

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2005

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

*(State or other Jurisdiction of
incorporation or organization)*

11-0853640

(I.R.S. Employer Identification No.)

616 N. North Court, Suite 120

Palatine, Illinois

(Address of Principal Executive Offices)

60067

(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 ☒ No ☐

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

Yes ☐ No ☒

As of July 14, 2005 the registrant had 23,152,438 shares of Common Stock, \$.01 par value, outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands)

	(Unaudited) June 30, 2005	December 31, 2004
	<u> </u>	<u> </u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 1,033	\$ 3,103
Cash and cash equivalents- restricted	200	--
Prepaid expenses and other current assets	<u>216</u>	<u>307</u>
Total current assets	1,449	3,410
PROPERTY, PLANT & EQUIPMENT, NET	1,422	1,555
OTHER ASSETS AND DEPOSITS	<u>7</u>	<u>2</u>
TOTAL ASSETS	<u><u>\$ 2,878</u></u>	<u><u>\$ 4,967</u></u>

See accompanying notes to consolidated financial statements.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	(Unaudited) June 30, 2005	December 31, 2004
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Senior secured term note payable	\$ 1,000	\$ --
Current maturities of capital lease obligations	30	29
Accrued expenses	369	959
Total current liabilities	1,399	988
TERM NOTE PAYABLE		
	5,000	5,000
CAPITAL LEASE OBLIGATIONS, less current maturities		
	48	64
TOTAL LIABILITIES	6,447	6,052
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Convertible Preferred Stock - \$.01 par value; authorized 290,000,000 shares; issued and outstanding, 217,694,414 and 217,972,986 shares, at June 30, 2005 and December 31, 2004, respectively	2,177	2,180
Common stock - \$.01 par value; authorized 650,000,000 shares; issued and outstanding, 23,152,438 and 22,466,967 shares at June 30, 2005 and December 31, 2004, respectively	232	225
Additional paid-in capital	277,378	277,129
Unearned compensation	(485)	(1,078)
Accumulated deficit	(282,871)	(279,541)
STOCKHOLDERS' DEFICIT	(3,569)	(1,085)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>\$ 2,878</u>	<u>\$ 4,967</u>

See accompanying notes to consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(In thousands, except share and per share data)

	JUNE 30,			
	FOR THE SIX MONTHS ENDED		FOR THE THREE MONTHS ENDED	
	2005	2004	2005	2004
Net revenues	\$ --	\$ 838	\$ --	\$ 210
Cost of manufacturing	--	1,437	--	184
Research and development	1,682	1,242	729	1,004
Selling, marketing, general and administrative	1,492	2,363	537	1,142
Loss from operations	(3,174)	(4,204)	(1,266)	(2,120)
<u>Other income (expense)</u>				
Interest expense	(263)	(2,152)	(137)	(1,194)
Interest income	24	22	9	15
Amortization of deferred debt discount and private debt offering costs	--	(24,655)	--	(13,812)
Gain on asset disposals	83	1,755	13	1
Gain on debt restructure	--	12,401	--	--
Other	--	401	(1)	(2)
Total other expense	(156)	(12,228)	(116)	(14,992)
NET LOSS	<u>\$ (3,330)</u>	<u>\$ (16,432)</u>	<u>\$ (1,382)</u>	<u>\$ (17,112)</u>
Basic and diluted loss per share	<u>\$ (0.15)</u>	<u>\$ (0.76)</u>	<u>\$ (0.06)</u>	<u>\$ (0.79)</u>
Weighted average number of outstanding shares	<u>22,772,803</u>	<u>21,612,382</u>	<u>22,948,679</u>	<u>21,623,061</u>

See accompanying notes to consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED

(UNAUDITED)

(In thousands)

	<u>June 30,</u>	
	<u>2005</u>	<u>2004</u>
Cash flows from Operating Activities:		
Net loss	\$ (3,330)	\$ (16,432)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	65	251
Amortization of deferred debt discount and private debt offering costs	--	24,655
Amortization of deferred product acquisition costs	--	205
Non-cash compensation charge on options	593	--
Gain on asset disposals	(82)	(1,755)
Gain on debt restructure	--	(12,401)
Changes in assets and liabilities		
Accounts receivable	--	315
Inventories	--	312
Prepaid expenses and other current assets	91	182
Other assets and deposits	(5)	149
Accounts payable	--	(1,895)
Accrued expenses	(338)	2,665
Total adjustments	<u>324</u>	<u>12,683</u>
Net cash used in operating activities	<u>(3,006)</u>	<u>(3,749)</u>
Cash flows from Investing Activities:		
Capital expenditures	(34)	(99)
Proceeds from asset disposals	<u>184</u>	<u>2,002</u>
Net cash provided by investing activities	<u>150</u>	<u>1,903</u>
Cash flows from Financing Activities:		
Payments on senior secured term note payable	--	(4,000)
Proceeds from issuance of senior secured term note payable, less restricted cash	800	--
Payments on capital lease obligations	(14)	(30)
Proceeds from issuance of subordinated convertible debentures	--	11,951
Payments to Department of Justice	--	(434)
Net cash provided by financing activities	<u>786</u>	<u>7,487</u>
(Decrease) increase in cash and cash equivalents	(2,070)	5,641
Cash and cash equivalents at beginning of period	<u>3,103</u>	<u>942</u>
Cash and cash equivalents at end of period	<u><u>\$ 1,033</u></u>	<u><u>\$ 6,583</u></u>
Cash paid for interest	<u><u>\$ 6</u></u>	<u><u>\$ 47</u></u>

See accompanying notes to consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

(UNAUDITED)

SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:

For the six months ended June 30, 2005:

1. The Company has issued 406,899 shares of Common Stock as payment of \$253,000 of Term Note Payable accrued interest.
2. The Company has 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.

For the six months ended June 30, 2004:

1. The Company's Convertible Subordinated Debentures contained beneficial conversation features, which were valued at \$14,000,000.
2. The Company has repaid \$166,000 of indebtedness in the form of product deliveries.
3. Bridge Loans of \$2,000,000 and accrued interest of \$49,000 were converted into like amounts of Convertible Subordinated Debentures.
4. The Company has issued 114,322 shares of Common Stock as payment of \$63,000 of Secured Term Note Payable accrued interest.

See accompanying notes to consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

SIX MONTHS ENDED JUNE 30, 2005

(UNAUDITED)

(In thousands)

	<u>Preferred Stock</u> <u>\$.01 Par Value</u>		<u>Common Stock</u> <u>\$.01 Par Value</u>		<u>Additional</u> <u>Paid-in</u> <u>Capital</u>	<u>Unearned</u> <u>Compensation</u>	<u>Accumulated</u> <u>Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Balance at January 1, 2005	<u>217,973</u>	<u>\$ 2,180</u>	<u>22,467</u>	<u>\$ 225</u>	<u>\$ 277,129</u>	<u>\$ (1,078)</u>	<u>\$ (279,541)</u>	<u>\$ (1,085)</u>
Issuance of Common Shares for interest	--	--	407	4	249	--	--	253
Conversion of Series C-1 Junior Convertible Preferred Shares	(279)	(3)	279	3	--	--	--	--
Amortization of unearned compensation	--	--	--	--	--	593	--	593
Net loss	--	--	--	--	--	--	(3,330)	(3,330)
Balance at June 30, 2005	<u>217,694</u>	<u>\$ 2,177</u>	<u>23,153</u>	<u>\$ 232</u>	<u>\$ 277,378</u>	<u>\$ (485)</u>	<u>\$ (282,871)</u>	<u>\$ (3,569)</u>

See accompanying notes to consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 and six months ended June 30, 2005, assuming that the Company will continue as a going concern, have been made. The results of operations for the three and six month period ended June 30, 2005 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2005. The unaudited consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2004 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

In the fourth quarter of 2003 and first quarter of 2004, the Company restructured its operations and ceased the manufacture, sale and distribution of the Company's generic finished dosage pharmaceutical products by the Company's subsidiary, Axiom Pharmaceutical Corporation ("Axiom"). Axiom's manufacturing operations ceased on January 30, 2004, packaging and labeling operations ceased approximately February 12, 2004 and quality assurance and related support activities ceased approximately February 27, 2004.

As restructured, the Company is an emerging specialty pharmaceutical company primarily engaged in research and development of proprietary abuse deterrent formulation technologies ("AversionTM Technology") intended to deter the abuse of orally administered opioid analgesic products. The Company is also engaged in collaborative research and development with a contract research organization and an academic institution for clinical evaluation and testing of the AversionTM Technology. In addition, to a much lesser extent, during 2004 and early 2005, the Company was 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 AversionTM Technology, the "Technologies") intended for use in the commercial production of certain bulk opioid APIs. The Company has suspended further development and commercialization efforts relating to the Opioid Synthesis Technologies. The Company expects to re-evaluate the development and commercialization of the Opioid Synthesis Technologies after the Administrative Law Judge's determination relating to the Company's Import Registration which was 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.

As of June 30, 2005, the Company has one (1) provisional US, two (2) non provisional US and one (1) international patent applications pending relating to its AversionTM Technology. Additionally, the Company has three (3) US patents issued, three (3) US Notices of Allowance granted, four (4) US and one (1) international patent applications pending related to its Opioid Synthesis Technologies. As of July 14, 2005, the Company retained ownership of all intellectual property and commercial rights to its product candidates and Technologies.

