ACURA PHARMACEUTICALS, INC
Form 10-Q
April 26, 2006

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20649

Form 10-Q

(Mark One)
þ**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the quarterly period ended March 31, 2006

or

¨**TRANSACTION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ______________________ to_______________________

Commission File Number 1-10113

Acura Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

New York	**11-0853640**
(State or other Jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
616 N. North Court, Suite 120 Palatine, Illinois	**60067**
(Address of Principal Executive Offices)	*(Zip Code)*

847 705 7709
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes o No þ

As of April 25, 2006 the registrant had 329,550,445 shares of Common Stock, $.01 par value, outstanding.

PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

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PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

UNAUDITED
(in thousands, except par values)

	March 31, 2006	December 31, 2005
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 650	$ 260
Prepaid insurance	92	179
Prepaid expenses and other current assets	-	5
Total current assets	742	444
PROPERTY, PLANT & EQUIPMENT, NET	1,305	1,341
DEPOSITS	7	7
TOTAL ASSETS	$ 2,054	$ 1,792
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Senior secured term notes payable	$ 4,050	$ 2,550
Current maturities of capital lease obligations	30	31
Accrued expenses	285	341
Total current liabilities	4,365	2,922
SECURED TERM NOTES PAYABLE	5,000	5,000
CAPITAL LEASE OBLIGATIONS, less current maturities	26	32
COMMITMENTS AND CONTINGENCIES		
TOTAL LIABILITIES	9,391	7,954
STOCKHOLDERS' DEFICIT		
Common stock - $.01 par value; 650,000 shares authorized; 329,550 and 329,293 shares issued and outstanding at March 31, 2006 and December 31, 2005, respectively	3,295	3,293
Convertible preferred stock - $.01 par value; 72,027 shares authorized and available for issuance and none issued and outstanding at March 31, 2006 or December 31, 2005	-	-
Additional paid-in capital	285,139	287,885
Unearned compensation	-	(5,724)
Accumulated deficit	(295,771)	(291,616)
STOCKHOLDERS' DEFICIT	(7,337)	(6,162)

TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$	2,054	$	1,792

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE MONTHS ENDED MARCH 31,

UNAUDITED
(in thousands, except per share data)

	2006	2005
Research and development	$ 1,506	$ 953
Marketing , general and administrative	2,421	955
LOSS FROM OPERATIONS	(3,927)	(1,908)
OTHER INCOME (EXPENSE)		
Interest expense	(225)	(126)
Interest income	4	15
(Loss) gain on asset disposals	(7)	70
Other	-	1
TOTAL OTHER EXPENSE	(228)	(40)
NET LOSS	$ (4,155)	$ (1,948)
Basic and diluted loss per common share	$ (0.01)	$ (0.09)
Weighted average number of outstanding common shares	329,304	22,336

See accompanying notes to the consolidated financial statements.

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ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIT

THREE MONTHS ENDED MARCH 31, 2006

UNAUDITED
(in thousands)

	Common Stock					
	Shares	**Amount**	**Additional Paid-in Capital**	**Unearned Compensation**	**Accumulated Deficit**	**Total**
Balance at December 31, 2005	**329,293**	**$ 3,293**	**$ 287,885**	**$ (5,724)**	**$ (291,616)**	**$ (6,162)**
Net loss	-	-	-	-	(4,155)	(4,155)
Issuance of common shares for interest	208	2	145	-	-	147
Adoption of FASB 123R	-	-	(5,724)	5,724	-	-
Issuance of restricted stock units	-	-	680	-	-	680
Other stock-based compensation	-	-	2,142	-	-	2,142
Issuance of common shares for exercise of options	30	-	11	-	-	11
Issuance of common shares for cashless exercise of warrant	19	-	-	-	-	-
Balance at March 31, 2006	**329,550**	**$ 3,295**	**$ 285,139**	**$ -**	**$ (295,771)**	**$ (7,337)**

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31,

UNAUDITED
(in thousands, except supplemental data)

		2006		2005
Cash flows from Operating Activities:				
Net loss	$	(4,155)	$	(1,948)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization		31		32
Non-cash stock compensation expense		2,822		363
(Gain) loss on asset disposals		7		(70)
Changes in assets and liabilities				
Prepaid expenses and other current assets		92		(19)
Accrued expenses		92		229
Total adjustments		3,044		535
Net cash used in operating activities		(1,111)		(1,413)
Cash flows from Investing Activities:				
Capital expenditures		(3)		(8)
Proceeds from asset disposals		-		172
Net cash (used in) provided by investing activities		(3)		164
Cash flows from Financing Activities:				
Proceeds from issuance of senior secured term notes payable		1,500		-
Proceeds from the exercise of stock options		11		-
Payments on capital lease obligations		(7)		(7)
Net cash provided (used in) by financing activities		1,504		(7)
Increase (decrease) in cash and cash equivalents		390		(1,256)
Cash and cash equivalents at beginning of period		260		3,103
Cash and cash equivalents at end of period	**$**	**650**	**$**	**1,847**
Cash paid for interest	$	76	$	2

See accompanying notes to the consolidated financial statements.

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ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

FOR THE THREE MONTHS ENDED MARCH 31, 2006

UNAUDITED
(in thousands, except supplemental data)

Supplemental disclosures of noncash investing and financing activities:

Three Months ended March 31, 2006

1. The Company issued 207,856 shares of Common Stock as payment of $147,000 of Secured Term Note Payable accrued interest.
2. Warrants to purchase 165,934 shares of Common Stock were exercised in March 2006 at an exercise price of $0.48 per share in a cashless exercise transaction resulting in the issuance of 19,065 shares of Common Stock.

Three Months ended March 31, 2005

1. The Company issued 200,876 shares of Common Stock as payment of $122,000 of Secured Term Note Payable accrued interest.
2. The Company issued 278,572 shares of Common Stock as result of the conversion of 278,572 shares of the Company's Series C-1 Junior Preferred Stock.

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2006 AND 2005

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements of Acura Pharmaceuticals, Inc. and subsidiaries (the "Company") have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles in the United States for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accrual adjustments, considered necessary to present fairly the financial position, results of operations and changes in cash flows for the three months ended March 31, 2006, assuming that the Company will continue as a going concern, have been made. The results of operations for the three month period ended March 31, 2006 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2006. The unaudited consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2005 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

NOTE 2 - LIQUIDITY MATTERS

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. At March 31, 2006, the Company had unrestricted cash and cash equivalents of $0.7 million, a working capital deficit of $3.6 million, and an accumulated deficit of $295.8 million. At December 31, 2005, the Company had cash and cash equivalents of $0.3 million, a working capital deficit of $2.5 million and an accumulated deficit of $291.6 million. The Company incurred a loss from operations of $3.9 million and a net loss of $4.2 million during the three months ended March 31, 2006 and a loss from operations of $11.6 million and a net loss of $12.1 million during the year ended December 31, 2005. Historically, the Company has incurred significant losses and until such time as its product candidates are commercialized, of which no assurance can be given, the Company will continue incurring losses. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

The Company estimates that its current cash reserves, including the net proceeds from the March 2006 Bridge Loan described in Note 9 will be sufficient to fund the development of the Aversion® Technology and related operating expenses through mid-May, 2006. To fund further operations and product development activities, the Company must raise additional financing, or enter into alliances or collaboration agreements with third parties relating to its Aversion® Technology. No assurance can be given that the Company will be successful in obtaining any such financing or in securing collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or collaborative agreements will provide for payments to the Company sufficient to continue to fund operations. In the absence of such financing or third-party collaborative agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws.

Even assuming the Company is successful in securing additional sources of financing and/or enters into alliances or collaborative agreements relating to the Aversion® Technology, there can be no assurance that the Company's development efforts will result in commercially viable products. The Company's failure to successfully develop the Aversion® Technology in a timely manner, to obtain issued U.S. patents relating to the Aversion® Technology and to avoid infringing third-party patents and other intellectual property rights will have a material adverse impact on its financial condition and results of operations.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying consolidated balance sheets is dependent upon continued operations of the Company, which in turn are dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to succeed in its future operations. The Company's financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

NOTE 3 - NEW ACCOUNTING PRONOUNCEMENTS

Share-Based Payment

On December 16, 2004, the Financial Accounting Standards Board (“FASB”) released FASB Statement No. 123 (revised 2004), “Share-Based Payment, (“FASB 123R”)”. These changes in accounting replace existing requirements under FASB Statement No. 123, “Accounting for Stock-Based Compensation” (“FASB 123”), and eliminates the ability to account for share-based compensation transaction using APB Opinion No.25, “Accounting for Stock Issued to Employees” (“APB 25”). The compensation cost relating to share-based payment transactions will be measured based on the fair value of the equity or liability instruments issued. This Statement did not change the accounting for similar transactions involving parties other than employees.

