to and we issued an additional 388,115 shares of our common stock to each of two consultants pursuant to the anti-dilution provisions contained in their option agreements.

On June 1, 2006, we issued 2006 6% Convertible Notes in the aggregate principal amount of \$1,500,000 under a private placement. Pursuant to this transaction, certain note holders who did not previously participate in our Preferred Stock offering received warrants to purchase in the aggregate 6,500,000 shares of our common stock at \$0.30 per share. Certain note holders who did participate in our Preferred Stock offering received adjustments to the conversion price of their Preferred Stock of equivalent value to what they invested in the 2006 6% Convertible Note offering, to \$0.15 per share which will require us to issue in the aggregate an additional 3,290,000 shares of common stock upon



conversion of their Preferred Stock and an adjustment to the warrants to purchase 105,000 shares of common stock originally issued with the Preferred Stock ,to \$.0.30 per share.

On June 1, 2006, the Company issued a warrant to purchase 50,000 shares of common stock at \$0.15 per share as a broker's fee under the 2006 6% Convertible Note offering. In addition, the Company issued a warrant to purchase a 2006 6% Convertible Note in the principal amount of \$142,500 and a warrant to purchase 650,000 shares of common stock at \$0.15 per share as yield enhancement fees under the 2006 6% Convertible Note offering.

On June 15, 2006, we issued a 2006 6% Convertible Note in the principal amount of \$125,000 under a private placement. Pursuant to this transaction, the note holder who did not previously participate in our Preferred Stock offering, received a warrant to purchase 833,333 shares of our common stock at \$0.30 per share.

On June 15, 2006, the Company issued a warrant to purchase a 2006 6% Convertible Note in the principal amount of \$12,500 and a warrant to purchase 83,333 shares of common stock at \$0.15 per share as yield enhancement fees under the 2006 6% Convertible Note offering.

On June 26, 2006, we issued ten-year options to purchase in the aggregate 16,000 shares of our common stock at \$0.21 per share to our three outside directors as compensation for preparing for and participating in our board of directors' meeting.

On June 29, 2006, we issued a three-year warrant to Cornell Capital to purchase 5,000,000 shares of our common stock at an initial exercise price of \$0.25 per share, to induce them to assign their rights and obligations under the 2005 Convertible Debentures.

#### FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-QSB contains forward-looking statements (as defined in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). To the extent that any statements made in this Report contain information that is not historical, these statements are essentially forward-looking. Forward-looking statements can be identified by the use of words such as "expects," "plans" "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning. These statements are subject to risks and uncertainties that cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, our ability to raise capital to finance the development of our products, the effectiveness, profitability and the marketability of those products, our ability to protect our proprietary information, general economic and business conditions, the impact of technological developments and competition, including entry of newly-developed alternative drug technologies, our expectations and estimates concerning future

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financial performance and financing plans, adverse results of any legal proceedings, the impact of current, pending or future legislation and regulation on the healthcare industry, our ability to satisfy government and commercial customers using our technology, our ability to develop manufacturing capabilities or the inability to enter into acceptable relationships with one or more contract manufacturers for our products and key components and the ability of such contract manufacturers to manufacture products or components of an acceptable quality on a cost-effective basis, the volatility of our operating results and financial condition, our ability to attract or retain qualified senior

management personnel, including sales and marketing and scientific personnel and other risks detailed from time to time in our filings with the SEC. We do not undertake any obligation to publicly update any forward-looking statements. As a result, you should not place undue reliance on these forward-looking statements.

We also use market data and industry forecasts and projections throughout this prospectus, which we have obtained from market research, publicly available information and industry publications. These sources generally state that the information they provide has been obtained from sources believed to be reliable, but that the accuracy and completeness of the information are not guaranteed. The forecasts and projections are based on industry surveys and the preparers' experience in the industry, and the projected amounts may not be achieved. Similarly, although we believe that the surveys and market research others have performed are reliable, we have not independently verified this information. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services.