The Company conducts research, development, laboratory, stability, manufacturing and warehousing activities relating to the AversionTM Technology at its Culver, Indiana 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 plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license the Company's Aversion™ Technology and further develop, register and commercialize multiple formulations and strengths of orally administered opioid-containing finished dosage products utilizing the Aversion™ Technology. 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. The Company also believes that it may derive revenues through contract manufacture and supply of clinical trial and commercial supplies of finished dosage products for use by such Partners.

The Company's development activities involve inherent risks. These risks include, among others, the feasibility and commercial acceptance of the Company's proprietary technologies, dependence on key personnel and determination of patentability and protection of the Company's products and technologies. Additionally, the Company's product candidates have not yet obtained the approval of the Food and Drug Administration. Successful future operations depend on the Company's ability to obtain approval for and commercialize these products.

NOTE 2 - LIQUIDITY MATTERS

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. At June 30, 2005, the Company had unrestricted cash and cash equivalents of \$1.0 million, working capital of \$0.1 million, and accumulated deficit of \$282.9 million. At December 31, 2004, the Company had cash and cash equivalents of \$3.1 million, working capital of \$2.4 million and accumulated deficit of \$279.5 million. The Company incurred a loss from operations of \$3.2 million and a net loss of \$3.3 million during the six months ended June 30, 2005 and a loss from operations of \$9.9 million and a net loss of \$70.0 million during the year ended December 31, 2004. Historically, the Company has incurred significant losses from operations and until such time as its research and development efforts are commercialized, of which no assurance can be given, the Company will continue to incur operating 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 will be sufficient to fund the development of the Aversion™ Technology and related operating expenses only through late August 2005. To fund operations through March, 2006, the Company estimates that it 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 an issued U.S. patent 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 (the “FASB”) released FASB Statement No. 123 (revised 2004), “Share-Based Payment, (“SFAS 123R”)”. These changes in accounting replace existing requirements under FASB Statement No. 123, “Accounting for Stock-Based Compensation”, and eliminates the ability to account for share-based compensation transaction using APB Opinion No.25, “Accounting for Stock Issued to Employees”. The compensation cost relating to share-based payment transactions will be measured based on the fair value of the equity or liability instruments issues. This Statement does not change the accounting for similar transactions involving parties other than employees. In April 2005, the Securities and Exchange Commission (the “SEC”) delayed implementation of SFAS 123R for publicly traded companies such that they must apply this Standard as of the beginning of the next fiscal year that begins after June 15, 2005. This Statement applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date. The cumulative effect of initially applying this Statement, if any, is recognized as of the required effective date. The Company has not completed it evaluation of the impact of adopting SFAS 123R on its consolidated financial statements, but anticipates that more compensation costs will be recorded in the future if the use of options for employees and director compensation continues as in the past.

Changes and Error Corrections

In May 2005, the FASB issued Statement of Financial Accounting Standards No. 154, “Accounting Changes and Error Corrections - A Replacement of APB Opinion No. 20 and FASB Statement No. 3.”, (“SFAS 154”). SFAS 154 primarily requires retrospective application to prior periods’ financial statements for the direct effects of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005, and early adoption is permitted. The Company is required to adopt the provision of SFAS 154, as applicable, beginning in fiscal 2007.

NOTE 4 - RECLASSIFICATIONS

Certain reclassifications have been made on the December 31, 2004 balance sheet to conform to the June 30, 2005 balance sheet presentation.

NOTE 5 - CASH AND CASH EQUIVALENTS

For purposes of the consolidated statements of cash flows, the Company considers all highly liquid debt instruments purchased with a maturity date of three months or less to be cash equivalents. At June 30, 2005, the Company did not have any purchased debt instruments. At December 31, 2004, cash equivalents consisted of bank investments totaling approximately \$2.6 million.

At June 30, 2005, the Company had pledged \$200,000 of cash against the \$1,000,000 Senior Secured Term Note Payable maturing on June 1, 2006.

NOTE 6 - RESEARCH AND DEVELOPMENT

Research and development expenses consist of direct costs and indirect costs. Direct research and development costs include salaries and related costs of research and development personnel, and the costs of consultants, patent counsel, facilities, materials and supplies associated with research and development projects as well as various laboratory studies. Indirect research and development costs include depreciation and other indirect overhead expenses. The Company considers that regulatory and other uncertainties inherent in the research and development of new products preclude it from capitalizing such costs. This includes up-front and milestone payments made to third parties in connection with research and development collaborations.

The Company had \$859,000 of research and development commitments with third parties at June 30, 2005. The Company had no research and development commitments with third parties at December 31, 2004.

NOTE 7 - INCOME TAXES

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 by the Company.

The Financial Accounting Standards Board Statement "Accounting for Income Taxes" ("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 June 30, 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.

NOTE 8 - STOCK-BASED COMPENSATION

The Company accounts for stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations ("APB No. 25") and has adopted the disclosure provisions of Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation -- Transition and Disclosure, an amendment of FASB Statement No. 123." Under APB No. 25, when the exercise price of the Company's employee stock options equals or exceeds the market price of the underlying stock on the date of grant, no compensation expense is recognized.

The following table illustrates the effect on net loss and loss per share had the Company applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," to stock-based employee compensation.

	JUNE 30,			
	FOR THE		FOR THE	
	SIX MONTHS ENDED		THREE MONTHS ENDED	
	2005	2004	2005	2004
	(In thousands, except per share data)			
Net loss, as reported	\$ (3,330)	\$ (16,432)	\$ (1,382)	\$ (17,112)
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(59)	(111)	(28)	(47)
Net loss, pro forma	<u>\$ (3,389)</u>	<u>\$ (16,543)</u>	<u>\$ (1,410)</u>	<u>\$ (17,159)</u>
Weighted average number of outstanding shares	<u>22,773</u>	<u>21,612</u>	<u>22,949</u>	<u>21,623</u>
<u>Earnings per share:</u>				
Basic and diluted loss per share, as reported	<u>\$ (0.15)</u>	<u>\$ (0.76)</u>	<u>\$ (0.06)</u>	<u>\$ (0.79)</u>
Basic and diluted loss per share, pro forma	<u>\$ (0.15)</u>	<u>\$ (0.77)</u>	<u>\$ (0.06)</u>	<u>\$ (0.79)</u>

Pro forma compensation expense may not be indicative of future disclosures because they do not take into effect pro forma compensation expense related to grants before 1995. For purposes of estimating the fair value of each option 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 stock price volatility. Because the Company's employee stock options 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.

NOTE 9 - UNEARNED COMPENSATION

The Company granted approximately 13,175,000 options to employees to purchase common stock for \$0.13 per share. As a result of the grant (in 2004), the Company recorded approximately \$3,030,000 of unearned compensation in accordance with APB Opinion No. 25; \$593,000 and \$0 of the unearned compensation was amortized to expense during the six months ended June 30, 2005 and June 30, 2004, respectively. The Company amortizes unearned compensation over the vesting period of the underlying option.

NOTE 10 - (LOSS) EARNINGS PER SHARE

Basic (loss) earnings per share is computed by dividing net (loss) earnings by the weighted average of common shares outstanding during the reporting period. Diluted (loss) earnings per share is computed by dividing net (loss) earnings by the weighted average of common shares plus potential dilutive common share equivalents outstanding during the reporting periods presented. Potential dilutive common share equivalents consist of outstanding stock options, assuming the exercise of all in-the-money stock options, warrants, convertible debentures and convertible preferred shares. The treasury stock method is used to calculate potential dilutive outstanding stock options and warrants.

	JUNE 30,			
	FOR THE SIX MONTHS ENDED		FOR THE THREE MONTHS ENDED	
	2005	2004	2005	2004
	(In thousands, except per share data)			
Numerator:				
Net loss	\$ (3,330)	\$ (16,432)	\$ (1,382)	\$ (17,112)
Denominator:				
Basic weighted average of shares outstanding	22,773	21,612	22,949	21,623
Convertible debentures	--	--	--	--
Convertible preferred stock	--	--	--	--
Warrants	--	--	--	--
Stock options	--	--	--	--
Diluted weighted average of shares outstanding	22,773	21,612	22,949	21,623
Earnings per share:				
Basic and diluted loss per share	\$ (0.15)	\$ (0.76)	\$ (0.06)	\$ (0.79)

For the six month periods ended June 30, 2005 and 2004, approximately 346.7 million and 340.5 million, respectively, and for the three month periods ended June 30, 2005 and 2004, approximately 341.2 million and 340.5 million, respectively, of common stock equivalents relating to outstanding warrants, options and convertible preferred shares have been excluded from the calculation of diluted loss per share because they are anti-dilutive.