The Company adopted FASB 123R effective January 1, 2006 under the modified prospective method, which recognizes compensation cost beginning with the effective date (a) based on the requirements of FASB 123R for all share-based payments granted after the effective date and to awards modified, repurchased, or cancelled after that date and (b) based on the requirements of FASB 123 for all awards granted to employees prior to the effective date of FASB 123R that remain unvested on the effective date. The only cumulative effect of initially applying this Statement for the Company was to reclassify $5.7 million of previously recorded unearned compensation into paid-in capital. The Company has estimated that an additional $102,000 will be expensed over the applicable remaining vesting periods for all share-based payments granted to employees on or before December 31, 2005 which remained unvested on January 1, 2006. The Company anticipates that more compensation costs will be recorded in the future if the use of options and restricted stock units for employees and director compensation continues as in the past.

NOTE 4 - RESEARCH AND DEVELOPMENT

The Company’s research and development (“R&D”) expenses were primarily associated with the Company’s Aversion® Technology. R&D expenses include internal R&D activities and external contract research organizations (CROs). Internal R&D expenses include facility overhead, maintenance, repair and depreciation, laboratory supplies, equipment maintenance, repair and depreciation, salaries, benefits, incentive compensation and other administrative expenses. CRO expenses include preclinical laboratory experiments, clinical trials, clinical trial and regulatory consulting and patent counsel. R&D expenses are charged to operations as incurred. The Company reviews and accrues clinical trial expenses based on work performed and relies on an estimate of the costs applicable to the stage of completion of a clinical trial. Accrued clinical costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. The Company had no binding research and development commitments with third parties at March 31, 2006 or at December 31, 2005.

NOTE 5 - INCOME TAXES

The Company accounts for income taxes under the liability method in accordance with Statement of Financial Accounting Standards No. 109 ("SFAS No. 109"), "Accounting for Income Taxes." Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. At December 31, 2005 the Company has net operating loss carryforwards aggregating approximately $129.7 million expiring during the years 2009 through 2024. The tax loss carryforwards of the Company and its subsidiaries may be subject to limitation by Section 382 of the Internal Revenue Code with respect to the amount utilizable each year. This limitation reduces the Company's ability to utilize net operating loss carryforwards each year. The amount of the limitation has not been quantified. SFAS 109 requires a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. At December 31, 2005, a valuation allowance equal to 100% of the net deferred income tax assets was used and primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards. In the event the Company were to determine that it would be able to realize some or all its deferred income tax assets in the future, an adjustment to the deferred income tax asset would increase income in the period such determination was made.

NOTE 6 - STOCK-BASED COMPENSATION

The Company has three stock-based compensation plans covering stock options and restricted stock units for its employees and directors. On January 1, 2006, the Company adopted FASB 123R. This change in accounting replaces existing requirements under FASB 123 and eliminates the ability to account for share-based compensation transaction using APB 25. The compensation cost relating to share-based payment transactions will be measured based on the fair value of the equity or liability instruments issued. For purposes of estimating the fair value of each stock option or restricted stock unit on the date of grant, the Company utilized the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of the company’s common stock (as determined by reviewing its historical public market closing prices). Because the Company's employee stock options and restricted stock units have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options or restricted stock units. Included in the results for the three months ended March 31, 2006, is $2,822,000 of stock-based compensation expense of which $680,000 was recognized immediately from the February 2006 grant of 2,000,000 restricted stock units to certain Company independent directors. The remaining expense relates to the fair value of stock options and restricted stock units, net of expected forfeitures, granted prior to 2006 which continue to vest over the related employees requisite service periods which generally end by March 2008.

The following table illustrates the effect on net loss and loss per share had the Company applied the fair value recognition provisions of FASB 123 for the period indicated (in thousands).

		Three Months Ended March 31, 2005
Net loss as reported	$	(1,948)
Add: Stock-based employee compensation expense included in reported net loss		363
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards		(395)
Net loss, pro forma	$	(1,980)
Weighted average number of outstanding shares		22,336
Earnings per share		
Basic and diluted loss per share, as reported	$	(0.09)
Basic and diluted loss per share, pro forma	$	(0.09)

Pro forma compensation expense may not be indicative of future expense.

Restricted Stock Unit Award Plan

On December 22, 2005, the Board of Directors adopted the Company's 2005 Restricted Stock Unit Award Plan (the "2005 RSU Plan") for its employees and non-employee directors. A Restricted Stock Unit ("RSU") represents the contingent obligation of the Company to deliver a share of its common stock to the holder of the RSU on a distribution date. RSUs for up to 30 million shares of common stock are authorized for issuance under the 2005 RSU Plan. The Company believes that the 2005 RSU Plan does not require shareholder approval. Nevertheless, the Company intends to seek shareholder ratification for the 2005 RSU Plan at its next Annual Shareholders' Meeting.

The RSU Plan is administered by the Company's Board of Directors or a Committee appointed by the Board of Directors. RSUs granted under the 2005 RSU Plan vest on a schedule determined by the Board of Directors or such Committee as set forth in a restricted stock unit award agreement. Unless otherwise set forth in such award agreement, the RSUs fully vest upon a change in control (as defined in the 2005 RSU Plan) of the Company or upon termination of an employee's employment with the Company without cause or due to death or disability, and in the case of a non-employee director, such person's death or disability or if such person is not renominated as a director (other than for "cause" or refusal to stand for re-election) or is not elected by the Company's stockholders, if nominated. Vesting of an RSU entitles the holder thereof to receive a share of common stock of the Company on a distribution date (after payment of the $0.01 par value per share).

Absent a change of control, one-fourth of vested shares of common stock underlying an RSU award will be distributed (after payment of $0.01 par value per share) on January 1 of each of 2011, 2012, 2013 and 2014. If a change in control occurs (whether prior to or after 2011), the vested shares underlying the RSU award will be distributed at or about the time of the change in control. No dividends accrue on the shares underlying the RSUs prior to issuance by the Company. The recipients of RSU awards need not be employees or directors of the Company on a distribution date. RSUs may generally not be transferred, except recipients of RSUs may designate beneficiaries to inherit their RSU's upon their death.

NOTE 7- EARNINGS (LOSS) PER SHARE

The computation of basic earnings (loss) per share of common stock is based upon the weighted average number of common shares outstanding during the period. Diluted earnings per share are based on the same number of common shares adjusted for the effect of other potentially dilutive securities. Excluded from the share computation for the three month periods ending March 31, 2006 and 2005 are approximately 63.3 million and 341.1 million, respectively, of outstanding restricted stock units, options, and warrants and the effects of outstanding convertible preferred stock which would have been antidilutive.

NOTE 8 - ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	March 31, 2006	December 31, 2005
Payroll, payroll taxes and benefits	$ 74	$ 50
Legal fees	61	74
Audit examination and tax preparation fees	26	65
Franchise taxes	20	20
Property taxes	58	52
Clinical, regulatory, trademarks, and patent consulting fees	30	78

Directors fees		-		2
Other fees and services		16		-
Total accrued expenses	$	285	$	341

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NOTE 9 - NOTES PAYABLE AND STOCK WARRANTS

At March 31, 2006 and December 31, 2005, notes payable consisted of the following (in thousands):

	March 31, 2006	December 31, 2005
Secured term notes payable (a)	$ 5,000	$ 5,000
Bridge loan agreements (b)	4,050	2,550
Capital lease obligations	56	63
	9,106	7,613
Less: Current maturities	(4,080)	(2,581)
Notes payable - long term	$ 5,026	$ 5,032

(a) **Secured Term Note Payable**

The Company was a party to a certain loan agreement with Watson Pharmaceuticals, Inc. ("Watson") pursuant to which Watson made term loans to the Company in the aggregate principal amount of $21.4 million as evidenced by two promissory notes (the "Watson Notes"). As part of a 2004 refinancing transaction, the Watson Notes were amended to, among other things, extend the maturity date of such notes from March 31, 2006 to June 30, 2007, to provide for satisfaction of future interest payments under the Watson Notes in the form of the Company's Common Stock, and to reduce the principal amount of the Watson Notes from $21.4 million to $5.0 million (resulting in a gain to the Company) (the Watson Notes as so amended, the "2004 Note"). Simultaneous with refinancing, the 2004 Note was purchased from Watson by certain of the Company's stockholders in consideration for a payment to Watson of $1.0 million.

The 2004 Note in the principal amount of $5.0 million is secured by a lien on all of the Company's and its subsidiaries' assets, carries a floating rate of interest equal to the prime rate plus 4.5% and matures on June 30, 2007. The carrying interest rate at March 31, 2006 was 12.25%. The 2004 Note contains a cross default provision with each of the outstanding Bridge Loans.