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Item 6. Exhibits

Exhibit Number	Description
2.1	Certificate of Ownership and Merger of CepTor Corporation into CepTor Research and Development Company (incorporated by reference herein to Exhibit 2.1 to the Company's Current Report on Form 8-K dated January 31, 2005 (the "January 2005 8-K"))
3.1	Amended and Restated Certificate of Incorporation, dated January 27, 2005 (incorporated herein by reference to Exhibit 3.1 to the January 2005 8-K)
3.2	Certificate of Correction to Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, dated February 10, 2005)
3.3	Amended and Restated By-laws (incorporated herein by reference to Exhibit 3.2 to the January 2005 8-K)
4.1	Form of Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004 (the "2004 10-KSB"))
4.2	CepTor Agreement, dated March 31, 2004 (the "CepTor Agreement"), by and among William Pursley, Xechem and the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, dated December 9, 2004 (the "2004 Form 8-K"))
4.3	First Amendment to CepTor Agreement effective April 23, 2004, by and among William Pursley, the Company and Xechem (incorporated herein by reference to Exhibit 4.2 to the 2004 8-K)
4.4	Second Amendment to CepTor Agreement, dated December 9, 2004, by and among William Pursley, the Company and Xechem (incorporated by reference to Exhibit 4.3 to the 2004 8-K)
4.5	Form of Unit Warrant (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form SB-2 as filed with the SEC on February 11, 2005 (the "Form SB-2"))

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- 4.6 Form of Amended and Restated Convertible Promissory Note (incorporated herein by reference to Exhibit 4.7 to the 2004 10-KSB)
- 4.7 Form of Subscription Agreement (incorporated herein by reference to Exhibit 4.6 to the Form SB-2)
- 4.8 Securities Purchase Agreement, dated June 17, 2005 by and between the Company, Xechem and William Pursley (incorporated herein by reference to Exhibit 99.01 to the Company's Current Report on Form 8-K filed on June 20, 2005)
- 4.9 Common Stock Purchase Agreement, dated October 7, 2005, between the Company and Fusion Capital Fund II, LLC ("Fusion") (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed October 11, 2005 (the "October 2005 8-K"))
- 4.10 Registration Rights Agreement, dated October 7, 2005, between the Company and Fusion (incorporated herein by reference to Exhibit 4.2 to the October 2005 8-K)
- 4.11 Common Stock Warrant with Fusion, dated October 7, 2005 (incorporated by reference herein to Exhibit 4.1 to the October 2005 8-K)
- 4.12 Agreement between the Company and Brown Advisory Securities, LLC, dated May 20, 2005 (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form SB-2 as filed with the SEC on October 17, 2005 (the "October 2005 SB-2"))
- 4.13 Secured Convertible Debenture, dated December 9, 2005, issued by the Company to Cornell Capital (incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed December 15, 2005 ("December 2005 8-K"))

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Exhibit Number	Description
4.14	Warrant issued to Cornell Capital, dated December 9, 2005 (incorporated herein by reference to Exhibit 4.2 to the December 2005 8-K)
4.15	Form of Redemption Warrant to Cornell Capital (incorporated herein by reference to Exhibit 4.3 to the December 2005 8-K)
4.16	\$250,000 Convertible Promissory Note, dated December 9, 2005, to Harbor Trust (incorporated herein by reference to Exhibit 4.4 to the December 2005 8-K)
4.17	\$452,991.10 Amended Promissory Note, dated December 9, 2005, to Harbor Trust (incorporated herein by reference to Exhibit 4.5 to the December 2005 8-K)
4.18	Secured Convertible Debenture, dated December 28, 2005, issued by the Company to Cornell Capital (incorporated herein by reference to Exhibit 4.10 to the Company's Registration Statement on Form SB-2, dated December 29, 2005 ("December 2005 SB-2"))
4.19	Non-Qualified Option Certificate and Addendum thereto, dated March 3, 2006, to Little Gem Life Sciences Fund, LLC (incorporated herein by reference to Exhibit 4.18 to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2005 ("2005 10-KSB"))
4.20	Non-Qualified Option Certificate and Addendum thereto, dated March 3, 2006, to Peter Chung (incorporated herein by reference to Exhibit 4.19 to the 2005 10-KSB)
4.21	Placement Agency Agreement (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on June 2, 2006)

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- 4.22 Form of Subscription Agreement (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on June 2, 2006)
- 4.23 Form of 6% Convertible Note (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on June 2, 2006)
- 4.24 Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on June 2, 2006)
- 4.25 Assignment Agreement, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.26 Secured Convertible Debenture with Longview Fund, LP, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.27 Secured Convertible Debenture with Longview Fund, LP, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.28 Secured Convertible Debenture with Alpha Capital, Aktiengesellschaft, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.29 Secured Convertible Debenture with Ellis International Ltd., dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.30 Secured Convertible Debenture with Momona Capital, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.31 Warrant, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.32\* Securities Purchase Agreement, dated August 14, 2006, by and between the Company and certain sellers and purchasers of Series A Preferred Stock