NOTE 11 - CONVERTIBLE PREFERRED STOCK

At June 30, 2005, convertible preferred stock consists of the following:

Convertible Preferred Stock	Authorized Shares	June 30, 2005			
		Issued and Outstanding Shares	\$.01 Par Value	Common Stock Equivalents	Liquidation Preference
Series A	45,000,000	21,963,757	\$ 219,638	109,818,785	\$ 70,558,570
Series B Junior	25,000,000	20,246,506	202,465	20,246,506	6,924,305
Series C-1 Junior	70,000,000	56,143,987	561,440	56,143,987	32,428,767
Series C-2 Junior	50,000,000	37,433,096	374,331	37,433,096	22,433,655
Series C-3 Junior	100,000,000	81,907,068	819,071	81,907,068	28,511,850
Total	290,000,000	217,694,414	\$ 2,176,945	305,549,442	\$ 160,857,147

2004 Debenture Offering

On February 10, 2004, the Company consummated a private offering of convertible senior secured debentures (the "2004 Debentures") in the aggregate principal amount of approximately \$12.3 million (the "2004 Debenture Offering"). The 2004 Debentures were issued by the Company pursuant to a certain Debenture and Share Purchase Agreement dated as of February 6, 2004 (the "2004 Purchase Agreement") by and among the Company, Care Capital Investments, Essex Woodlands Health Ventures, Galen Partners and each of the purchasers listed on the signature page thereto. On April 14, 2004 and May 26, 2004, the Company completed additional closings under the 2004 Purchase Agreement raising the aggregate gross proceeds received by the Company from the offering of the 2004 Debentures to \$14.0 million. As the conversion price of the 2004 Debentures was less than the fair market value of the Company's Common Stock on the date of issue, beneficial conversion features were determined to exist. The Company recorded approximately \$14.0 million of debt discount limited to the face amount of the new debt. The debt discount was amortized over the life of the debt, which matured on August 13, 2004, the date the 2004 Debentures were automatically converted into the Company's Series A Convertible Preferred Stock.

Pursuant to the terms of the 2004 Purchase Agreement and other documents executed in connection with the 2004 Debentures, effective August 13, 2004, each of the holders of the Company's 2004 Debentures converted the 2004 Debentures into the Company's Series A preferred shares (the "Series A Preferred"). In addition, effective August 13, 2004, each of the holders of the Company's 5% convertible senior secured debentures issued during the period 1998 through and including 2003 converted such debentures into the Company's Series B Preferred Stock (the "Series B Preferred") and/or Series C-1, C-2 and/or C-3 preferred stock (collectively, the "Series C Preferred"). The Series C Preferred shares together with the Series B Preferred shares are herein referred to as the "Junior Preferred Shares"). Upon conversion of the Company's outstanding debentures, the Company issued approximately 21.9 million Series A Preferred shares, approximately 20.2 million Series B Preferred shares, approximately 56.4 million Series C-1 Preferred shares, approximately 37.4 million Series C-2 Preferred shares and approximately 81.9 million Series C-3 Preferred shares. The Series A Preferred shares and the Junior Preferred Shares are convertible into an aggregate of approximately 349.7 million shares of the Company's Common Stock.

Series A Preferred Stock Liquidation Preference, Conversion Right and Participation Right

In general, the Series A Preferred Shares have a liquidation preference equal to five (5) times the initial \$0.6425 Series A conversion price (the "Series A Liquidation Preference"). In addition, the Series A Preferred Shares are convertible into the Company's Common Stock, with each Series A Preferred Share convertible into the number of shares of Common Stock obtained by dividing (i) the Series A Liquidation Preference, by (ii) the \$0.6425 Series A conversion price, as such conversion price may be adjusted, from time to time, pursuant to the dilution protections of such shares. Without limiting the Series A Liquidation Preference, the holders of Series A Preferred Shares also have the right to participate with the holders of the Company's Common Stock upon the occurrence of a liquidation event, including the Company's merger, sale of all or substantially all of its assets or a change of control transaction, on an as-converted basis (but for these purposes only, assuming the Series A Preferred Shares to be convertible into only thirty percent (30%) of the shares of Common Stock into which they are otherwise then convertible). The holders of Series A Preferred Shares also have the right to vote as part of a single class with all holders of the Company's voting securities on all matters to be voted on by such security holders. Each holder of Series A Preferred Shares will have such number of votes as shall equal the number of votes he would have had if such holder converted all Series A Preferred Shares held by such holder into shares of Common Stock immediately prior to the record date relating to such vote.

Liquidation Preference of Junior Preferred Shares

In general, the Series B and Series C Preferred Shares (collectively, the "Junior Preferred Shares") have a liquidation preference equal to one (1) times the principal amount plus accrued and unpaid interest of the Debentures that were converted into Junior Preferred Shares. The liquidation preference of the Series B Preferred has priority over, and will be satisfied prior to, the liquidation preference of the Series C Preferred. The liquidation preference for each class of the Junior Preferred Shares is equal to the conversion prices of such shares. The Junior Preferred Shares are convertible into the Company's Common Stock, with each Junior Preferred Share convertible into one share of Common Stock. The holders of the Junior Preferred Shares have the right to vote as part of the single class with all holders of the Company's Common Stock and the holders of the Series A Preferred on all matters to be voted on by such stockholders, with each holder of Junior Preferred Shares having such number of votes as shall equal the number of votes he would have had if such holder had converted all Junior Preferred Shares held by such holder into Common Stock immediately prior to the record date relating to such vote.

Conversions

During the six months ended June 30, 2005 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.

NOTE 12 - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	<u>June 30, 2005</u>	<u>December 31, 2004</u>
	(In thousands)	
Bonus, Payroll, Payroll Taxes and Benefits	67	573
Legal Fees	75	124
Audit Examination and Tax Preparation Fees	51	85
Litigation Settlement	35	25
Franchise Taxes	60	--
Property and Sales Taxes	53	30
Medicaid Rebates	16	50
Regulatory, Trademarks and Patent Consulting	12	40
Other	--	32
	<u>\$ 369</u>	<u>\$ 959</u>

Bridge Loan Financing

The Company is a party to a Loan Agreement, dated June 22, 2005 (the “Bridge Loan Agreement”) by and among Essex Woodlands Health Venture V, L.P., Care Capital Investments II, L.P., Care Capital Offshore Investments II, L.P., Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (collectively, the “Bridge Lenders”) providing for bridge financing to the Company in the principal amount of \$1.0 million (the “2005 Bridge Loan”). The net proceeds from the 2005 Bridge Loan, after the satisfaction of related expenses, will be used by the Company to continue the development of its Aversion™ Technology and to fund operating expenses. The 2005 Bridge Loan is 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 2005 Bridge Loan bears interest at the rate of ten percent (10%) per annum and matures on June 1, 2006. The 2005 Bridge Loan is 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 cash proceeds to the Company, net of all costs and expenses, of at least \$3.5 million. The Bridge Loan Agreement requires that the Company maintain minimum cash deposits of at least \$200,000. The Bridge Loan Agreement 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.

Original Terms of Watson Term Loan

In connection with various transactions between the Company and Watson completed in 2001, Watson advanced \$17.5 million to the Company under the terms of a certain loan agreement by and between the Company and Watson (“Watson Term Loan”), dated as of March 29, 2000, as subsequently amended on each of June 30, 2000, December 20, 2002 and February 6, 2004. The Watson Term Loan was evidenced by a note in the principal amount of \$17.5 million (the “Original Watson Note”). The Watson Term Loan was secured by a first lien on all of the Company’s assets, senior to the lien securing all other Company indebtedness, and carried a floating rate of interest equal to prime plus two percent and had an original maturity date of June 30, 2004.

2002 Amendment to Watson Term Loan and Issuance of the Watson Warrant

As part of the Company’s 2002 Debenture Offering, the Watson Term Loan was amended to (1) extend the maturity date to June 30, 2006, (2) increase the interest rate to prime plus four and one half percent and (3) increase the principal amount to approximately \$21.4 million to reflect the inclusion of the Company’s payment obligations under the Core Products Supply Agreement between Watson and the Company. As amended, the Watson Term Loan was evidenced by the Original Watson Note and an additional note in the principal amount of approximately \$ 3.9 million (collectively, the “Watson Notes”). In consideration of the amendment to the Watson Term Loan, the Company issued to Watson a common stock purchase warrant (“Watson Warrant”) exercisable for 10,700,665 shares of the Company’s common stock at an exercise price of \$0.34 per share. The warrant has a term expiring December 31, 2009. The fair value of the Watson Warrant on the date of grant, as calculated using the Black-Scholes option-pricing model, of \$11,985,745 was charged to earnings on the date of grant as a loss on the extinguishment of debt. As of December 31, 2003, Watson had advanced approximately \$21.4 million to the Company under the Watson Term Loan and the interest rate was 8.50%.

2004 Amendment to Watson Term Loan

In satisfaction of a condition to the completion of the Company’s 2004 Debenture Offering, simultaneous with the initial closing of such offering, the Watson Term Loan was further amended, as a result of which (1) the Company paid Watson the sum of approximately \$4.3 million (which amount was funded from the proceeds of the 2004 Debenture Offering), (2) the Company conveyed to Watson certain Company assets in consideration for Watson’s forgiveness of approximately \$16.4 million of indebtedness under the Watson Notes, (3) all

then-current supply agreements between the Company and Watson were terminated , (4) Watson waived the dilution protections contained in the Watson Warrant, to the extent such dilution protections were triggered by the transactions provided in the 2004 Debenture Offering and (5) the Watson Notes were consolidated into a single note in the principal amount of \$5.0 million (the “2004 Note”), which (i) bears interest at the rate equal to the prime rate plus four and one half percent (4.5%) per annum, (ii) has a maturity date of June 30, 2007 (extended from June 30, 2006), (iii) provides for satisfaction of future quarterly interest payments thereunder in the form of the Company’s Common Stock, (iv) provides for the forbearance from the exercise of rights and remedies upon the occurrence of certain events of default thereunder and (v) is secured by a first lien on all assets of the Company. Further, the Company’s obligations under the 2004 Note are guaranteed by Acura Pharmaceutical Technologies, Inc. and Axiom Pharmaceutical Corporation, each a wholly-owned subsidiary of the Company, which guarantees are secured by all assets of such subsidiaries, and, in the case of Acura Pharmaceutical Technologies, Inc., by a mortgage lien on its real property located in Culver, Indiana.