(b) **Bridge Loan Agreements**

The Company is party to various similar Loan Agreements, dated March 2006, January 2006, November 2005, September 2005, and June 2005, with its major shareholder and its affiliates and certain other lenders under which it has borrowed an aggregate $4,050,000 (the "Bridge Loans"). The net proceeds from the Bridge Loans, after the satisfaction of related legal expenses, have been and will be used by the Company to continue the development of its Aversion® Technology and to fund related operating expenses. The Bridge Loans are secured by a lien on all of the Company's assets, senior in right of payment and lien priority to all other indebtedness of the Company. The Bridge Loans bear interest at the rate of ten percent (10%) per annum and mature on June 1, 2006. The Bridge Loans are subject to mandatory pre-payment by the Company upon the Company's completion of equity or debt financing or any sale, transfer, license or similar arrangement pursuant to which the Company or any of its Subsidiaries sells, licenses or otherwise grant rights in any material portion of the Company's intellectual property to any third party, provided that the consummation of any such transaction results in certain minimum amounts of cash proceeds to the Company, net of all costs and expenses. The Bridge Loans restrict the Company's ability to issue any shares of its currently authorized Series A, B or C preferred stock without the prior consent of the Bridge Lenders, and grants the Bridge lenders preemptive rights relating to the issuance of the Company's Series A, B and C preferred stock. The Bridge

Loans contain cross default provisions with the amended 2004 Note and each of the other outstanding Bridge Loans. The Bridge Loans also contains normal and customary affirmative and negative covenants, including restrictions on the Company's ability to incur additional debt or grant any lien on the assets of the Company or its subsidiaries, subject to certain permitted exclusions.

Stock Warrants

At December 31, 2005, the Company had outstanding common stock purchase warrants exercisable for an aggregate of 16,241,571 shares of common stock. Of such warrants, 5,390,906 were issued in connection with the issuance of convertible debentures, bridge loans and financing commitments during the years 1998 through 2003, 10,700,665 were issued to Watson Pharmaceuticals, Inc. in connection with their agreement to amend the Watson Loan at December 20, 2002, and 150,000 were issued in 2003 as part of the settlement terms with a former executive officer of the Company. In March 2006, warrants to purchase 165,934 shares of common stock were exercised at an exercise price of $0.48 per share in a cashless exercise transaction resulting in the issuance of 19,065 shares of common stock. At March 31, 2006, the Company had outstanding common stock purchase warrants exercisable for an aggregate 16,075,637 shares of common stock and approximately 31,000, 310,000, 154,000 and 15,581,000 warrants will expire if unexercised during the years 2006, 2007, 2008 and years thereafter, respectively. The exercise prices of the warrants range from $0.13 to $0.66 per share.

NOTE 10 - CONVERSION OF PREFERRED SHARES INTO COMMON SHARES

Effective November 10, 2005, all of the issued and outstanding preferred shares of the Company were automatically and mandatorily converted into the Company's common stock, $.01 par value per share (the "Common Stock") in accordance with the terms of the Company's Restated Certification of Incorporation (the "Preferred Stock Conversion"). In accordance with the conversion provisions contained in the Restated Certificate of Incorporation, all issued and outstanding shares of the Company's Series A Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock and Series C-3 Preferred Stock (collectively, the "Preferred Stock") were converted automatically into the Company's Common Stock upon the Company's receipt of the written consent to the Preferred Stock Conversion from the holders of at least 51% of the shares of the Company's Series A Preferred Stock. On November 10, 2005, the Company received the consent to the Preferred Stock Conversion from GCE Holdings LLC (the assignee of all of the Company's Preferred Stock (prior to its conversion into Common Stock) formerly held by each of Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners International III, L.P., Galen Partners III, L.P. and Galen Employee Fund III, L.P.), such entity holding in the aggregate in excess of 51% of the issued and outstanding shares of the Company's Series A Preferred Stock. In accordance with the terms of the Company's Restated Certificate of Incorporation, all shares of the Company's Preferred Stock were automatically converted into an aggregate of approximately 305.4 million shares of the Company's Common Stock.

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

This discussion and analysis should be read in conjunction with the Company's financial statements and accompanying notes included elsewhere in this Report. Historical operating results are not necessarily indicative of results that may occur in future periods.

Forward Looking Statements

Certain statements in this Report including, without limitation, in this Item 2 constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"). Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. The most significant of such factors include, but are not limited to, the Company's ability to secure additional financing to fund continued product development and operations, the Company's ability to enter into contractual arrangements with qualified pharmaceutical partners to license, develop and commercialize the Company's technology and product candidates, and the Company's ability to fulfill the U.S. Food and Drug Administration's requirements for approving the Company's product candidates for commercial distribution in the United States. Other important factors that may also affect future results include, but are not limited to: the Company's ability to attract and retain highly skilled personnel; its ability to secure and protect its patents, trademarks and proprietary rights; its ability to avoid infringement of patents, trademarks and other proprietary rights or trade secrets of third parties; litigation or regulatory action that could require the Company to pay significant damages or change the way it conducts its business; the Company's ability to compete successfully against current and future competitors; its dependence on third-party suppliers of raw materials; its ability to secure U.S. Drug Enforcement Administration quotas and source controlled substances that constitute the active ingredients of the Company's products in development; difficulties or delays in clinical trials for Company products or in the manufacture of Company products; and other risks and uncertainties detailed in this Report. The Company is at development stage and may not ever have any products or technologies that generate revenue. When used in this Report, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions are intended to identify forward-looking statements.

Company Overview

The Company is a specialty pharmaceutical development company primarily engaged in development of proprietary abuse deterrent, abuse resistant and tamper resistant formulation technologies ("Aversion® Technology") intended to discourage abuse of orally administered opioid analgesic products. The Company utilizes several contract research organizations and an academic institution for laboratory and clinical evaluation and testing of product candidates incorporating the Aversion® Technology. The Company also conducts research, development, laboratory, stability, manufacturing and warehousing activities relating to the Aversion® Technology at its Culver, Indiana operations facility (the "Culver Facility"). The Culver Facility is registered by the DEA to perform research, development and manufacture for certain Schedule II - V controlled substances in bulk and finished dosage forms.

The Company is focused on (i) development and evaluation, in concert with contract research organizations (“CROs”), in laboratory settings and clinical trials, of product candidates utilizing the Company's Aversion® Technology; (ii) manufacture, quality assurance testing and release, and stability studies of clinical trial supplies and NDA submission batches of certain finished dosage form product candidates utilizing the Company’s Aversion® Technology; (iii) prosecution of the Company’s patent applications relating to the Aversion® Technology with the United States Patent and Trademark Office (“PTO”) and foreign equivalents; (iv) negotiation and execution of license and development agreements with strategic pharmaceutical company partners providing that such licensees will further develop certain finished dosage product candidates utilizing the Aversion® Technology and file for regulatory approval with the FDA and other regulatory authorities and commercialize such products and (vi) prosecution of the Company's application to the U.S. Drug Enforcement Administration (“DEA”) for registration to import narcotic raw materials (“NRMs”).

In addition, the Company was historically engaged in research, development and manufacture of proprietary, high-yield, short cycle time, environmentally sensitive opioid synthesis processes (the "Opioid Synthesis Technologies" and, collectively with the Aversion® Technology, the “Technologies”) intended for use in the commercial production of certain bulk opioid active pharmaceutical ingredients (“APIs”). In early 2005 the Company suspended development and commercialization efforts relating to the Opioid Synthesis Technologies pending the Administrative Law Judge’s determination relating to the Company’s Import Registration filed with the U.S. Drug Enforcement Administration (the “DEA”) in early 2001. The Import Registration, if ultimately granted, for which there can be no assurance, could provide the Company with an economical source of narcotic raw materials (“NRMs”) for use as starting materials in the commercial manufacture and supply of certain opioid APIs.

Company’s Present Financial Condition, Focus and Status

At March 31, 2006, the Company had unrestricted cash and cash equivalents of $0.7 million compared to $0.3 million at December 31, 2005. The Company had a working capital deficit of $3.6 million at March 31, 2006 and working capital deficit of $2.5 million at December 31, 2005. The Company had an accumulated deficit of $295.8 million and $291.6 million at March 31, 2006 and December 31, 2005, respectively. The Company incurred a loss from operations of $3.9 million and a net loss of $4.2 million during the three months ended March 31, 2006, compared to losses of $1.9 million from both operations and net loss during the three months ended March 31, 2005. At April 25, 2006, the Company had cash and cash equivalents of approximately $475,000. The Company estimates that its current cash reserves, including the net proceeds from the January and March 2006 Bridge Loans, will fund continued development of the Aversion® Technology and related operating expenses through mid-May 2006.

The Company has incurred net losses since 1992 and the Company's consolidated financial statements for each of the years ended December 31, 2005, 2004 and 2003 have been prepared on a going-concern basis, expressing substantial doubt about the Company's ability to continue as a going-concern as a result of recurring losses and negative cash flows. The Company's future profitability will depend on several factors, including (i) the Company’s ability to secure additional financing to fund continued operations; (ii) the successful completion of the formulation development, clinical testing and acceptable regulatory review of product candidates utilizing the Aversion® Technology; (iii) the receipt of issued patents from the U.S. Patent and Trademark Office (“PTO”) for the material claims in the Company's patent applications relating to the Aversion® Technology; (iv) the Company's ability to negotiate and execute appropriate licensing, development and commercialization agreements with interested third parties relating to the Company's product candidates; and, (v) the successful commercialization by licensees of products incorporating the Aversion® Technology without infringing the patents and other intellectual property rights of third parties.