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Exhibit Number	Description
10.1	Employment Agreement, dated March 31, 2004, by and between William H. Pursley and the Company (incorporated herein by reference to Exhibit 10.1 to the Form SB-2)
10.2	Employment Agreement, dated April 26, 2004, by and between Norman A. Barton, M.D., Ph.D. and the Company (incorporated herein by reference to Exhibit 10.2 to the Form SB-2)
10.3	Employment Agreement, dated March 31, 2004, by and between Donald W. Fallon and the Company (incorporated herein by reference to Exhibit 10.3 to the Form SB-2)
10.4	Founders' Plan (incorporated herein by reference to Exhibit 10.5 to the Form SB-2)
10.5	2004 Incentive Stock Plan (incorporated herein by reference to Exhibit 10.6 to the Form SB-2)
10.6	Deferred Stock Plan for Non-Employee Directors under the 2004 Incentive Stock Plan (incorporated herein by reference to Exhibit 10.7 to the 2004 10-KSB)
10.7	2006 Incentive Stock Plan (incorporated herein by reference to Exhibit 10.7 to the 2005 10-KSB)

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- 10.8 Sublease Agreement, dated March 4, 2004, by and between the Company and Millennium Inorganic Chemicals, Inc. (incorporated herein by reference to Exhibit 10.7 to the Form SB-2)
- 10.9 Exclusive License Agreement, dated September 15, 2004, between the Company and JCR Pharmaceuticals Company, Ltd. (incorporated herein by reference to Exhibit 10.8 to the Form SB-2)
- 10.10 Indemnification Agreement, dated October 6, 2005, by and between William H. Pursley and the Company (incorporated herein by reference to Exhibit 10.9 to the October 2005 SB-2)
- 10.11 Indemnification Agreement, dated October 6, 2005, by and between Norman W. Barton and the Company (incorporated herein by reference to Exhibit 10.10 to the October 2005 SB-2)
- 10.12 Indemnification Agreement, dated October 6, 2005, by and between Donald W. Fallon and the Company (incorporated herein by reference to Exhibit 10.11 to the October 2005 SB-2)
- 10.13 Indemnification Agreement, dated June 1, 2004, by and between Leonard A. Mudry and the Company (incorporated herein by reference to Exhibit 10.12 to the October 2005 SB-2)
- 10.14 Securities Purchase Agreement, dated December 9, 2005, between the Company and Cornell Capital (incorporated herein by reference to Exhibit 10.1 to the December 2005 8-K)
- 10.15 Side Letter, dated December 9, 2005, between the Company and Cornell Capital (incorporated herein by reference to Exhibit 10.2 to the December 2005 8-K)
- 10.16 Investor Registration Rights Agreement, dated December 9, 2005, between the Company and Cornell Capital (incorporated herein by reference to Exhibit 10.3 to the December 2005 8-K)
- 10.17 Security Agreement, dated December 9, 2005, between the Company and Cornell Capital (incorporated herein by reference to Exhibit 10.4 to the December 2005 8-K)
- 10.18 Rights Agreement, dated March 7, 2006, between the Company and American Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 1 to the Company's Registration Statement on Form 8-A, dated March 8, 2006)
- 10.19 Manufacture and Supply Agreement entered into as of April 18, 2005 by and among Peninsula Laboratories Inc., Bachem AG, Bachem Americas and the Company (incorporated by reference herein to Exhibit 10.14 to the Company's Quarterly Report on Form 10-QSB for the quarter ended March 31, 2005)

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Exhibit Number	Description
10.20	Term Sheet, dated May 3, 2006, by and between the Company and Margie Chassman (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed May 9, 2006)
31.1*	Section 302 Certification of Principal Executive Officer
31.2*	Section 302 Certification of Principal Financial Officer
32.1*	Section 906 Certification of Principal Executive Officer
32.2*	Section 906 Certification of Principal Financial Officer

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\*Filed herewith.