Purchase of the 2004 Note

Simultaneous with the issuance of the 2004 Note, each of the investors in the 2004 Debentures at the initial closing of the offering on February 10, 2004 (collectively, the “Watson Note Purchasers”) purchased the 2004 Note from Watson in consideration for a payment to Watson of \$1.0 million. The 2004 Note was secured by a first 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%, provides for the satisfaction of interest payments in the form of the Company’s Common Stock and matures on June 30, 2007. The rate of interest at June 30, 2005 was 10.50%. Effective July 1, 2005, the rate of interest increased to 10.75%. As part of the completion of the 2005 Bridge Loan, the Watson Note Purchasers and the Bridge Lenders executed a Subordination Agreement, dated June 22, 2005, providing for the subordination of the lien and payment priority of the 2004 Note in favor of the lien and payment priority of the 2005 Bridge Loan.

NOTE 14 - COMMITMENTS AND CONTINGENCIES

Employment Contracts

Andrew D. Reddick is employed pursuant to an Employment Agreement effective as of August 26, 2003, which provides that Mr. Reddick will serve as the Company's Chief Executive Officer and President for an initial term expiring August 26, 2005. The term of the Employment Agreement provides for automatic one (1) year renewals in the absence of written notice to the contrary from the Company or Mr. Reddick at least ninety (90) days prior to the expiration of the initial term or any subsequent renewal period. The Employment Agreement was amended on May 24, 2005 to reduce the written notice period from at least ninety (90) days to thirty (30) days prior to the expiration of the initial term.

Peter A. Clemens is employed pursuant to an Employment Agreement effective as of March 10, 1998, with amendments dated June 28, 2000, and May 4, 2001. On January 5, 2005, the employment agreement was amended to provide that Mr. Clemens will serve as the Company's Senior Vice President and Chief Financial Officer for a term expiring April 30, 2006.

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. Operating results are not necessarily indicative of results that may occur in future periods.

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 Acura Pharmaceuticals, Inc. ("Acura" or 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, general economic conditions, competitive conditions, technological conditions and governmental legislation. More specifically, important factors that may affect future results include, but are not limited to: changes in laws and regulations, particularly those affecting the Company's operations; the Company's ability to continue to attract, assimilate 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 successfully develop and market its products; customer responsiveness to new products and distribution channels; its ability to compete successfully against current and future competitors; its dependence on third-party suppliers of raw materials; the availability of 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 an early stage of development and may not ever have any products that generate significant revenue. When used in this Report, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions are intended to identify forward-looking statements. Additionally, such forward-looking statements are subject to the risks and uncertainties discussed below under the section entitled "Risk Factors Relating to the Company".

Overview

In November 2003, the Company commenced the restructuring of its operations to focus its efforts on research and development relating to the Aversion™ Technology and Opioid Synthesis Technologies and to provide for the cessation of operations, and the sale of assets, relating to the manufacture and distribution of finished dosage generic products conducted at the Company's Congers, New York facilities (the "Congers Facilities").

To fund continuing operations and the research and development of the Company's proprietary Technologies, on February 10, 2004, the Company completed a private offering of debentures in the aggregate principal amount of approximately \$12.3 million (the "2004 Debenture Offering"). As part of the completion of the 2004 Debenture Offering, the Company retired approximately \$16.4 million in indebtedness under the Company's \$21.4 million term loan with Watson Pharmaceuticals. On April 14, 2004 and May 26, 2004 the Company completed additional funding under the 2004 Debenture Offering in the aggregate principal amount of approximately \$1.7 million resulting in an aggregate principal amount of convertible secured debentures issued as part of the 2004 Debenture Offering of \$14.0 million. In accordance with the terms of the documents executed in connection with the 2004 Debenture Offering, effective August 13, 2004, the aggregate principal amount of the 2004 Debentures as well as Company's other convertible debentures issued during the period 1998 through 2003 (aggregating approximately \$80.6 million) converted into various classes of the Company's preferred shares.

On February 18, 2004, the Company sold certain of its inactive, non-revenue generating Abbreviated New Drug Applications ("ANDAs") to Mutual Pharmaceutical Company, Inc. in consideration of \$2.0 million. On March 19, 2004, the Company and its wholly-owned subsidiary, Axiom Pharmaceutical Corporation, entered into an Asset Purchase Agreement with IVAX Pharmaceuticals New York LLC ("IVAX") pursuant to which the Company and Axiom agreed to sell to IVAX substantially all of the Company's assets used in the operation of the Congers Facilities in consideration of \$2.5 million. On August 13, 2004, the Company completed the sale of the assets used in the operation of the Congers Facilities to IVAX.

As restructured, the Company is an emerging specialty pharmaceutical company primarily engaged in research and development of proprietary abuse deterrent formulation technologies ("Aversion™ Technology") intended to deter the abuse of orally administered opioid analgesic products. In addition, to a lesser extent, during 2004 and early 2005, the Company was 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"). The Company has suspended further development and commercialization efforts relating to the Opioid Synthesis Technologies. The Company expects to re-evaluate the development and commercialization of the Opioid Synthesis Technologies after the Administrative Law Judge's determination relating to the Company's Import Registration.

As of June 2005, the Company has one (1) provisional US, two (2) non provisional US and one (1) international patent applications pending relating to its Aversion™ Technology. Additionally, the Company has three (3) US patents issued, three (3) US Notice of Allowance granted, four (4) US and one (1) international patent applications pending related to its Opioid Synthesis Technologies.

Company's Present Financial Condition and Commercial Focus

At June 30, 2005, the Company had unrestricted cash and cash equivalents of approximately \$1.0 million compared to approximately \$3.1 million at December 31, 2004. The Company had working capital of \$0.1 million and \$2.4 million at June 30, 2005 and December 31, 2004, respectively. The Company had an accumulated deficit of approximately \$282.9 million and approximately \$279.5 million at June 30, 2005 and December 31, 2004, respectively. The Company incurred a loss from operations of approximately \$3.2 million and a net loss of approximately \$3.3 million during the six months ended June 30, 2005, as compared to a loss from operations and net loss of \$4.2 million and \$16.4 million, respectively, for the six months ended June 30, 2004.

In implementing the restructuring adopted by the Board, the Company has transitioned to a single vertically integrated operations facility located in Culver, Indiana. The Company's strategy and key activities to be conducted at the Culver Facility are as follows:

- o Development, in concert with Contract Research Organizations ("CROs"), of the Company's Aversion™ Technology for use in orally administered opioid finished dosage product candidates.
- o Manufacture and quality assurance release of clinical trial supplies of certain finished dosage form product candidates utilizing the Aversion™ Technology.
- o Evaluation, in concert with CROs, of certain finished dosage product candidates utilizing the Aversion™ Technology in clinical trials.
- o Scale-up and manufacture of commercial quantities of certain product candidates utilizing the Aversion™ Technology for sale by the Company's licensees.
- o Prosecution of the Company's application to the U.S. Drug Enforcement Administration ("DEA") for registration to import narcotic raw materials ("NRMs").
- o Negotiating and executing 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, file for regulatory approval with the FDA and other regulatory authorities and commercialize such products.

The Company has incurred net losses since 1992 and the Company's consolidated financial statements for each of the years ended December 31, 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:

- o The successful completion of the development, scale-up, clinical testing and acceptable regulatory review of the Aversion™ Technology;
- o The receipt of a Notice of Allowance and 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;
- o The commercialization of products incorporating the Aversion™ Technology without infringing the patents and other intellectual property rights of third parties; and,
- o The interest of third parties in the Technologies and the Company's ability to negotiate and execute commercially viable collaboration agreements with interested third parties relating to the Technologies.

Many of these factors will depend upon circumstances beyond the Company's control.

As of July 14, 2005, the Company had unrestricted cash and cash equivalents of approximately \$0.7 million. The Company estimates its current cash reserves will be sufficient to fund the development of the Aversion™ Technology and related operating expenses only through August, 2005. See “Liquidity and Capital Resources - Commercial Focus, Cash Reserves and Funding Requirements.”

To complete the development and regulatory approval of the Company's product candidates and commercialize such products, if any are approved by the FDA, the Company intends to enter into development and commercialization agreements with third party pharmaceutical company partners providing that such partners license the Company's Technologies and further develop, register and commercialize the Company's orally administered opioid-containing finished dosage products utilizing such 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 Company's Technologies. As of July 14, 2005, the Company did not have any such collaborative agreements, nor can there be any assurance that the Company will enter into collaborative agreements in the future.