Status of Patent Applications and Issued Patents

As of the date of this Report, the Company has three (3) non-provisional US, one (1) provisional US and two (2) international patent applications pending relating to its Aversion® Technology. Additionally, the Company has six (6) US patents issued, one (1) US Notice of Allowance granted, and one (1) US patent application pending related to its Opioid Synthesis Technologies. As of the date of this Report, the Company retained ownership of all intellectual property and commercial rights to its product candidates and Technologies.

Status of Strategy with Commercial Partners

To generate revenue the Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license product candidates utilizing the Company's Aversion® Technology and further develop, register and commercialize multiple formulations and strengths of such product candidates. The Company expects to receive milestone payments and a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Aversion® Technology. Future revenue, if any, will be derived from milestone payments and a share of profits and/or royalty payments relating to such collaborative partners' sale of products incorporating the Aversion® Technology. As of the date of this Report, the Company did not have any executed collaborative agreements with Partners, nor can there be any assurance that the Company will successfully enter into such collaborative agreements in the future.

Status of Development of OxyADF™ Tablets

The Company's lead product candidate, OxyADF™ is an orally administered tablet being developed pursuant to an active investigational new drug application ("IND") on file with the United States Food and Drug Administration ("FDA"). The FDA has confirmed that OxyADF™ is an appropriate product candidate for submission as a 505(b)(2) new drug application ("NDA"). To date the Company, in concert with CROs, has completed patient enrollment in one phase I clinical trial and one phase II clinical trial relating to the development of OxyADF™. The Company intends to use such data in its 505(b)(2) NDA submission for OxyADF™. In written correspondence to the Company the FDA has confirmed that completion of certain additional clinical studies will be required prior to submission of a 505(b)(2) NDA for OxyADF™.

In addition, the Company, in concert with a CRO, has completed a pivotal bioequivalence study for OxyADF™ using tablets from batches manufactured by the Company at its Culver Facility at a scale of sufficient size to fulfill the FDA's requirements for a 505(b)(2) NDA submission. The final report from the CRO confirms that OxyADF™ is bioequivalent to the applicable reference listed drug. The Company intends to use such data in its 505(b)(2) NDA submission for OxyADF™.

In addition, the Company, in concert with an independent laboratory CRO, completed a pivotal study to assess certain properties of OxyADF™ using tablets from batches manufactured by the Company at its Culver Facility at a scale of sufficient size to fulfill the FDA's requirements for a 505(b)(2) NDA submission. The final report from this pivotal laboratory study confirms that extracting the active opioid ingredient from OxyADF™ tablets in a form which may be abused via intravenous injection is substantially more difficult than extracting the active opioid ingredient from several currently marketed opioid-based commercial products. The Company intends to utilize the data from this pivotal laboratory study in its 505(b)(2) NDA submission for OxyADF™.

Estimating the dates of completion of clinical development, and the costs to complete development, of the Company's product candidates, including OxyADF™, would be highly speculative, subjective and potentially misleading. Pharmaceutical products require significant time to research, develop and commercialize. The Company expects to reassess its future research and development plans based on the review of data received from current research and development activities. The cost and pace of future research and development activities are linked and subject to change. At this stage there can be no assurance that any of the Company’s research and development efforts, including those for OxyADF™, will lead to a 505(b)(2) NDA submission or that if NDA submissions are made with the FDA, that any such submission will be approved by the FDA.

<u>Results of Operations for the Three Months Ended March 31, 2006 and March 31, 2005</u>

The Company is a specialty pharmaceutical development company primarily engaged in development of proprietary abuse deterrent, abuse resistant and tamper resistant formulation technologies ("Aversion® Technology") intended to discourage abuse of orally administered opioid analgesic products. To generate revenue the Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license product candidates utilizing the Company's Aversion® Technology and further develop, register and commercialize multiple formulations and strengths of such product candidates. The Company had no revenues for the three months ended March 31, 2006 and 2005 and relied upon capital and bridge loans provided by third parties to fund operations and development activities.

<u>Research and Development Expenses</u>

The Company's research and development expenses for the three months ended March 31, 2006 and March 31, 2005 were as follows (in thousands):

3 MONTHS ENDED 3/31/06 R&D EXPENSES	3 MONTHS ENDED 3/31/05 R&D EXPENSES	3 MONTHS ENDED 3/31/06 and 3/31/05 R&D EXPENSES CHANGE ($)	3 MONTHS ENDED 3/31/06 and 3/31/05 R&D EXPENSES CHANGE (%)
$1,506	$953	$553	58%

Research and development expense in the three months ended March 31, 2006 and March 31, 2005 consisted primarily of development of our Aversion® Technology, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2006 and 2005 results are non-cash stock-based compensation charges of $949 and $105, respectively. Excluding the stock-based compensation expense, the decrease in overall expenses was primarily attributed to lower wage and incentive costs of $197 reflecting the fewer number of Company employees in 2006 as compared to 2005. The increase in stock-based compensation expense of $844 relates to the fair value of stock options and restricted stock units, net of expected forfeitures, granted prior to 2006 which continue to vest over the related employees requisite service periods which generally end by March 2008.

<u>Marketing , General and Administrative Expenses</u>

Marketing, general and administrative expenses for the three months ended March 31, 2006 and 2005 were as follows (in thousands):

3 MONTHS ENDED 3/31/06 MARKETING, G&A EXPENSES	3 MONTHS ENDED 3/31/05 MARKETING, G&A EXPENSES	3 MONTHS ENDED 3/31/06 and 3/31/05 MARKETING, G&A EXPENSES CHANGE ($)	3 MONTHS ENDED 3/31/06 and 3/31/05 MARKETING, G&A EXPENSES CHANGE (%)
$2,421	$955	$1,466	154%

During the three months ended March 31, 2006, the marketing expenses consisted of costs of Aversion® Technology market research studies and payroll costs. The Company’s general and administrative expenses consisted of legal and other professional fees, corporate insurance, and payroll costs. Included in the 2006 and 2005 results is $1,873 and $258, respectively, of stock-based compensation expense. Excluding the stock-based compensation expense, the decrease in overall expenses was primarily attributed to incentive payroll costs of $58, market research study costs of $46 incurred in 2005, and $10 of lower corporate insurance costs. Of the increase in stock-based compensation expense, $680,000 was from the February 2006 grant of 2,000,000 restricted stock units to certain Company independent directors. The remaining increase in stock-compensation expense of $786 relates to the fair value of stock options and restricted stock units, net of expected forfeitures, granted prior to 2006 which continue to vest over the related employees requisite service periods which generally end by March 2008.

Environmental Compliance Expenses

During the three months ended March 31, 2006 and March 31, 2005, the Company did not incur environmental compliance expenses.

Interest Expense, net of Interest Income

The Company's interest expense, net of interest income for the three months ended March 31, 2006 and March 31, 2005 was as follows (in thousands):

3 MONTHS ENDED 3/31/06 INTEREST EXPENSE, NET OF INTEREST INCOME	3 MONTHS ENDED 3/31/05 INTEREST EXPENSE, NET OF INTEREST INCOME	3 MONTHS ENDED 3/31/06 and 3/31/05 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE ($)	3 MONTHS ENDED 3/31/06 and 3/31/05 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (%)
$221	$111	($110)	99%

The Company incurs interest at the prime interest rate plus 4.5%, payable quarterly in common stock, on its $5.0 million Secured Term Note Payable and incurs 10.0% interest, payable quarterly in cash, on its $4.1 million Secured Term Notes Payable. The increase in net interest expense in 2006 resulted from both the addition of $4.1 million of bridge loans since March 2005 and increases in the prime interest rate.

Net Loss

The Company's net loss for the three months ended March 31, 2006 and March 31, 2005 was as follows (in thousands):

3 MONTHS ENDED 3/31/06 NET LOSS	3 MONTHS ENDED 3/31/05 NET LOSS	3 MONTHS ENDED 3/31/06 and 3/31/05 NET LOSS CHANGE ($)	3 MONTHS ENDED 3/31/06 and 3/31/05 NET LOSS CHANGE (%)
$4,155	$1,948	$2,207	113%

Liquidity and Capital Resources

At March 31, 2006, the Company had unrestricted cash and cash equivalents of $0.7 million compared to $0.3 million at December 31, 2005. The Company had a working capital deficit of $3.6 million at March 31, 2006 compared to a working capital deficit of $2.5 million at December 31, 2005.

