SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
|X| QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2004

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.
(FORMERLY HALSEY DRUG CO., INC.)
(Exact name of registrant as specified in its charter)

NEW YORK	11-0853640
(State or other Jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
616 N. NORTH COURT, SUITE 120 PALATINE, ILLINOIS (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 |X| No |_|

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

Yes |_| No |X|

As of November 12, 2004 the registrant had 22,189,252 shares of Common Stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. & SUBSIDIARIES

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PART II. OTHER INFORMATION

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	UNAUDITED SEPTEMBER 30, 2004	AUDITED DECEMBER 31, 2003
	(IN THOUSANDS)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$4,616	$942
Accounts receivable - net of allowance for doubtful accounts of $0 and $428 at September 30, 2004 and December 31, 2003, respectively	--	467
Inventories	--	312
Prepaid expenses and other current assets	225	401
Total current assets	4,841	2,122
PROPERTY, PLANT & EQUIPMENT, NET	1,413	3,394
DEFERRED PRIVATE DEBT OFFERING COSTS, net of accumulated amortization of $0 and $318 at September 30, 2004 and December 31, 2003, respectively	--	714
OTHER ASSETS AND DEPOSITS	28	392
TOTAL ASSETS	$6,282	$6,622

See accompanying notes to the condensed consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	UNAUDITED SEPTEMBER 30, 2004	AUDITED DECEMBER 31, 2003
	(IN THOUSANDS, EXCEPT SHARE DATA)	
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Current maturities of capital lease obligations	28	45
Accounts payable	--	1,895
Accrued interest	113	1,544
Accrued expenses	867	2,108
Department of Justice settlement	--	300
Total current liabilities	1,008	5,892
SENIOR SECURED TERM NOTE PAYABLE	5,000	21,401
BRIDGE LOANS	--	2,000
Less: debt discount	--	(568)
	--	1,432
CONVERTIBLE SUBORDINATED DEBENTURES	--	86,632
Less: debt discount	--	(56,893)
	--	29,739
CAPITAL LEASE OBLIGATIONS, less current maturities	71	92
DEPARTMENT OF JUSTICE SETTLEMENT, less current portion	--	133
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock - $.01 par value; authorized 560,000,000 shares; issued and outstanding, 21,927,943 and 21,601,704 shares at September 30, 2004 and December 31, 2003, respectively	219	216
Convertible Preferred Stock - $.01 par value; authorized 290,000,000 shares; issued and outstanding, 217,972,986 and 0 shares, at September 30, 2004 and December 31, 2003, respectively (see Note 8)	2,180	--
Additional paid-in capital	275,261	157,262
Accumulated deficit	(277,457)	(209,545)
STOCKHOLDERS' EQUITY (DEFICIT)	203	(52,067)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 6,282	$ 6,622

See accompanying notes to the condensed consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)
(IN THOUSANDS, EXCEPT SHARE DATA)

	SEPTEMBER 30,			
	FOR THE NINE MONTHS ENDED		FOR THE THREE MONTHS ENDED	
	2004	2003	2004	2003
Net product revenues	$ 838	$ 4,210	$ --	$ 1,478
Cost of manufacturing	1,437	7,405	--	2,267
Research and development	3,179	955	1,937	339
Selling, marketing, general and administrative	4,236	6,114	1,873	2,197
Loss from operations	(8,014)	(10,264)	(3,810)	(3,325)
Other income (expense)				
Interest expense	(2,839)	(4,436)	(687)	(1,532)
Interest income	40	22	18	1
Amortization and writeoff of deferred debt discount and private debt offering costs	(72,491)	(18,050)	(47,836)	(6,367)
Gain on asset disposals	2,388	--	633	--
Gain on debt restructure	12,401	--	--	--
Other	603	(464)	202	(367)
NET LOSS	$(67,912)	$ (33,192)	$ (51,480)	$ (11,590)
Basic and diluted loss per share	$ (3.12)	$ (1.57)	$ (2.35)	$ (0.55)
Weighted average number of outstanding shares	21,749,212	21,196,131	21,927,943	21,222,993