Estimating the dates of completion of clinical development, and the costs to complete development, of the Company's product candidates would be highly speculative, subjective and potentially misleading. Pharmaceutical products require significant time to research, develop and commercialize, with the clinical trial portion of development generally taking several years to complete. 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.

Results of Operations for the Six Months Ended June 30, 2005 and June 30, 2004

In comparing results of operations for the six months ended June 30, 2005 with those for 2004 it is important to consider that in 2004 the Company, as restructured, focused the majority of its efforts and resources on research and development activities and subsequent to March, 2004, no longer maintained any generic manufacturing facilities or conducted any finished dosage manufacturing activities. Net product revenues and manufacturing expenses realized in 2004 were incurred as part of an orderly phase out of all generic product manufacturing and distribution activities.

Net Revenues

The Company's net revenues for the six months ended June 30, 2005 and June 30, 2004 were as follows (in thousands):

6/30/05 NET REVENUES	6/30/04 NET REVENUES	6/30/05-6/30/04 NET REVENUES CHANGE (\$)	6/30/05-6/30/04 NET REVENUES CHANGE (%)
\$ --	\$838	\$(838)	(100%)

The decrease in net revenues was a result of the Company's decision to restructure operations and cease the manufacture and distribution of finished dosage generic pharmaceutical products. The net revenues for the six months ended June 30, 2004 reflect the sale of remaining inventories of finished dosage generic pharmaceutical products during such period.

Cost of Manufacturing

The Company's cost of manufacturing for the six months ended June 30, 2005 and June 30, 2004 were as follows (in thousands):

6/30/05 COST OF MANUFACTURING	6/30/04 COST OF MANUFACTURING	6/30/05-6/30/04 COST OF MANUFACTURING CHANGE (\$)	6/30/05-6/30/04 COST OF MANUFACTURING CHANGE (%)
\$ --	\$1,437	\$(1,437)	(100%)

For the six months ended June 30, 2004 cost of manufacturing includes the fixed costs of the Company's generic finished dosage manufacturing operations primarily incurred in the first quarter of 2004. The Company's generic finished dosage manufacturing operations ceased in March 2004.

Research and Development Expenses

The Company's research and development expenses for the six months ended June 30, 2005 and June 30, 2004 were as follows (in thousands):

6/30/05 R&D EXPENSES	6/30/04 R&D EXPENSES	6/30/05-6/30/04 R&D EXPENSES CHANGE (\$)	6/30/05-6/30/04 R&D EXPENSES CHANGE (%)
\$1,682	\$1,242	\$440	35.4%

Research and development expense in the six months ended June 30, 2004 consisted primarily of product development costs associated with the manufacture and sale of finished dosage pharmaceutical products. Subsequent to June 30, 2004, research and development expense consists of drug development primarily associated with 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 2005 results is a \$284,000 benefit from the reversal of a bonus accrual and a non cash compensation charge of \$162 recorded for the vesting of non qualified stock options granted in the prior year.

Selling, Marketing, General and Administrative Expenses

Selling, marketing, general and administrative expenses for the six months ended June 30, 2005 and 2004 were as follows (in thousands):

6/30/05 SELLING, MARKETING, G&A EXPENSES	6/30/04 SELLING, MARKETING, G&A EXPENSES	6/30/05-6/30/04 SELLING, MARKETING, G&A EXPENSES CHANGE (\$)	6/30/05-6/30/04 SELLING, MARKETING, G&A EXPENSES CHANGE (%)
\$1,492	\$2,363	\$(871)	(36.9%)

Selling and marketing expense in the six months ended June 30, 2004 consisted primarily of costs associated with a manufacturer and distributor of finished dosage products. The decrease in selling, marketing, general and administrative expenses resulted from the Company's decision to restructure operations by discontinuing the distribution and sale of generic finished dosage pharmaceutical products and reducing its administrative support staff. During the six months ended June 30, 2005, the Company did not incur selling expenses and the marketing expenses consisted of costs of Aversion™ Technology market research studies and internal payroll costs. The Company's general and administrative expenses consisted of legal and other professional fees, corporate insurance, and payroll costs. Included in the 2005 results is a \$211,000 benefit from the reversal of a bonus accrual and a non cash compensation charge of \$431 recorded for the vesting of non qualified stock options granted in the prior year.

Environmental Compliance Expenses

During the six months ended June 30, 2005 and June 30, 2004, the Company incurred the following expenses in connection with environmental compliance (in thousands):

6/30/05 ENVIRONMENTAL COMPLIANCE EXPENSES	6/30/04 ENVIRONMENTAL COMPLIANCE EXPENSES	6/30/05-6/30/04 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE (\$)	6/30/05-6/30/04 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE (%)
\$ --	\$180	\$(180)	(100%)

The environmental compliance expenses related primarily to disposal of hazardous and controlled substances waste and related personnel costs for environmental compliance during the six month period ended June 30, 2004 when the Company maintained its manufacturing operations.

Interest Expense, Net of Interest Income

The Company's interest expense, net of interest income for the six months ended June 30, 2005 and June 30, 2004 was as follows (in thousands):

6/30/05 INTEREST EXPENSE, NET OF INTEREST INCOME	6/30/04 INTEREST EXPENSE, NET OF INTEREST INCOME	6/30/05-6/30/04 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (\$)	6/30/05-6/30/04 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (%)
\$239	\$2,130	\$(1,891)	(88.8%)

The change in the interest expense, net of interest income reflects the interest savings from the restructuring of the Company's Secured Term Note indebtedness to Watson Pharmaceuticals, Inc. in February, 2004 and the conversion of the Company's 5% convertible debentures into convertible preferred stock on August 13, 2004. The Company incurs interest at the prime interest rate plus 4.5% on its \$5.0 million Secured Term Note Payable and incurs 10.0% interest on its \$1.0 million Senior Secured Term Note Payable.

Amortization of Deferred Debt Discount and Private Debt Offering Costs

The Company's deferred debt discount and private debt offering costs for the six months ended June 30, 2005 and June 30, 2004 were as follows (in thousands):

6/30/05 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	6/30/04 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	6/30/05-6/30/04 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE (\$)	6/30/05-6/30/04 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE (%)
\$ -, consisting of	\$24,655, consisting of	\$(24,655)	(100%)
· \$ - private debt offering costs	· \$234 private debt offering costs		
· \$ - deferred debt discount	· \$24,421 deferred debt discount		

The Company incurred no debt discount nor debt offering cost amortization during the six months ended June 30, 2005 as a result of the conversion of all convertible debentures into convertible preferred stock at August 13, 2004, and all remaining unamortized deferred debt discount and private debt offering cost balances were written off to expense.

Net Loss

The Company's net loss for the six months ended June 30, 2005 and June 30, 2004 was as follows (in thousands):

6/30/05 NET LOSS	6/30/04 NET LOSS	6/30/05-6/30/04 NET (LOSS) CHANGE (\$)	6/30/05-6/30/04 NET INCOME (LOSS) CHANGE (%)
\$(3,330)	\$(16,432)	\$(13,102)	(79.7%)

Included in the net loss is for the six months ended June 30, 2005 is \$83 on gain from asset disposals. Included in net income for the six months ended June 30, 2004 are gains on debt restructuring of \$12,401 and asset sales of \$1,755 and other income of \$401 relating to settlement of a liability at discount.

Results of Operations for the Three Months Ended June 30, 2005 and June 30, 2004

In comparing results of operations for the three months ended June 30, 2005 with those for 2004 it is important to consider that in 2004 the Company, as restructured, has focused the majority of its efforts and resources on research and development activities and subsequent to March, 2004, no longer maintained any generic manufacturing facilities or conducted any finished dosage manufacturing and distribution activities. Net product revenues and manufacturing expenses realized in 2004 were incurred as part of an orderly phase out of all generic product manufacturing and distribution activities.

Net Revenues

The Company's net revenues for the three months ended June 30, 2005 and June 30, 2004 were as follows (in thousands):

3 MONTHS ENDED 6/30/05 NET REVENUES	3 MONTHS ENDED 6/30/04 NET REVENUES	3 MONTHS ENDED 6/30/05-6/30/04 NET REVENUES CHANGE (\$)	3 MONTHS ENDED 6/30/05-6/30/04 NET REVENUES CHANGE (%)
\$ --	\$210	\$(210)	(100%)

The decrease in net revenues was a result of the Company's decision to restructure operations and cease the manufacture and distribution of finished dosage generic pharmaceutical products. The net revenues for the three months ended June 30, 2004 reflect the sale of remaining inventories of saleable finished dosage generic pharmaceutical products during such period.

Cost of Manufacturing

The Company's cost of manufacturing for the three months ended June 30, 2005 and June 30, 2004 were as follows (in thousands):

3 MONTHS ENDED 6/30/05 COST OF MANUFACTURING	3 MONTHS ENDED 6/30/04 COST OF MANUFACTURING	3 MONTHS ENDED 6/30/05-6/30/04 COST OF MANUFACTURING CHANGE (\$)	3 MONTHS ENDED 6/30/05-6/30/04 COST OF MANUFACTURING CHANGE (%)
\$ --	\$184	\$(184)	(100%)

For the three months ended June 30, 2004 cost of manufacturing includes remaining costs of the Company's generic finished dosage manufacturing operations which ceased in March 2004.