Secured Term Note Payable

The Company was a party to a certain loan agreement with Watson Pharmaceuticals, Inc. ("Watson") pursuant to which Watson made term loans to the Company (the "Watson Term Loan Agreement") in the aggregate principal amount of $21.4 million as evidenced by two promissory notes (the "Watson Notes”). As part of 2004 refinancing transaction, the Watson Notes were amended to, among other things, extend the maturity date of such notes from March 31, 2006 to June 30, 2007, to provide for satisfaction of future interest payments under the Watson Notes in the form of the Company's Common Stock, and to reduce the principal amount of the Watson Notes from $21.4 million to $5.0 million (resulting in a gain to the Company) (the Watson Note as so amended, the “2004 Note”). Simultaneous with refinancing, the 2004 Note was purchased from Watson by certain of the Company’s stockholders in consideration for a payment to Watson of $1.0 million.

The 2004 Note in the principal amount of $5.0 million is secured by a lien on all of the Company's and its subsidiaries' assets, carries a floating rate of interest equal to the prime rate plus 4.5% and matures on June 30, 2007. The carrying interest rate at March 31, 2006 was 12.25%. The 2004 Note contains a cross default provision with each of the outstanding Bridge Loans.

Bridge Loan Agreements

The Company is party to various similar Loan Agreements, dated March 2006, January 2006, November 2005, September 2005, and June 2005, with its major shareholder and its affiliates and certain other lenders under which it has borrowed an aggregate $4,050,000 (the “Bridge Loans”). The net proceeds from the Bridge Loans, after the satisfaction of related legal expenses, have been and will be used by the Company to continue the development of its Aversion® Technology and to fund related operating expenses. The Bridge Loans are secured by a lien on all of the Company’s assets, senior in right of payment and lien priority to all other indebtedness of the Company. The Bridge Loans bear interest at the rate of ten percent (10%) per annum and mature on June 1, 2006. The Bridge Loans are subject to mandatory pre-payment by the Company upon the Company’s completion of equity or debt financing or any sale, transfer, license or similar arrangement pursuant to which the Company or any of its Subsidiaries sells, licenses or otherwise grant rights in any material portion of the Company’s intellectual property to any third party, provided that the consummation of any such transaction results in certain minimum amounts of cash proceeds to the Company, net of all costs and expenses. The Bridge Loans restrict the Company’s ability to issue any shares of its currently authorized Series A, B or C preferred stock without the prior consent of the Bridge Lenders, and grants the Bridge Lenders preemptive rights relating to the issuance of the Company’s Series A, B and C preferred stock. The Bridge Loans contain cross default provisions with the 2004 Note and each of the other outstanding Bridge Loans. The Bridge Loans also contains normal and customary affirmative and negative covenants, including restrictions on the Company’s ability to incur additional debt or grant any lien on the assets of the Company or its subsidiaries, subject to certain permitted exclusions.

Commercial Focus, Cash Reserves and Funding Requirements

As of April 25, 2006, the Company had cash and cash equivalents of approximately $475,000. The majority of such cash reserves will be dedicated to the development of the Company's Aversion® Technology, the prosecution of the Company's patent applications relating to the Aversion® Technology and for related operating expenses. The Company has suspended further development and commercialization efforts relating to the Opioid Synthesis Technologies.

The Company must rely on its current cash reserves to fund the development of its Aversion® Technology and related operating expenses. The Company's future sources of revenue, if any, will be derived from contract signing fees, milestone payments and royalties and/or profit sharing payments from licensees for the Company's Aversion® Technology. The Company estimates that its current cash reserves, including the net proceeds from the March and

January 2006 Bridge Loans, will fund continued development of the Aversion® Technology and related operating expenses through mid-May 2006. To fund further operations and product development activities the Company must raise additional financing, or enter into alliances or collaboration agreements with third parties. No assurance can be given that the Company will be successful in obtaining any such financing or in securing collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or collaborative agreements will provide for payments to the Company sufficient to continue to fund operations. In the absence of such financing or third-party collaborative agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws.

Even assuming the Company is successful in securing additional sources of financing to fund the continued development of the Aversion® Technology, or otherwise enters into alliances or collaborative agreements relating to the Aversion® Technology, there can be no assurance that the Company's development efforts will result in commercially viable products. The Company's failure to successfully develop the Aversion® Technology in a timely manner, to obtain issued U.S. patents relating to the Aversion® Technology and to avoid infringing third-party patents and other intellectual property rights will have a material adverse impact on its financial condition and results of operations.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying consolidated balance sheets is dependent upon continued operations of the Company, which in turn are dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to succeed in its future operations. The Company's financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

The following table presents the Company's expected cash requirements for contractual obligations outstanding as of March 31, 2006 (In thousands):

	TOTAL	DUE IN 2006	DUE IN 2007	DUE IN 2008	DUE THEREAFTER
Term notes	$ 9,050	$ 4,050	$ 5,000	$ -	$ -
Cash interest on term notes	68	68	-	-	-
Capital leases	56	24	25	7	-
Operating leases	32	27	5	-	-
Employment agreements	555	555	-	-	-
Total Contractual Cash Obligations	$ 9,761	$ 4,724	$ 5,030	$ 7	$ -

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, as contained in the Company's Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. In preparing these financial statements, the Company has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company does not believe there is a consequential likelihood that materially different amounts would be reported under different conditions or using different assumptions. The Company's critical accounting policies are as follows:

Income Taxes

Deferred income taxes are recognized for temporary differences between financial statement and income tax bases of assets and liabilities and loss carry-forwards for which income tax benefits are expected to be realized in future years. A valuation allowance is established, when necessary, to reduce deferred tax assets to the amount expected to be realized. In estimating future tax consequences, the Company generally considers all expected future events other than an enactment of changes in the tax laws or rates. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to the amount that is more likely than not to be realized. In the event the Company were to determine that it would be able to realize its deferred income tax assets in the future, an adjustment to reduce the valuation allowance would increase income in the period such determination was made.

Stock Compensation

The Company now accounts for stock-based employee compensation arrangements in accordance with the provisions of FASB Statement No. 123 (revised 2004) " Share-Based Payment" which requires that various estimates be used to determine fair value of stock options. Management determines the amount of the compensation associated with options, based in part, on the fair values ascribed to these instruments through the use of the Black-Scholes valuation model. Inherent in the Black-Scholes valuation model are assumptions made by management regarding the estimated life of these instruments, the estimated volatility of the Company's common stock (as determined by reviewing its historical public market closing prices) and the expected dividend yield.

New Accounting Pronouncements

Share-Based Payment

On December 16, 2004, the Financial Accounting Standards Board ("FASB") released FASB Statement No. 123 (revised 2004), "Share-Based Payment, ("FASB 123R")". These changes in accounting replace existing requirements under FASB Statement No. 123, "Accounting for Stock-Based Compensation" ("FASB 123"), and eliminates the ability to account for share-based compensation transaction using APB Opinion No.25, "Accounting for Stock Issued to Employees" ("APB 25"). The compensation cost relating to share-based payment transactions will be measured based on the fair value of the equity or liability instruments issued. This Statement did not change the accounting for similar transactions involving parties other than employees.

The modified prospective method, which recognizes compensation cost beginning with the effective date (a) based on the requirements of FASB 123R for all share-based payments granted after the effective date and to awards modified, repurchased, or cancelled after that date and (b) based on the requirements of FASB Statement No. 123 for all awards granted to employees prior to the effective date of FASB 123R that remain unvested on the effective date. The only cumulative effect of initially applying this Statement for the Company was to reclassify $5.7 million of previously recorded unearned compensation into its paid-in capital. The Company has estimated that an additional $102,000 will be expensed over the applicable remaining vesting periods for all share-based payments granted to employees on or before December 31, 2005 which remained unvested on January 1, 2006. The Company anticipates that more compensation costs will be recorded in the future if the use of options and restricted stock units for employees and director compensation continues as in the past.

Risk Factors Relating To The Company

The Company Received a "Going Concern" Opinion from Its Registered Independent Public Accounting Firm, Has a History of Operating Losses and May Not Achieve Profitability Sufficient to Generate a Positive Return on Shareholders' Investment

We have incurred net losses of approximately $4.2 million for the three months ended March 31, 2006, $12.1 million for the year ended December 31, 2005 and $70.0 million, $48.5 million, and $59.6 million for 2004, 2003, and 2002, respectively. As of March 31, 2006, our accumulated deficit was approximately $295.8 million. The Company's consolidated financial statements for the years ended December 31, 2005 and 2004 have been prepared on a "going concern" basis; however, in its report dated February 1, 2006 regarding those financial statements, our registered independent public accounting firm referred to substantial doubt about the Company's ability to continue as a going concern as a result of recurring losses, net capital deficiency and negative cash flows. Our future profitability will depend on many factors, including: (i) the Company's ability to secure additional financing to fund continued operations, (ii) the successful completion of the formulation development, clinical testing and acceptable regulatory review of product candidates utilizing the Aversion® Technology; (iii) the receipt of issued patents from the U.S.