See accompanying notes to the condensed consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	NINE MONTHS ENDED SEPTEMBER 30	
	2004	2003
	(IN THOUSANDS)	
Cash flows from operating activities		
Net loss	$(67,912)	$(33,192)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	328	640
Amortization of deferred debt discount and private debt offering costs	30,684	18,050
Write off unamortized deferred debt discount and private debt offering costs	41,807	--
Non-cash compensation charge on options	1,442	--
(Gain) loss on asset disposals	(2,388)	10
Increase in fair value of warrants	--	457
Gain on debt restructuring	(12,401)	--
Gain on Department of Justice settlement	(403)	--
Bad debt reserve	(428)	--
Changes in assets and liabilities		
Accounts receivable	729	(1,521)
Inventories	312	(353)
Prepaid expenses and other current assets	176	(364)
Other assets and deposits	159	66
Accounts payable	(1,895)	(18)
Accrued expenses	1,650	4,387
Total adjustments	59,772	21,354
Net cash used in operating activities	(8,140)	(11,838)
Cash flows from investing activities		
Capital expenditures	(273)	(1,306)
Proceeds from asset disposals	4,520	--
Net cash provided by (used in) investing activities	4,247	(1,306)
Cash flows from financing activities		
Payments on senior secured term note payable	(4,000)	--
Payments on capital lease obligations	(38)	(33)
Proceeds from issuance of subordinated convertible debentures	11,951	5,100
Payments on private offering costs	(315)	--
Payments to Department of Justice	(31)	(245)
Net cash provided by financing activities	7,567	4,822
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,674	(8,322)
Cash and cash equivalents at beginning of period	942	9,211
Cash and cash equivalents at end of period	$ 4,616	$ 889
Cash paid for interest	$ 47	$ 405

See accompanying notes to the condensed consolidated financial statements.

SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:

FOR THE NINE MONTHS ENDED SEPTEMBER 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 326,239 shares of common stock as payment of $169,000 of Senior Secured Term Note Payable accrued interest.

5. Convertible Subordinated Debentures of $100,632,000 and accrued interest of $3,939,000 were converted into 217,973,000 shares of Convertible Preferred Stock (See Note 8).

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2003:

1. The Company issued 645,000 warrants with an estimated relative fair value of $581,000 for the lending commitment in the form of Debentures.

2. The Company has repaid $1,578,000 of indebtedness in the form of product deliveries.

3. The Company issued 189,075 shares of common stock upon the conversion of $110,000 of Debentures.

4. The Company issued 150,000 warrants with an estimated relative fair value of $112,000 in connection with the termination of an employment agreement.

5. Equipment financed through capital leases aggregated approximately $111,000.

See accompanying notes to the condensed consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

NINE MONTHS ENDED SEPTEMBER 30, 2004

(IN THOUSANDS, EXCEPT SHARE DATA)

(UNAUDITED)

	COMMON STOCK $.01 PAR VALUE		CONVERTIBLE PREFERRED STOCK $.01 PAR VALUE (NOTE 8)				
	SHARES	AMOUNT	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL
BALANCE AT JANUARY 1, 2004	21,601,704	$ 216	--	$ --	$ 157,262	$ (209,545)	$ (52,067)
Net loss for the nine months ended September 30, 2004						(67,912)	(67,912)
Issuance of Common Shares for payment of interest	326,239	3			166		169
Fair value of options issued to employees					1,442		1,442
Issuance of Series A Convertible Preferred Shares for convertible debentures			21,963,757	220	13,892		14,112
Issuance of Series B Junior Convertible Preferred Shares for convertible debentures			20,246,506	203	6,722		6,925
Issuance of Series C-1 Junior Convertible Preferred Shares for convertible debentures			56,422,558	564	32,025		32,589
Issuance of Series C-2 Junior Convertible Preferred Shares for convertible debentures			37,433,096	374	22,059		22,433
Issuance of Series C-3 Junior Convertible Preferred Shares for convertible debentures			81,907,069	819	27,693		28,512
Beneficial conversion features in conjunction with issuance of convertible debentures					14,000		14,000
BALANCE AT SEPTEMBER 30, 2004	21,927,943	$ 219	217,972,986	$ 2,180	$ 275,261	$ (277,457)	$ 203

See accompanying notes to the condensed consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(A DEVELOPMENT STAGE ENTERPRISE)

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited condensed 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 nine months ended September 30, 2004, assuming that the Company will continue as a going concern, have been made. The results of operations for the nine month period ended September 30, 2004 are not necessarily indicative of the results that may be expected for the full year ended December 31, 2004. The unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2003 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, as more fully described in "Item 2. Management's Discussion and Analysis of Financial Condition and Results of 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 a development state enterprise engaged in the development of proprietary opioid abuse deterrent formulation technology (the "ADF Technology"), the manufacture, packaging and stability testing of clinical trial supplies of finished product candidates utilizing the ADF Technology, the evaluation of such product candidates in appropriate clinical trials, the development and scale up of novel active pharmaceutical ingredient ("API") opioid synthesis technologies (the "Opioid Synthesis Technologies"), and the prosecution of the Company's application to the Drug Enforcement Administration ("DEA") for a registration to import narcotic raw materials ("NRMs"). The Company proposes to enter into license agreements with strategic partners providing that such licensees will further develop abuse deterrent formulation finished dosage product candidates, file for regulatory approval with the U.S. Food and Drug Administration ("FDA") and other regulatory authorities and commercialize such products. The Company intends to manufacture commercial supplies of such products for sale by the Company's licensees.