Research and Development Expenses

The Company's research and development expenses for the three months ended June 30, 2005 and June 30, 2004 were as follows (in thousands):

3 MONTHS ENDED 6/30/05 R&D EXPENSES	3 MONTHS ENDED 6/30/04 R&D EXPENSES	3 MONTHS ENDED 6/30/05-6/30/04 R&D EXPENSES CHANGE (\$)	3 MONTHS ENDED 6/30/05-6/30/04 R&D EXPENSES CHANGE (%)
\$729	\$1,004	\$(275)	(27.4)%

Research and development expense in the three months ended June 30, 2004 consisted primarily of product development costs associated with the manufacture and sale of finished dosage pharmaceutical products. Subsequent to June 30, 2004, research and development expense consists of drug development work primarily associated with 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 2005 results is a \$379,000 benefit from the reversal of a bonus accrual and a non cash compensation charge of \$57 recorded for the vesting of non qualified stock options granted in the prior year.

Selling, Marketing, General and Administrative Expenses

Selling, marketing, general and administrative expenses for the three months ended June 30, 2005 and 2004 were as follows (in thousands):

3 MONTHS ENDED 6/30/05 SELLING, MARKETING, G&A EXPENSES	3 MONTHS ENDED 6/30/04 SELLING, MARKETING, G&A EXPENSES	3 MONTHS ENDED 6/30/05-6/30/04 SELLING, MARKETING, G&A EXPENSES CHANGE (\$)	3 MONTHS ENDED 6/30/05-6/30/04 SELLING, MARKETING, G&A EXPENSES CHANGE (%)
\$537	\$1,142	\$(605)	(53.0)%

Selling and marketing expense in the three months ended June 30, 2004 consisted primarily of costs associated with a manufacturer and distributor of finished dosage products. The decrease in selling, marketing, general and administrative expenses resulted from the Company's decision to restructure operations by discontinuing the distribution and sale of generic finished dosage pharmaceutical products and reducing its administrative support staff. During the three months ended June 30, 2005, the Company did not incur selling expenses and 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 2005 results is a \$282,000 benefit from the reversal of a bonus accrual and a non cash compensation charge of \$173 recorded for the vesting of non qualified stock options granted in the prior year.

Environmental Compliance Expenses

During the three months ended June 30, 2005 and June 30, 2004, the Company incurred the following expenses in connection with environmental compliance (in thousands):

3 MONTHS ENDED 6/30/05 ENVIRONMENTAL COMPLIANCE EXPENSES	3 MONTHS ENDED 6/30/04 ENVIRONMENTAL COMPLIANCE EXPENSES	3 MONTHS ENDED 6/30/05-6/30/04 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE (\$)	3 MONTHS ENDED 6/30/05-6/30/04 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE (%)
\$ -	\$83	\$(83)	(100%)

The environmental compliance expenses related primarily to disposal of hazardous and controlled substances waste and related personnel costs for environmental compliance during the three month period ended June 30, 2004 when the Company maintained its manufacturing operations.

Interest Expense, Net of Interest Income

The Company's interest expense, net of interest income for the three months ended June 30, 2005 and June 30, 2004 was as follows (in thousands):

3 MONTHS ENDED 6/30/05 INTEREST EXPENSE, NET OF INTEREST INCOME	3 MONTHS ENDED 6/30/04 INTEREST EXPENSE, NET OF INTEREST INCOME	3 MONTHS ENDED 6/30/05-6/30/04 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (\$)	3 MONTHS ENDED 6/30/05-6/30/04 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (%)
\$128	\$1,179	(\$1,051)	(89.1%)

The change in the interest expense, net of interest income reflects the interest savings from the restructuring of the Company's Secured Term Note indebtedness to Watson Pharmaceuticals, Inc. in February, 2004 as well as the conversion of the Company's 5.0% convertible debentures into convertible preferred stock on August 13, 2004. The Company incurs interest at the prime interest rate plus 4.5% on its \$5.0 million Secured Term Note Payable and incurs 10.0% interest on its \$1.0 million Senior Secured Term Note Payable.

Amortization of Deferred Debt Discount and Private Debt Offering Costs

The Company's deferred debt discount and private debt offering costs for the six months ended June 30, 2005 and June 30, 2004 were as follows (in thousands):

3 MONTHS ENDED 6/30/05 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	3 MONTHS ENDED 6/30/04 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	3 MONTHS ENDED 6/30/05-6/30/04 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE (\$)	3 MONTHS ENDED 6/30/05-6/30/04 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE (%)
\$ -, consisting of	\$13,812, consisting of	\$(13,812)	(100%)
· \$ - private debt offering costs	· \$136 private debt offering costs		
· \$ - deferred debt discount	· \$13,676 deferred debt discount		

The Company incurred no debt discount nor debt offering cost amortization during the three months ended June 30, 2005 as a result of the conversion of all convertible debentures into convertible preferred stock at August 13, 2004, and all remaining unamortized deferred debt discount and private debt offering cost balances were written off to expense.

Net Loss

The Company's net loss for the three months ended June 30, 2005 and June 30, 2004 was as follows (in thousands):

3 MONTHS ENDED 6/30/05 NET LOSS	3 MONTHS ENDED 6/30/04 NET LOSS	3/31/05-3/31/04 NET LOSS CHANGE (\$)	3/31/05-3/31/04 NET LOSS CHANGE (%)
\$(1,382)	\$(17,112)	\$(15,730)	(91.9%)

Included in the net loss for the three months ended June 30, 2005 is \$13 on gain from asset disposals. Included in net loss for the three months ended June 30, 2004 is amortization of deferred debt discount and deferred private offering costs of \$13,812.

Liquidity and Capital Resources

At June 30, 2005, the Company had unrestricted cash and cash equivalents of approximately \$1.0 million as compared to approximately \$3.1 million at December 31, 2004. The Company had working capital of approximately \$0.1 million at June 30, 2005 as compared to working capital of approximately \$2.4 million at December 31, 2004.

Bridge Loan Financing

The Company is a party to a Loan Agreement, dated June 22, 2005 (the "Bridge Loan Agreement") by and among Essex Woodlands Health Venture V, L.P., Care Capital Investments II, L.P., Care Capital Offshore Investments II, L.P., Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (collectively, the "Bridge Lenders") providing for bridge financing to the Company in the principal amount of \$1.0 million (the "2005 Bridge Loan"). The net proceeds from the 2005 Bridge Loan, after the satisfaction of related expenses, will be used by the Company to continue the development of its Aversion™ Technology and to fund operating expenses. The 2005 Bridge Loan is 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 2005 Bridge Loan bears interest at the rate of ten percent (10%) per annum and matures on June 1, 2006. The 2005 Bridge Loan is 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 cash proceeds to the Company, net of all costs and expenses, of at least \$3.5 million. The Bridge Loan Agreement requires that the Company maintain minimum cash deposits of at least \$200,000. The Bridge Loan Agreement 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.

2004 Debenture Offering

On February 10, 2004, the Company consummated a private offering of convertible senior secured debentures (the "2004 Debentures") in the aggregate principal amount of approximately \$12.3 million (the "2004 Debenture Offering"). The 2004 Debentures were issued by the Company pursuant to a certain Debenture and Share Purchase Agreement dated as of February 6, 2004 (the "2004 Purchase Agreement") by and among the Company, Care Capital Investments, Essex Woodlands Health Ventures, Galen Partners and each of the purchasers listed on the signature page thereto. On April 14, 2004 and May 26, 2004, the Company completed additional closings under the 2004 Purchase Agreement raising the aggregate gross proceeds received by the Company from the offering of the 2004 Debentures to \$14.0 million. As the conversion price of the 2004 Debentures was less than the fair market value of the Company's Common Stock on the date of issue, beneficial conversion features were determined to exist. The Company recorded approximately \$14.0 million of debt discount limited to the face amount of the new debt. The debt discount was amortized over the life of the debt, which matured on August 13, 2004, the date the 2004 Debentures were automatically converted into the Company's Series A Convertible Preferred Stock.

Pursuant to the terms of the 2004 Purchase Agreement and other documents executed in connection with the 2004 Debentures, effective August 13, 2004, each of the holders of the Company's 2004 Debentures converted the 2004 Debentures into the Company's Series A preferred shares (the "Series A Preferred"). In addition, effective August 13, 2004, each of the holders of the Company's 5% convertible senior secured debentures issued during the period 1998 through and including 2003 converted such debentures into the Company's Series B Preferred Stock (the "Series B Preferred") and/or Series C-1, C-2 and/or C-3 preferred stock (collectively, the "Series C Preferred"). The Series C Preferred shares together with the Series B Preferred shares are herein referred to as the "Junior Preferred Shares"). Upon conversion of the Company's outstanding debentures, the Company issued approximately 21.9 million Series A Preferred shares, approximately 20.2 million Series B Preferred shares, approximately 56.4 million Series C-1 Preferred shares, approximately 37.4 million Series C-2 Preferred shares and approximately 81.9 million Series C-3 Preferred shares. The Series A Preferred shares and the Junior Preferred Shares are convertible into an aggregate of approximately 349.7 million shares of the Company's Common Stock.