Patent and Trademark Office (“PTO”) for the material claims in the Company's patent applications relating to the Aversion® Technology; (iv) the Company's ability to negotiate and execute appropriate licensing, development and commercialization agreements with qualified third parties relating to the Company’s product candidates; and (v) the successful commercialization by licensees of products incorporating the Aversion® Technology without infringing the patents and other intellectual property rights of third parties. We cannot assure you that we will ever have a product approved by the FDA, that we will bring any product to market or, if we are successful in doing so, that we will ever become profitable.

We Require Additional Funding

Our requirements for additional new funding will depend on many factors, including: (i) the time required and expenses incurred in the development and commercialization of products incorporating our Aversion® Technology; (ii) the structure of any future collaborative or development agreements relating to the Aversion® Technology, including the timing and amount of payments, if any, that may be received under possible future collaborative agreements; (iii) our ability to develop additional product candidates utilizing the Aversion® Technology; (iv) our ability to negotiate agreements with qualified third parties for development, manufacture, marketing, sale and distribution of products utilizing our Aversion® Technology; (v) the prosecution, defense and enforcement of patent claims and other intellectual property rights relating to the Aversion® Technology; and (vi) the successful commercialization by licensees of products incorporating our Aversion® Technology without infringing third-party patents or other intellectual property rights.

To continue funding operations the Company must raise additional financing, or enter into alliances or collaborative agreements with third parties providing for net proceeds to the Company. No assurance can be given that the Company will be successful in obtaining any such financing or in securing collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or collaborative agreements will provide for payments to the Company sufficient to continue to fund operations. In the absence of such financing or third-party collaborative agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. Even assuming the Company is successful in securing additional sources of financing to fund the continued development of the Aversion® Technology, or otherwise enters into alliances or collaborative agreements relating to the Aversion® Technology, there can be no assurance that the Company's development efforts will result in commercially viable products.

We Have No Near Term Sources of Revenue and Must Rely on Current Cash Reserves, Third-Party Financing, and Technology Licensing Fees to Fund Operations

Pending the negotiation of appropriate licensing agreements with pharmaceutical company partners, of which no assurance can be given, the Company must rely on its current cash reserves, third-party financing and technology licensing fees to fund the Company's operations. No assurance can be given that current cash resources will be sufficient to fund the continued development of our product candidates until such time as we generate revenue from the license of products incorporating the Aversion® Technology to third parties. Moreover, no assurance can be given that we will be successful in raising additional financing to fund operations or, if funding is obtained, that such funding will be sufficient to fund operations until the Company's product candidates incorporating our Aversion® Technology, may be commercialized.

The Company Is Subject to Restrictions on the Incurrence of Additional Indebtedness, Which May Adversely Impact the Company's Ability to Fund Operations

Pursuant to the terms of each of the Company's outstanding secured term Loan Agreements the Company is limited as to the type and amount of future indebtedness it may incur. The restriction on the Company's ability to incur additional indebtedness in the future may adversely impact the Company's ability to fund the development of its product candidates and commercialization of its products.

Our Product Candidates Are Based on Technology That Could Ultimately Prove Ineffective

Our lead product candidate, OxyADF™ incorporating our Aversion® Technology is a tablet formulation intended for oral administration and has an active IND on file with FDA. The Company is focusing substantially all of its product development activities on OxyADF™ tablets. Additional clinical and non-clinical testing will be required to continue development of OxyADF™ tablets and for the preparation and submission of a 505(b)(2) new drug application ("NDA") with the FDA. There can be no assurance that OxyADF™ tablets or any other product candidate developed using the Aversion® Technology will lead to a NDA submission to the FDA and that if a NDA is submitted, that the FDA will accept such submission and subsequently approve such regulatory application to allow for commercial distribution of the product.

The Company is committing substantially all of its resources and available capital to the development of OxyADF™ tablets and the prosecution of its patent applications for the Aversion® Technology. The failure of the Company to successfully develop a product candidate utilizing the Aversion® Technology, to successfully obtain an issued patent from the PTO relating to the Aversion® Technology and to avoid infringing third-party patents and intellectual property rights in the commercialization of products utilizing the Aversion® Technology will have a material adverse effect on the Company's operations and financial condition.

If Pre-Clinical or Clinical Testing For Our Product Candidates Are Unsuccessful or Delayed, We Will Be Unable to Meet Our Anticipated Development and Commercialization Timelines

To obtain FDA approval to commercially market any of our product candidates, we must submit to the FDA a NDA demonstrating, among other things, that the product candidate is safe and effective for its intended use. This demonstration requires significant pre-clinical and clinical testing. As we do not possess the resources or employ all the personnel necessary to conduct such testing we rely on contract research organizations for the majority of this testing with our product candidates. As a result, we have less control over the timing and other aspects of our development program than if we performed the testing entirely on our own. Third parties may not perform their responsibilities on our anticipated schedule. Delays in our development programs could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to a delay in the development program, may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials with our product candidates may be delayed for several reasons, including but not limited to delays in demonstrating sufficient pre-clinical safety required to obtain regulatory approval to commence a clinical trial, reaching agreements on acceptable terms with prospective collaborative partners, manufacturing and quality assurance release of a sufficient supply of a product candidate for use in our clinical trials and/or obtaining institutional review board approval to conduct a clinical trial at a prospective site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA or other regulatory authorities due to several factors, including ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials, failure to conduct clinical trials in accordance with regulatory requirements, lower than anticipated recruitment or retention rate of patients in clinical trials, inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities, the imposition of a clinical hold by FDA, lack of adequate funding to continue clinical trials; and/or negative or unanticipated results of clinical trials.

Clinical trials, where required by the FDA for commercial approval, may not demonstrate safety or efficacy of our product candidates. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. Even if the results of our pivotal clinical trials are positive, we and our collaborative partners may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we can submit NDAs or obtain regulatory approval for our product candidates.

Clinical trials may be expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, if participating subjects or patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we, our collaborative partner(s) or the FDA believes that participating patients are being exposed to unacceptable health risks, our collaborative partner(s) may have to suspend the clinical trials. Failure can occur at any stage of the trials, and our collaborative partner(s) could encounter problems causing the abandonment of clinical trials or the need to conduct additional clinical studies, relating to a product candidate.

Even if our clinical trials are completed as planned, their results may not support our targeted product label claims. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their intended use. Such failure would cause us or our collaborative partner to abandon a product candidate and may delay the development of other product candidates.

We May Not Obtain Required FDA Approval; the FDA Approval Process Is Time-Consuming and Expensive

The development, testing, manufacturing, marketing and sale of pharmaceutical products are subject to extensive federal, state and local regulation in the United States and other countries. Satisfaction of all regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product candidate, and requires the expenditure of substantial resources for research, development and testing. Substantially all of the Company's operations are subject to compliance with FDA regulations. Failure to adhere to applicable FDA regulations by the Company or its licensees, if any, would have a material adverse effect on the Company's operations and financial condition. In addition, in the event the Company is successful in developing product candidates for sale in other countries, the Company would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive.

We may encounter delays or rejections during any stage of the regulatory approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the products to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of a marketing application, in the form of a new drug application ("NDA"), or a 505(b)(2) NDA the FDA may deny the application, may require additional testing or data and/or may require post-marketing testing and surveillance to monitor the safety or efficacy of a product. The FDA commonly takes one to two years to grant final approval for a NDA, or 505(b)(2) NDA.. Further, the terms of approval of any marketing application, including the labeling content, may be more restrictive than we desire and could affect the marketability of the products incorporating the Aversion® Technology.

Even if we comply with all FDA regulatory requirements, we may never obtain regulatory approval for any of our product candidates. If we fail to obtain regulatory approval for any of our product candidates, we will have fewer saleable products and corresponding lower revenues. Even if we receive regulatory approval of our products, such approval may involve limitations on the indicated uses or marketing claims we may make for our products.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the drug-approval process, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions to close manufacturing plants allegedly not operating in conformity with current Good Manufacturing Practices (cGMP) and to stop shipments of allegedly violative products. As any future source of Company revenue will be derived from the sale of FDA approved products, the taking of any such action by the FDA would have a material adverse effect on the Company.

We Must Maintain FDA Approval to Manufacture Our Products Candidates at Our Facility; Failure to Maintain Compliance with FDA Requirements May Prevent or Delay the Manufacture of Our Product Candidates and Costs of Manufacture May Be Higher Than Expected

We have constructed and installed the equipment necessary to manufacture clinical trial supplies of our Aversion® Technology product candidates in tablet formulations at our Culver, Indiana facility. To be used in clinical trials, all of our product candidates must be manufactured in conformity with current Good Manufacturing Practice (cGMP) regulations as interpreted and enforced by the FDA. All such product candidates must be manufactured, packaged, and labeled and stored in accordance with cGMPs. Modifications, enhancements or changes in manufacturing sites of marketed products are, in many circumstances, subject to FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain. Our Culver, Indiana facility, as well as those of any third-party manufacturers that we may use, are periodically subject to inspection by the FDA and other governmental agencies, and operations at these facilities could be interrupted or halted if such inspections are unsatisfactory. Failure to comply with FDA or other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production or distribution, suspension of FDA review of our products, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution.