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SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: September 5, 2006	CEPTOR CORPORATION By: /s/ William H. Pursley William H. Pursley Chairman and Chief Executive Officer (Principal Executive Officer)
Dated: September 5, 2006	By: /s/ Donald W. Fallon Donald W. Fallon Chief Financial Officer, Senior Vice President, Finance and Administration and Secretary (Principal Financial Officer and Principal Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description
2.1	Certificate of Ownership and Merger of CepTor Corporation into CepTor Research and Development Company (incorporated by reference herein to Exhibit 2.1 to the Company's Current Report on Form 8-K dated January 31, 2005 (the "January 2005 8-K"))
3.1	Amended and Restated Certificate of Incorporation, dated January 27, 2005 (incorporated herein by reference to Exhibit 3.1 to the January 2005 8-K)
3.2	Certificate of Correction to Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, dated February 10, 2005)

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- 3.3 Amended and Restated By-laws (incorporated herein by reference to Exhibit 3.2 to the January 2005 8-K)
- 4.1 Form of Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004 (the "2004 10-KSB"))
- 4.2 CepTor Agreement, dated March 31, 2004 (the "CepTor Agreement"), by and among William Pursley, Xechem and the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, dated December 9, 2004 (the "2004 Form 8-K"))
- 4.3 First Amendment to CepTor Agreement effective April 23, 2004, by and among William Pursley, the Company and Xechem (incorporated herein by reference to Exhibit 4.2 to the 2004 8-K)
- 4.4 Second Amendment to CepTor Agreement, dated December 9, 2004, by and among William Pursley, the Company and Xechem (incorporated by reference to Exhibit 4.3 to the 2004 8-K)
- 4.5 Form of Unit Warrant (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form SB-2 as filed with the SEC on February 11, 2005 (the "Form SB-2"))
- 4.6 Form of Amended and Restated Convertible Promissory Note (incorporated herein by reference to Exhibit 4.7 to the 2004 10-KSB)
- 4.7 Form of Subscription Agreement (incorporated herein by reference to Exhibit 4.6 to the Form SB-2)
- 4.8 Securities Purchase Agreement, dated June 17, 2005 by and between the Company, Xechem and William Pursley (incorporated herein by reference to Exhibit 99.01 to the Company's Current Report on Form 8-K filed on June 20, 2005)
- 4.9 Common Stock Purchase Agreement, dated October 7, 2005, between the Company and Fusion Capital Fund II, LLC ("Fusion") (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed October 11, 2005 (the "October 2005 8-K"))
- 4.10 Registration Rights Agreement, dated October 7, 2005, between the Company and Fusion (incorporated herein by reference to Exhibit 4.2 to the October 2005 8-K)
- 4.11 Common Stock Warrant with Fusion, dated October 7, 2005 (incorporated by reference herein to Exhibit 4.1 to the October 2005 8-K)
- 4.12 Agreement between the Company and Brown Advisory Securities, LLC, dated May 20, 2005 (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form SB-2 as filed with the SEC on October 17, 2005 (the "October 2005 SB-2"))
- 4.13 Secured Convertible Debenture, dated December 9, 2005, issued by the Company to Cornell Capital (incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed December 15, 2005 ("December 2005 8-K"))

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Exhibit Number	Description
4.14	Warrant issued to Cornell Capital, dated December 9, 2005 (incorporated herein by reference to Exhibit 4.2 to the December 2005 8-K)

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- 4.15 Form of Redemption Warrant to Cornell Capital (incorporated herein by reference to Exhibit 4.3 to the December 2005 8-K)
- 4.16 \$250,000 Convertible Promissory Note, dated December 9, 2005, to Harbor Trust (incorporated herein by reference to Exhibit 4.4 to the December 2005 8-K)
- 4.17 \$452,991.10 Amended Promissory Note, dated December 9, 2005, to Harbor Trust (incorporated herein by reference to Exhibit 4.5 to the December 2005 8-K)
- 4.18 Secured Convertible Debenture, dated December 28, 2005, issued by the Company to Cornell Capital (incorporated herein by reference to Exhibit 4.10 to the Company's Registration Statement on Form SB-2, dated December 29, 2005 ("December 2005 SB-2"))
- 4.19 Non-Qualified Option Certificate and Addendum thereto, dated March 3, 2006, to Little Gem Life Sciences Fund, LLC (incorporated herein by reference to Exhibit 4.18 to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2005 ("2005 10-KSB"))
- 4.20 Non-Qualified Option Certificate and Addendum thereto, dated March 3, 2006, to Peter Chung (incorporated herein by reference to Exhibit 4.19 to the 2005 10-KSB)
- 4.21 Placement Agency Agreement (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on June 2, 2006)
- 4.22 Form of Subscription Agreement (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on June 2, 2006)
- 4.23 Form of 6% Convertible Note (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on June 2, 2006)
- 4.24 Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on June 2, 2006)
- 4.25 Assignment Agreement, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.26 Secured Convertible Debenture with Longview Fund, LP, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.27 Secured Convertible Debenture with Longview Fund, LP, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.28 Secured Convertible Debenture with Alpha Capital, Aktiengesellschaft, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.29 Secured Convertible Debenture with Ellis International Ltd., dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.30 Secured Convertible Debenture with Momona Capital, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.31 Warrant, dated June 29, 2006 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2006)
- 4.32\* Securities Purchase Agreement, dated August 14, 2006, by and between the Company and certain sellers and purchasers of Series A Preferred Stock