Amendment to Watson Term Loan Agreement

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"). It was a condition to the completion of the 2004 Debenture Offering that simultaneous with the closing of the 2004 Purchase Agreement, the Company shall have paid Watson the sum of approximately \$4.3 million (which amount was funded from the proceeds of the 2004 Debenture Offering) and conveyed to Watson certain Company assets in consideration for Watson's forgiveness of approximately \$16.4 million of indebtedness under the Watson Notes. A part of such transaction, the Watson Notes were amended to extend the maturity date of such notes from June 30, 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, to reduce the principal amount of the Watson Notes from \$21.4 million to \$5.0 million, and to provide for the forbearance from the exercise of rights and remedies upon the occurrence of certain events of default under the Watson Notes (the Watson Notes as so amended, the "2004 Note"). Simultaneous with the issuance of the 2004 Note, each of Care Capital, Essex Woodlands Health Ventures, Galen Partners and the other investors in the 2004 Debentures as of February 10, 2004 (collectively, the "Watson Note Purchasers") purchased the 2004 Note from Watson in consideration for a payment to Watson of \$1.0 million.

In addition to Watson's forgiveness of approximately \$16.4 million under the Watson Notes, as additional consideration for the Company's payment to Watson of approximately \$4.3 million and the Company's conveyance of certain Company assets, all supply agreements between the Company and Watson were terminated and Watson waived the dilution protections contained in the Common Stock purchase warrant dated December 20, 2002 exercisable for approximately 10.7 million shares of the Company's Common Stock previously issued by the Company to Watson, to the extent such dilution protections were triggered by the transactions provided in the 2004 Debenture Offering.

Terms of the 2004 Note

The 2004 Note in the principal amount of \$5.0 million as purchased by the Watson Note Purchasers was secured by a first lien on all of the Company's and its subsidiaries' assets, senior to the lien securing the Outstanding Debentures and all other Company indebtedness, carries a floating rate of interest equal to the prime rate plus 4.5% (paid quarterly in the Company's common stock) and matures on June 30, 2007.

As part of the completion of the 2005 Bridge Loan, the Watson Note Purchasers and the Bridge Lenders executed a Subordination Agreement, dated June 22, 2005, providing for the subordination of the lien and payment priority of the 2004 Note in favor of the lien and payment priority of the 2005 Bridge Loan.

Sale of Certain Company Assets

On March 19, 2004, the Company and its wholly-owned subsidiary, Axiom Pharmaceutical Corporation ("Axiom"), entered into an Asset Purchase Agreement with IVAX Pharmaceuticals New York LLC ("IVAX"). Pursuant to the Purchase Agreement, the Company and Axiom agreed to sell to IVAX substantially all of the Company's assets used in the operation of the Company's former generic manufacturing and packaging operations located in Congers, New York in consideration of an immediate payment of \$2.0 million and an additional payment \$0.5 million upon receipt of shareholder approval of the transaction. Shareholder approval of the asset sale transaction with IVAX was obtained on August 12, 2004 and the closing was completed on August 13, 2004, at which time the Company received the remaining payment of \$0.5 million from IVAX.

Commercial Focus, Cash Reserves and Funding Requirements

As of July 13, 2005, the Company had unrestricted cash and cash equivalents of approximately \$0.9 million. 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 administrative and related operating expenses. The Company has suspended further development and commercialization efforts relating to the Opioid Synthesis Technologies and expects to minimize the use of cash and cash equivalents for the prosecution of patent applications relating to the Opioid Synthesis Technologies.

As restructured, the Company is no longer engaged in the manufacture and sale of finished dosage generic pharmaceutical products. As a result, the Company has no ability presently to generate revenue from product sales. Accordingly, the Company must rely on its current cash reserves to fund the development of its Aversion™ Technology and related ongoing administrative and 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 will be sufficient to fund the development of the Aversion™ Technology and related operating expenses only through late August 2005. To fund operations through March, 2006, the Company estimates that it 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 an issued U.S. patent 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 June 30, 2005:

	<u>TOTAL</u>	<u>DUE IN 2005</u>	<u>DUE IN 2006</u>	<u>DUE IN 2007</u>	<u>DUE THEREAFTER</u>
	(In thousands)				
Term notes	\$ 6,000	\$ --	\$ 1,000	\$ 5,000	\$ --
Interest on term notes	1,168	322	579	267	--
Capital leases	79	15	32	25	7
Operating leases	20	15	5	--	--
Contract research obligations	859	859	--	--	--
Employment agreements	395	270	125	--	--
Total Contractual Cash Obligations	<u>\$ 8,521</u>	<u>\$ 1,481</u>	<u>\$ 1,741</u>	<u>\$ 5,292</u>	<u>\$ 7</u>

Critical Accounting Policies

Financial Reporting Release No. 60, which was released by the Securities and Exchange Commission ("SEC") in December 2001, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note A of the Notes to Consolidated Financial Statements included as a part of this Report, 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 accounts for stock-based employee compensation arrangements in accordance with provisions of APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25") and complies with the disclosure provision of SFAS No. 148, "Accounting for Stock-based Compensation - Transition and Disclosure, an amendment of FASB Statement No. 123" ("SFAS No. 148"). The amounts disclosed include various estimates used to determine fair value of stock options. If the Company were to include the cost of stock-based employee compensation in the financial statements, the Company's operating results would decline based on the fair value of the stock-based employee compensation.

Deferred Debt Discount

Deferred debt discount will result from the issuance of stock warrants and beneficial conversion features in connection with the issuance of subordinated debt, common stock interest payments and other notes payable. The amount of the discount is recorded as a reduction of the related obligation and is amortized over the remaining life of the related obligations. Management determines the amount of the discount, based, in part, by the relative fair values ascribed to the warrants determined by an independent valuation or 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 the warrant, the estimated volatility of the Company's common stock and the expected dividend yield.

New Accounting Pronouncements

Share-Based Payment

On December 16, 2004, the Financial Accounting Standards Board (the "FASB") released FASB Statement No. 123 (revised 2004), "Share-Based Payment, ("SFAS 123R)". These changes in accounting replace existing requirements under FASB Statement No. 123, "Accounting for Stock-Based Compensation", and eliminates the ability to account for share-based compensation transaction using APB Opinion No.25, "Accounting for Stock Issued to Employees". The compensation cost relating to share-based payment transactions will be measured based on the fair value of the equity or liability instruments issues. This Statement does not change the accounting for similar transactions involving parties other than employees. In April 2005, the Securities and Exchange Commission (the "SEC") delayed implementation of SFAS 123R for publicly traded companies such that they must apply this Standard as of the beginning of the next fiscal year that begins after June 15, 2005. This Statement applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date. The cumulative effect of initially applying this Statement, if any, is recognized as of the required effective date. The Company has not completed it evaluation of the impact of adopting SFAS 123R on its consolidated financial statements, but anticipates that more compensation costs will be recorded in the future if the use of options for employees and director compensation continues as in the past.

Changes and Error Corrections

In May 2005, the FASB issued Statement of Financial Accounting Standards No. 154, "Accounting Changes and Error Corrections - A Replacement of APB Opinion No. 20 and FASB Statement No. 3.", ("SFAS 154"). SFAS 154 primarily requires retrospective application to prior periods' financial statements for the direct effects of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005, and early adoption is permitted. The Company is required to adopt the provision of SFAS 154, as applicable, beginning in fiscal 2007.

Risk Factors Relating To The Company

The Company Received a "Going Concern" Opinion from Its Independent Registered 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 since 1992, including net losses of approximately \$3.3 million for six months ended June 30, 2005, \$70.0 million for the year ended December 31, 2004 and \$48.5 million, \$59.6 million and \$12.6 million for fiscal 2003, 2002 and 2001, respectively. As of June 30, 2005 our accumulated deficit was approximately \$282.9 million. The Company's consolidated financial statements for the year ended December 31, 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. Our future profitability will depend on several factors, including:

- the successful completion of the formulation development, clinical testing and acceptable regulatory review of our Aversion™ Technologies;
- the receipt of a notice of allowance and issued patents from the US Patent and Trademark Office ("PTO") for the material claims in our patent applications relating to the Aversion™ Technologies;
- the Aversion™ Technologies not infringing third-party patents or other intellectual property rights;
- the interest of qualified third parties in our Aversion™ Technologies and our Opioid Synthesis Technologies (collectively the "Technologies") and our ability to negotiate and execute commercially viable collaboration agreements with qualified third parties relating to the Technologies.

Many of these factors will depend on circumstances beyond our control. 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 capital will depend on many factors, including:

- the time required and expenses incurred in the development and commercialization of products incorporating our Aversion™ Technologies;
- the structure of any future collaborative or development agreements relating to the Aversion™ Technologies, including the timing and amount of payments, if any, that may be received under possible future collaborative agreements;
- our ability to develop additional products utilizing the Aversion™ Technologies;
- our ability to negotiate agreements with third parties for development, manufacture, marketing, sale and distribution of products utilizing our Aversion™ Technologies;
- the prosecution, defense and enforcement of patent claims and other intellectual property rights relating to the Aversion™ Technologies; and
- the commercialization of products incorporating our Aversion™ Technologies without infringing third-party patents or other intellectual property rights.