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 September 30, 2004 the Company had cash and cash equivalents of $4.6 million, working capital of $3.8 million, and accumulated deficit of $277.5 million. At December 31, 2003, the Company had cash and cash equivalents of $.9 million, working capital deficit of $3.8 million and a stockholders' deficit of $52.1 million. The Company incurred a loss from operations of $8.0 million and a net loss of $67.9 million during the nine months ended September 30, 2004. The Company incurred a loss from operations of $17.2 million and a net loss of $48.5 million during the year ended December 31, 2003. 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. Reference is made to "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

NOTE 3 - 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 September 30, 2004 and December 31, 2003, cash equivalents consisted of bank commercial paper totaling approximately $4.0 million and $0, respectively.

NOTE 4 - RESEARCH AND DEVELOPMENT

Research and development expenses consist of direct costs and indirect costs. Direct research and development costs include salaries and related research costs of research and development personnel, and the costs of consultants, 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 no research and development commitments with third parties at September 30, 2004 or December 31, 2003.

NOTE 5 - INCOME TAXES

The Company has net operating loss carryforwards aggregating in excess of $100 million expiring during the years 2011 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 September 30, 2004, a valuation allowance equal to 100% of the deferred tax assets was used and primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards.

NOTE 6 - 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 (in thousands, except per share data):

	NINE MONTHS ENDED SEPTEMBER 30,		THREE MONTHS ENDED SEPTEMBER 30,	
	2004	2003	2004	2003
Net loss, as reported	$ (67,912)	$ (33,192)	$ (51,480)	$ (11,590)
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(342)	(554)	(250)	(265)
Net loss, pro forma	$ (68,254)	$ (33,746)	$ (51,730)	$ (11,855)
Basic EPS -- as reported	$ (3.12)	$ (1.57)	$ (2.35)	$ (0.55)
Basic EPS -- pro forma	$ (3.14)	$ (1.59)	$ (2.36)	$ (0.56)
Diluted EPS -- as reported	$ (3.12)	$ (1.57)	$ (2.35)	$ (0.55)
Diluted EPS -- pro forma	$ (3.14)	$ (1.59)	$ (2.36)	$ (0.56)

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 7 - LOSS PER SHARE

Basic loss per share is computed by dividing net loss by the weighted average common shares outstanding during the reporting period. Diluted loss per share is computed by dividing net loss by the weighted average 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.

In all periods presented we have reported a loss and therefore all potential shares of common stock related to potentially dilutive securities have been excluded from the calculation of diluted loss per share because they are anti-dilutive.

Excluded from the computation of diluted loss per share are approximately 355,943,000 and 239,305,000 common share equivalents for both the nine months and three months ended September 30, 2004 and September 30, 2003, respectively.

NOTE 8 - CONVERTIBLE PREFERRED STOCK

As further discussed in Note 11, at August 13, 2004 the holders of the Company's 5% convertible debentures converted their debentures into various series of convertible preferred stock. At September 30, 2004, convertible preferred stock consists of the following:

SEPTEMBER 30, 2004

CONVERTIBLE PREFERRED STOCK	$.01 PAR VALUE, AUTHORIZED SHARES	ISSUED AND OUTSTANDING SHARES	PAR VALUE	COMMON STOCK EQUIVALENTS
Series A	45,000,000	21,963,757	$ 220	109,818,785
Series B Junior	25,000,000	20,246,506	203	20,246,506
Series C-1 Junior	70,000,000	56,422,558	564	56,422,558
Series C-2 Junior	50,000,000	37,433,096	374	37,433,096
Series C-3 Junior	100,000,000	81,907,069	819	81,907,069
Total	290,000,000	217,972,986	$ 2,180	349,755,528

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) time 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.