If We Retain Collaborative Partners and Our Partners Do Not Satisfy Their Obligations, We Will Be Unable to Develop Our Partnered Product Candidates

To complete the development and regulatory approval of our products and commercialize our product candidates, if any are approved by the FDA, we plan to enter into development and commercialization agreements with strategically focused pharmaceutical company partners providing that such partners license our Aversion® Technologies and further develop, register, manufacture and commercialize multiple formulations and strengths of each product candidate utilizing our Aversion® Technology. We expect to receive a share of profits and/or royalty payments derived from such collaborative partners' sale of products incorporating our Aversion® Technologies. Currently, we do not have any such collaborative agreements, nor can there be any assurance that we will actually enter into collaborative agreements in the future. Our inability to enter into collaborative agreements, or our failure to maintain such agreements, would limit the number of product candidates that we can develop and ultimately, decrease our potential sources of any future revenues. In the event we enter into any collaborative agreements, we may not have day-to-day control over the activities of our collaborative partners with respect to any product candidate. Any collaborative partner may not fulfill its obligations under such agreements. If a collaborative partner fails to fulfill its obligations under an agreement with us, we may be unable to assume the development of the product covered by that agreement or to enter into alternative arrangements with a third-party. In addition, we may encounter delays in the commercialization of the product candidate that is the subject of a collaboration agreement. Accordingly, our ability to receive any revenue from the product candidates covered by collaboration agreements will be dependent on the efforts of our collaborative partner. We could be involved in disputes with a collaborative partner, which could lead to delays in or termination of, our development and commercialization programs and result in time consuming and expensive litigation or arbitration. In addition, any such dispute could diminish our collaborative partners' commitment to us and reduce the resources they devote to developing and commercializing our products. If any collaborative partner terminates or breaches its agreement, or otherwise fails to complete its obligations in a timely manner, our chances of successfully developing or commercializing our product candidates would be materially and adversely effected. Additionally, due to the nature of the market for our product candidates, it may be necessary for us to license all or a significant portion of our product candidates to a single collaborator, thereby eliminating our opportunity to commercialize other product candidates with other collaborative partners.

The Market May Not Be Receptive to Products Incorporating Our Aversion® Technology

The commercial success of products incorporating our Aversion® Technology that are approved for marketing by the FDA and other regulatory authorities will depend on acceptance by health care providers and others that such products are clinically useful, cost-effective and safe. There can be no assurance given, even if we succeed in the development of products incorporating our Aversion® Technology and receive FDA approval for such products, that products incorporating the Aversion® Technology would be accepted by health care providers and others. Factors that may materially affect market acceptance of products incorporating our Aversion® Technology include: (i) the relative advantages and disadvantages of our Aversion® Technology compared to competitive abuse deterrent technologies; (ii) the relative timing to commercial launch of products utilizing our Aversion® Technology compared to products incorporating competitive abuse deterrent technologies; (iii) the relative timing of the receipt of marketing approvals and the countries in which such approvals are obtained; (iv) the relative safety and efficacy of products incorporating our Aversion® Technology compared to competitive products; and/or (v) the willingness of third party payors to reimburse for or otherwise pay for products incorporating our Aversion® Technology.

Our product candidates, if successfully developed and commercially launched, will compete with both currently marketed and new products marketed by other companies. Health care providers may not accept or utilize any of our product candidates. Physicians and other prescribers may not be inclined to prescribe the products utilizing our Aversion® Technology unless our products bring clear and demonstrable advantages over other products currently marketed for the same indications. If our products licensed to partners do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

In the Event That We Are Successful in Bringing Any Products to Market, Our Revenues May Be Adversely Affected If We Fail to Obtain Acceptable Prices or Adequate Reimbursement For Our Products From Third-Party Payors

Our ability to commercialize pharmaceutical products successfully may depend in part on the availability of reimbursement for our products from government and health administration authorities, private health insurers, and other third-party payors, including Medicaid and Medicare. We cannot predict the availability of reimbursement for newly-approved products incorporating our Aversion® Technology. Third-party payors, including state Medicaid programs and Medicare, are challenging the prices charged for pharmaceutical products. Government and other third-party payors increasingly are limiting both coverage and the level of reimbursement for new drugs. Third-party insurance coverage may not be available to patients for any of our products. The continuing efforts of government and third-party payors to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payors do not provide adequate coverage and reimbursement for any product incorporating our Aversion® Technology, health care providers may not prescribe them or patients may ask to have their health care providers to prescribe competing products with more favorable reimbursement. In some foreign markets, pricing and profitability of pharmaceutical products are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. In addition, we expect that increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we receive for any products in the future. Further, cost control initiatives could impair our ability or the ability of our partners to commercialize our products and our ability to earn revenues from this commercialization.

Our Success Depends on Our Ability to Protect Our Intellectual Property

Our success depends in significant part on our ability to obtain patent protection for our Aversion® Technology, in the United States and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual questions. There is no assurance that any of our patent applications for our Aversion® Technology will issue or, if issued, that such patent(s) will be valid and enforceable against third-party infringement or that such patent(s) will not infringe any third-party patent or intellectual property. Moreover, even if patents do issue on our Aversion® Technology, the claims allowed may not be sufficiently broad to protect the products incorporating the Aversion® Technology. In addition, issued patents may be challenged, invalidated or circumvented. Even if issued, our patents may not afford us protection against competitors with similar technology or permit the commercialization of our products without infringing third-party patents or other intellectual property rights.

Our success also depends on our not infringing patents issued to competitors or others. We may become aware of patents and patent applications belonging to competitors and others that could require us to alter our technologies. Such alterations could be time consuming and costly. We may not be able to obtain a license to any technology owned by or licensed to a third party that we require to manufacture or market one or more products incorporating our Aversion® Technology. Even if we can obtain a license, the financial and other terms may be disadvantageous.

Our success also depends on our maintaining the confidentiality of our trade secrets and know-how. We seek to protect such information by entering into confidentiality agreements with employees, potential collaborative partners, potential investors and consultants. These agreements may be breached by such parties. We may not be able to obtain an adequate, or perhaps, any remedy to such a breach. In addition, our trade secrets may otherwise become known or be independently developed by our competitors. Our inability to protect our intellectual property or to commercialize our products without infringing third-party patents or other intellectual property rights would have a material adverse effect on our operations and financial condition.

We May Become Involved in Patent Litigation or Other Intellectual Property Proceedings Relating to Our Products, Aversion® Technology or Opioid Synthesis Technologies Which Could Result in Liability for Damages or Delay or Stop Our Development and Commercialization Efforts

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The types of situations in which we may become parties to such litigation or proceedings include: (i) we may initiate litigation or other proceedings against third parties to enforce our patent rights or other intellectual property rights; (ii) we may initiate litigation or other proceedings against third parties to seek to invalidate the patents held by such third parties or to obtain a judgment that our products or processes do not infringe such third parties' patents; (iii) if our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention; and (iv) if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we will need to defend against such proceedings.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our competitors will be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

Our Aversion® Technology may be found to infringe upon claims of patents owned by others. If we determine or if we are found to be infringing on a patent held by another, we might have to seek a license to make, use, and sell the patented technologies. In that case, we might not be able to obtain such license on terms acceptable to us, or at all. If a legal action is brought against us, we could incur substantial defense costs, and any such action might not be resolved in our favor. If such a dispute is resolved against us, we may have to pay the other party large sums of money and our use of our Aversion® Technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited. Even prior to resolution of such a dispute, use of our Aversion® Technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited.

Moreover, other parties could have blocking patent rights to products made using the Aversion® Technology. The Company is aware of certain United States and International pending patent applications owned by third parties claiming abuse deterrent technologies. If such patent applications result in issued patents, with claims encompassing our Aversion® Technology or products, the Company may need to obtain a license to such patents, should one be available, or alternatively, alter the Aversion® Technology so as to avoid infringing such third-party patents. If the Company is unable to obtain a license on commercially reasonable terms, the Company could be restricted or prevented from commercializing products utilizing the Aversion® Technology. Additionally, any alterations to the Aversion® Technology in view of pending third-party patent applications could be time consuming and costly and may not result in technologies or products that are non-infringing or commercially viable.

The Company expects to seek and obtain licenses to such patents or patent applications when, in the Company's judgment, such licenses are needed. If any such licenses are required, there can be no assurances that the Company would be able to obtain any such license on commercially favorable terms, or at all, and if these licenses are not obtained, the Company might be prevented from making, using and selling the Aversion® Technology and products. The Company's failure to obtain a license to any technology that it may require would materially harm the Company's business, financial condition and results of operations. We cannot assure that the Company's products and/or actions in developing products incorporating our Aversion® Technology will not infringe third-party patents.

We May Be Exposed to Product Liability Claims and May Not Be Able to Obtain Adequate Product Liability Insurance

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise possess regulatory approval for commercial sale.