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Exhibit Number	Description
10.1	Employment Agreement, dated March 31, 2004, by and between William H. Pursley and the Company (incorporated herein by reference to Exhibit 10.1 to the Form SB-2)
10.2	Employment Agreement, dated April 26, 2004, by and between Norman A. Barton, M.D., Ph.D. and the Company (incorporated herein by reference to Exhibit 10.2 to the Form SB-2)
10.3	Employment Agreement, dated March 31, 2004, by and between Donald W. Fallon and the Company (incorporated herein by reference to Exhibit 10.3 to the Form SB-2)
10.4	Founders' Plan (incorporated herein by reference to Exhibit 10.5 to the Form SB-2)
10.5	2004 Incentive Stock Plan (incorporated herein by reference to Exhibit 10.6 to the Form SB-2)
10.6	Deferred Stock Plan for Non-Employee Directors under the 2004 Incentive Stock Plan (incorporated herein by reference to Exhibit 10.7 to the 2004 10-KSB)
10.7	2006 Incentive Stock Plan (incorporated herein by reference to Exhibit 10.7 to the 2005 10-KSB)
10.8	Sublease Agreement, dated March 4, 2004, by and between the Company and Millennium Inorganic Chemicals, Inc. (incorporated herein by reference to Exhibit 10.7 to the Form SB-2)
10.9	Exclusive License Agreement, dated September 15, 2004, between the Company and JCR Pharmaceuticals Company, Ltd. (incorporated herein by reference to Exhibit 10.8 to the Form SB-2)
10.10	Indemnification Agreement, dated October 6, 2005, by and between William H. Pursley and the Company (incorporated herein by reference to Exhibit 10.9 to the October 2005 SB-2)
10.11	Indemnification Agreement, dated October 6, 2005, by and between Norman W. Barton and the Company (incorporated herein by reference to Exhibit 10.10 to the October 2005 SB-2)
10.12	Indemnification Agreement, dated October 6, 2005, by and between Donald W. Fallon and the Company (incorporated herein by reference to Exhibit 10.11 to the October 2005 SB-2)
10.13	Indemnification Agreement, dated June 1, 2004, by and between Leonard A. Mudry and the Company (incorporated herein by reference to Exhibit 10.12 to the October 2005 SB-2)
10.14	Securities Purchase Agreement, dated December 9, 2005, between the Company and Cornell Capital (incorporated herein by reference to Exhibit 10.1 to the December 2005 8-K)
10.15	Side Letter, dated December 9, 2005, between the Company and Cornell Capital (incorporated herein by reference to Exhibit 10.2 to the December 2005 8-K)
10.16	Investor Registration Rights Agreement, dated December 9, 2005, between the Company and Cornell Capital (incorporated herein by reference to Exhibit 10.3 to the December 2005 8-K)
10.17	Security Agreement, dated December 9, 2005, between the Company and Cornell Capital (incorporated herein by reference to Exhibit 10.4 to the December 2005 8-K)
10.18	Rights Agreement, dated March 7, 2006, between the Company and American Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 1 to the Company's Registration Statement on Form 8-A, dated March 8, 2006)
10.19	Manufacture and Supply Agreement entered into as of April 18, 2005 by and among Peninsula Laboratories Inc., Bachem AG, Bachem Americas and the Company

(incorporated by reference herein to Exhibit 10.14 to the Company's Quarterly Report on Form 10-QSB for the quarter ended March 31, 2005)

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Exhibit Number	Description
10.20	Term Sheet, dated May 3, 2006, by and between the Company and Margie Chassman (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed May 9, 2006)
31.1*	Section 302 Certification of Principal Executive Officer
31.2*	Section 302 Certification of Principal Financial Officer
32.1*	Section 906 Certification of Principal Executive Officer
32.2*	Section 906 Certification of Principal Financial Officer

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\*Filed herewith.

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