We currently have no committed sources of capital. We anticipate that our existing capital resources will be sufficient to fund operations only through late August, 2005. 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 Technologies, or otherwise enters into alliances or collaborative agreements relating to the Aversion™ Technologies, 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 Capital Resources, Third-Party Financing, and Technology Licensing Fees to Fund Operations

Pending the completion of the development and commercial scale-up of our Aversion™ Technologies, and the receipt of regulatory approval of products incorporating such technology, of which no assurance can be given, the Company must rely on its current capital resources, third-party financing and technology licensing fees to fund the Company's operations. As of July 13, 2005, we had unrestricted cash and cash equivalents of approximately \$0.9 million. No assurance can be given that such cash resources will be sufficient to fund the continued development of our Technologies until such time as we generate revenue from the license of products incorporating the Technologies to third parties. Moreover, in the event of a cash shortfall, 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 Aversion™ Technologies, or products incorporating such Technologies, may be commercialized.

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

The first product candidate ("Product Candidate #1") resulting from the Aversion™ Technology is a tablet formulation intended for oral administration and has an active IND on file with FDA relating to such product candidate. The Company has additionally formulated a second product candidate ("Product Candidate #2") incorporating the Aversion™ Technology and has an active IND on file with the FDA for such product candidate. Since the formulation of Product Candidate #2, the Company has suspended all new development activities for Product Candidate #1 and will focus future development activities on Product Candidate #2. Additional clinical and non-clinical testing will be required to continue development of Product Candidate #2 and for the preparation and submission of a new drug application ("NDA") with the FDA. There can be no assurance that Product Candidate #2 or any other product 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 the Aversion™ Technology and the prosecution of its patent applications for such Technology. The failure of the Company to successfully develop the Aversion™ Technology, to successfully obtain an issued patent from the PTO relating to the Aversion™ Technology and product candidates utilizing the Aversion™ Technology, and to avoid infringing third-party patents and intellectual property rights in the commercialization of such Aversion™ Technology will have a material adverse effect on the Company's operations and financial condition.

If Laboratory, Animal and/or Human 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 an NDA demonstrating, among other things, that the product candidate is safe and effective in humans for its intended use. This demonstration requires significant laboratory, animal and human testing. As we do not possess the resources or employ all the personnel necessary to conduct such testing it is our intention to rely on contract research organizations for the majority of this testing with our product candidates. As a result, we will 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 can be delayed for a variety of reasons, including delays in demonstrating sufficient pre-clinical safety data required to obtain regulatory approval to commence a clinical trial, reaching agreement 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 a number of 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 resulting in the imposition of a clinical hold, lack of adequate funding to continue clinical trials; and/or negative results of clinical trials.

Clinical trials, where required by the FDA for commercial approval of the Company's Product Candidates, may not demonstrate the 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 final FDA approval for our product candidates.

Clinical trials are often very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. Further, if participating patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we, our collaborative partner or the FDA believes that participating patients are being exposed to unacceptable health risks, our collaborative partner may have to suspend the clinical trials. Failure can occur at any stage of the trials, and our collaborative partner could encounter problems that cause 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 product 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 could delay the development of other product candidates.

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 products, 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 orally administered opioid-containing finished dosage products utilizing such Technologies. We expect to receive a share of profits and/or royalty payments derived from such collaborative partners' sale of products incorporating the 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 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 Technologies

The commercial success of products incorporating our Technologies that are approved for marketing by the FDA and other regulatory authorities will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost-effective and safe. There can be no assurance given, even if we succeed in the development of products incorporating our Technologies and receive FDA approval for such products, that our products incorporating the Technologies would be accepted by the medical community and others. Factors that we believe could materially affect market acceptance of these products include:

- the relative advantages and disadvantages of our Technologies and timing to commercial launch of products utilizing our Technologies compared to products incorporating competitive technologies;
- the timing of the receipt of marketing approvals and the countries in which such approvals are obtained;
- the safety and efficacy of products incorporating our Technologies as compared to competitive products; and/or
- the cost-effectiveness of products incorporating our Technologies and the ability to receive third-party reimbursement.

Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by other brand focused pharmaceutical companies, biotechnology companies and manufacturers of generic products. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept or utilize any of our product candidates. Physicians may not be inclined to prescribe the products utilizing the Aversion™ Technology unless our products bring substantial and demonstrable advantages over other products currently marketed for the same indications. If our products do not achieve market acceptance, we will 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 Medicare.

We cannot predict the availability of reimbursement for newly-approved health care products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. 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 we bring to market, doctors may not prescribe them or patients may ask to have their physicians 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 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 Technologies. 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 or 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:

- we may initiate litigation or other proceedings against third parties to enforce our patent rights or other intellectual property rights;
- 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;
- 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
- 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. Some of our competitors may 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 Technologies 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 Technologies 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 Technologies 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. For example, the Company is aware of certain United States and European 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 commercialize products incorporating the Aversion™ Technology, 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 the Company's Aversion™ Technology will not infringe third-party patents.

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 applications ("NDA"), a 502(b)(2) NDA, or an Abbreviated New Drug Application ("ANDA"), 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 to a marketing application (NDA, 505(b)(2) NDA or ANDA). 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™ Technologies.

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.

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 Obtain Required DEA Approval for Our Narcotic Raw Materials Import Registration

We are seeking to obtain a registration from the DEA to import narcotic raw materials ("NRMs") and have been engaged in the application process seeking approval to import NRMs directly from foreign countries for use in our opioid API manufacturing efforts since early 2001. 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. Furthermore, our cash flow and limited sources of available financing make it uncertain that the Company will have sufficient capital to re-initiate the development of the Opioid Synthesis Technologies, to obtain required DEA approvals and to fund the capital improvements necessary for the commercial manufacture of APIs and finished dosage products incorporating the Opioid Synthesis Technologies.

We Must Obtain FDA Approval to Manufacture Our Products at Our Facilities; Failure to Obtain FDA Approval and Maintain Compliance with FDA Requirements May Prevent or Delay the Manufacture of Our Products 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™ 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.

We Face Significant Competition, Which May Result in Others Discovering, 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 opioid analgesics already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do as well as significantly greater experience in developing products, conducting pre-clinical testing and human clinical trials, obtaining FDA and other regulatory approvals, formulating and manufacturing drugs, and commercializing drugs.

We will be concentrating all of our efforts on the development of the Technologies. The commercial success of products using our Technologies will depend, in large part, on the intensity of competition from branded opioid containing products, generic versions of branded opioid containing products and other drugs and technologies that compete with the products incorporating our Technologies, as well as the timing of product approval.

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 addition, the opioid active ingredients in all of our product candidates are readily available for use in generic products. Companies selling generic opioid containing products may represent substantial competition. Most of these organizations competing with us have substantially greater capital resources, larger research and development staff and facilities, greater experience in drug development and in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do.

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.

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.

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

Galen Partners beneficially owns in excess of an aggregate of approximately 44% of the Company's common stock (after giving effect to the conversion of outstanding common stock purchase warrants held by Galen Partners). In addition, pursuant to the terms of the Amended and Restated Voting Agreement dated February 6, 2004, between the Company and the holders of the Company's outstanding convertible preferred stock, all holders of the Company's convertible preferred stock have agreed that the Board of Directors shall be comprised of not more than 7 members, 4 of whom shall be the designees of each of Care Capital Investments II, LP, Essex Woodlands Health Venture V, L.P. and Galen Partners. Each of Care Capital, Essex Woodlands and Galen Partners has the right to designate one member of the Company's Board of Directors and each of such investors collectively may designate one additional member to the Board. As a result, Galen Partners, in view of its ownership percentage of the Company, and each of Care Capital, Essex Woodlands and Galen Partners, by virtue of their controlling positions 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 Care Capital, Essex Woodlands and Galen Partners may not always coincide with the interests of other shareholders and such entities may take action in advance of their 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 the principal members our of management and scientific team, particularly Andrew Reddick, our President and Chief Executive Officer, and Ron 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. We are not aware of any present intention of any of our key personnel

to leave our Company or to retire. However, while we have employment agreements with certain of our employees, all of our employees are at-will employees who may terminate their employment at any time. We do not currently 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 research, development and business objectives and could materially adversely affect our business, financial condition and results of such operations.

We Expect That 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.

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 indebtedness and the Investor Rights Agreement with the holders of the Company's convertible preferred stock, 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 and commercialization of its products.

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 June 30, 2005, the Company issued 206,023 shares of the Company's common stock as payment of \$130,000 of interest payable due June 30, 2005 on the Company's \$5.0 million Secured Term Note Payable.

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 holders of the senior secured term note 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

- (a) 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.

ACURA PHARMACEUTICALS, INC.

Date: July 13, 2005

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.

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Andrew D. Reddick, the Chief Executive Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: July 13, 2005

/s/ Andrew D. Reddick

Andrew D. Reddick
Chief Executive Officer

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Peter A. Clemens, the Chief Financial Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - d) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - e) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - f) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: July 13, 2005

/s/ Peter A. Clemens

Peter A. Clemens
Chief Financial Officer

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

In connection with the Quarterly Report of Acura Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew D. Reddick, the Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: July 13, 2005

/s/ Andrew D. Reddick

Andrew D. Reddick
Chief Executive Officer

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

In connection with the Quarterly Report of Acura Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter A. Clemens, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: July 13, 2005

/s/ Peter A. Clemens

Peter A. Clemens
Chief Financial Officer