We are currently covered by clinical trial product liability insurance on a claims-made basis. This coverage may not be adequate to cover any product liability claims. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to liability claims. Any claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations.

The pharmaceutical industry is characterized by frequent litigation. Those companies with significant financial resources will be better able to bring and defend any such litigation. No assurance can be given that we would not become involved in such litigation. Such litigation may have material adverse consequences to the Company's financial conditions and operations.

We Face Significant Competition Which May Result in Others Developing or Commercializing Products Before or More Successfully Than We Do

The pharmaceutical industry is highly competitive and is affected by new technologies, governmental regulations, health care legislation, availability of financing, litigation and other factors. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at lower costs. If our products are unable to capture and maintain market share, we will not achieve significant product revenues and our financial condition will be materially adversely affected.

We will compete for market share against fully integrated pharmaceutical companies or other companies that collaborate with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have products already approved, marketed or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs, have substantially greater financial resources, experience in developing products, obtaining FDA and other regulatory approvals, formulating and manufacturing drugs, and commercializing drugs than we do.

We are concentrating substantial all of our efforts on developing product candidates incorporating our Aversion® Technology. The commercial success of products using our Aversion® Technology will depend, in large part, on the intensity of competition from other companies marketing branded opioid containing products, generic versions of branded opioid containing products and other drugs and technologies that compete with the products incorporating our Aversion® Technology, and the relative timing and sequence of new product approvals. Alternative technologies and products are being developed to improve or replace the use of opioids for pain management, several of which are in clinical trials or are awaiting approval from the FDA. In the event that such alternatives to opioid containing products are widely adopted, then the market for products incorporating our Aversion® Technology may be substantially decreased subsequently reducing the Company's opportunity to generate future revenues and profits.

The U.S. Drug Enforcement Administration ("DEA") Limits the Availability of the Active Ingredients Used in Our Product Candidates and, as a Result, Our Quota May Not Be Sufficient to Complete Clinical Trials or to Meet Commercial Demand or May Result in Development Delays

The DEA regulates certain finished products and bulk active pharmaceutical ingredients. Certain opioid active pharmaceutical ingredients in our current product candidates are classified by the DEA as Schedule II substances under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of regulation. Furthermore, the amount of Schedule II substances we can obtain for clinical trials and commercial distribution is limited by the DEA and our quota may not be sufficient to complete clinical trials or meet commercial demand. There is a risk that DEA regulations may interfere with the supply of the products used in our clinical trials, and, in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

We May Not Be Successful in Commercializing Our Opioid Synthesis Technologies

Historically the Company was engaged in research, development and manufacture of proprietary, high yield, short cycle time, environmentally sensitive opioid manufacturing processes (the "Opioid Synthesis Technologies") intended for use in the commercial manufacturing of certain bulk opioid active pharmaceutical ingredients ("APIs"). In early 2005 the Company suspended further development and commercialization efforts relating to its Opioid Synthesis Technologies. We have determined based on our limited cash reserves, the additional funding required for facility improvements for commercial scale up for our Opioid Synthesis Technologies, the projected timeline for resolution of our application to the DEA for a narcotic raw material import registration (the "Import Registration"), and other factors that suspending activities relating to the Opioid Synthesis Technologies is in our best interest. We expect to re-evaluate the development and commercialization of the Opioid Synthesis Technologies after the Administrative Law Judge and deputy DEA Administrator makes a determination relating to our Import Registration. No assurance can be given that development and commercialization efforts relating to the Opioid Synthesis Technologies will resume in the future, or even if such activities resume, that the Opioid Synthesis Technologies will be capable of commercial scale up or will be commercialized.

We May Not Obtain DEA Approval for Our Import Registration

Since early 2001 we have been engaged in the application process to obtain an Import Registration from the DEA to import narcotic raw materials directly from foreign countries for use in commercial manufacturing certain bulk opioid APIs. No assurance can be given that the Import Registration application will be approved by the DEA or that if granted by DEA, the Import Registration would be upheld following an appellate challenge.

The Market Price of Our Common Stock May Be Volatile

The market price of our common stock, like the market price for securities of pharmaceutical, biopharmaceutical and biotechnology companies, has historically been highly volatile. The market from time to time experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors, such as fluctuations in our operating results, future sales of our common stock, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements, clinical trial results, government regulation, developments in patent or other proprietary rights, public concern as to the safety of drugs developed by us or others, changes in reimbursement policies, comments made by securities analysts and general market conditions may have a significant effect on the market price of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources.

The Company's common stock trades on the OTC Bulletin Board, a NASD-sponsored inter-dealer quotation system. As the Company's common stock is not quoted on a stock exchange and is not qualified for inclusion on the NASD Small-Cap Market, our common stock could be subject to a rule by the Securities and Exchange Commission that imposes additional sales practice requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent for a transaction prior to sale. Consequently, the rule may affect the ability of broker-dealers to sell the Company's common stock and the ability of purchasers in the offering to sell the common stock received upon conversion of the Preferred Shares in the secondary market. There is no guarantee that an active trading market for our common stock will be maintained on the OTC Bulletin Board. Investors may be not able to sell their shares of common stock quickly or at the latest market price if trading in our common stock is not active.

Our Quarterly Results of Operations Will Fluctuate, and These Fluctuations Could Cause Our Stock Price to Decline

Our quarterly operating results are likely to fluctuate in the future. These fluctuations could cause our stock price to decline. The nature of our business involves variable factors, such as the timing of the research, development and regulatory pathways of our product candidates that could cause our operating results to fluctuate.

No Dividends

The Company has not declared and paid cash dividends on its common stock in the past, and the Company does not anticipate paying any cash dividends in the foreseeable future. The Company's senior term loan indebtedness prohibits the payment of cash dividends.

Control of the Company

GCE Holdings LLC beneficially owns approximately 78% of the Company's outstanding common stock. In addition, pursuant to the terms of the Amended and Restated Voting Agreement dated February 6, 2004, as amended, between the Company and the former holders of the Company's outstanding convertible preferred stock, all such shareholders have agreed that the Board of Directors shall be comprised of not more than 7 members, 4 of whom shall be the designees of GCE Holdings LLC (the assignee of all Preferred Stock prior to its conversion into common stock) formerly held by each of Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners International III, L.P., Galen Partners III, L.P. and Galen Employee Fund III, L.P.), As a result, GCE Holdings LLC, in view of its ownership percentage of the Company and by virtue of its controlling position on the Company's Board of Directors, will be able to control or significantly influence all matters requiring approval by our shareholders, including the approval of mergers or other business combination transactions. The interests of GCE Holdings LLC may not always coincide with the interests of other shareholders and such entity may take action in advance of its interests to the detriment of our other shareholders.

Key Personnel Are Critical to Our Business, and Our Future Success Depends on Our Ability to Retain Them

We are highly dependent on our management and scientific team, including Andrew D. Reddick, our President and Chief Executive Officer, and Ron J. Spivey, Ph.D. our Senior Vice President and Chief Scientific Officer. We may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. While we have employment agreements with certain employees, all of our employees are at-will employees who may terminate their employment with the Company at any time. We do not have key personnel insurance on any of our officers or employees. The loss of any of our key personnel, or the inability to attract and retain such personnel, may significantly delay or prevent the achievement of our product and technology development and business objectives and could materially adversely affect our business, financial condition and results of such operations.

Item 4. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures. The Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-14 as of the end of the period covered by this Report. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including its consolidated subsidiaries) required to be included in the Company's periodic Securities and Exchange Commission filings. No significant changes were made in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

Changes in Internal Control over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the period covered by this quarterly report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II

Item 2. ***Changes in Securities, Use of Proceed and Issuer Purchases of Equity Securities***

Issuance of Common Shares

During the quarter ended March 31, 2006, the Company issued its Common Stock in the amount of a) 207,856 shares as payment of $147,000 of interest payable due March 31, 2006 on the Company’s $5.0 million Secured Term Note Payable, b) 30,000 shares from the exercise of stock options and c) 19,065 shares from the cashless exercise of warrants.

Exemption from Registration

The Company issued the above-described Common Stock in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended and/or Regulation D promulgated under the Securities Act of 1933. Each of the recipients of such shares represented to the Company that such holder was an accredited investor as defined in Rule 501(a) of the Securities Act of 1933 and that the securities issued pursuant thereto were being acquired for investment purposes.

Item 6. ***Exhibits***

The exhibits required to be filed as part of this Report on form 10-Q are listed in the attached Exhibit Index.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: April 25, 2006
ACURA PHARMACEUTICALS, INC.
By: /s/ Andrew D. Reddick
Andrew D. Reddick
President & Chief Executive Officer

By: /s/ Peter A. Clemens
Peter A. Clemens
Senior VP & Chief Financial Officer

Exhibit Index

Exhibit	Document
31.1	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
31.2	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
32.1	Certification of Periodic Report by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Periodic Report by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.