NOTE 9 - INVENTORIES

Inventories consist of the following:

	SEPTEMBER 30, 2004	DECEMBER 31, 2003
	(IN THOUSANDS)	
Finished Goods	$ --	$ 357
Work in Process	--	953
Raw Materials	--	356
	--	1,666
Less impairment reserve	--	(1,354)
	$ --	$ 312

NOTE 10 - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	SEPTEMBER 30, 2004	DECEMBER 31, 2003
	(IN THOUSANDS)	
Payroll, Payroll Taxes and Benefits	$ 448	$ 468
Legal and Audit Fees	170	519
Property and Sales Taxes	114	142
Medicaid Rebates and Other Customer Allowances	81	50
Benefit Plan Taxes	--	200
Restructuring Costs	54	100
Investment Fees	--	201
Director Fees	--	45
Other	--	383
	$ 867	$ 2,108

NOTE 11 - CONVERTIBLE SUBORDINATED DEBENTURES

Convertible Subordinated Debentures consist of the following:

	SEPTEMBER 30, 2004	DECEMBER 31, 2003
	(IN THOUSANDS)	
1998 Debentures	$ 31,212	$ 31,212
1999 Debentures	21,485	21,485
2002 Debentures	27,303	27,303
2003 Debentures	6,632	6,632
2004 Debentures	14,000	--
	100,632	86,632
Debentures converted into Convertible Preferred Stock	(100,632)	--
	--	86,632
Less: Unamortized Debt Discount	(--)	(56,893)
Convertible Subordinated Debentures, net	$ --	$ 29,739

The 2004 Debentures plus interest accrued automatically converted into the Company's Series A convertible preferred stock (the "Series A Preferred") on August 13, 2004, the business day following the Company's receipt of shareholder approval to restate the Company's Certificate of Incorporation (the "Charter Amendment") to authorize the Series A Preferred and the Junior Preferred Shares (See "Liquidity and Capital Resources") and the filing of the Charter Amendment with the Office of the New York Department of State, as provided in the 2004 Debenture Purchase Agreement. The 2004 Debentures and interest converted into an aggregate of 21,963,757 Series A Preferred shares based on a $0.6425 per share conversion price.

In accordance with the terms of the Conversion Agreement among the Company and the holders of the Company's Convertible Debentures, effective August 13, 2004, each holder of 1998-2002 Debentures converted the 1998-2002 Debentures held by such holder into the Company's Series B convertible preferred stock (the "Series B Preferred") and/or Series C-1, C-2 and/or C-3 convertible preferred stock (collectively, the "Series C Preferred").

Under the Conversion Agreement, the holders of approximately $6.6 million in principal amount of 2002 Debentures issued during 2003 converted such 2002 Debentures (plus accrued and unpaid interest) into Series B Preferred Shares. Of the remaining approximate $80 million in principal amount of the 1998-2002 Debentures, approximately $31.2 million was comprised of 1998 Debentures, approximately $21.5 million was comprised of 1999 Debentures and approximately $27.3 million was comprised of 2002 Debentures. Effective August 13, 2004, the 1998 Debentures were converted into Series C-1 Preferred shares, the 1999 Debentures were converted into Series C-2 Preferred shares and the remaining balance of the 2002 Debentures were converted into Series C-3 Preferred shares.

The number of Junior Preferred Shares issued by the Company to by each holder of 1998-2002 Debentures was based on the respective prices at which the 1998-2002 Debentures were convertible into Common Stock. The 2002 Debentures issued in 2003 had a conversion price of $0.3420 per share. The 1998 Debentures, 1999 Debentures and the remaining balance of the 2002 Debentures had conversion prices of $0.5776, $0.5993 and $0.3481 per share, respectively. Upon the automatic conversion of the 1998-2002 Debentures on August 13, 2004, the Company issued an aggregate of 20,246,506 Series B Preferred shares, 56,422,558 Series C-1 Preferred shares, 37,433,096 Series C-2 Preferred shares and 81,907,069 Series C-3 Preferred shares.

During the nine months ended September 30, 2004, the Company incurred $30.4 million and $0.3 million for the amortization of deferred debt discount and private debt offering costs, respectively. As a result of the August 13, 2004 conversion of the Company's 2004 and 1998-2002 Debentures, unamortized debt discount of $41.1 million and unamortized private debt offering costs of $0.7 million were charged off to expense.

Related-Party Transactions

A Company Officer and a former Director of the Company held certain of the 1998 Debentures and 1999 Debentures. The aggregate principal amount of such debentures was approximately $175,000 at December 31, 2003. Interest expense on these debentures was approximately $5,500 and $6,500 for the nine months ended September 30, 2004 and 2003, respectively, of which approximately $0 and $3,100 was paid through the issuance of like debentures for the nine months ended September 30, 2004 and 2003, respectively. Interest expense on these debentures was approximately $1,100 and $2,200, for the three months ended September 30, 2004 and 2003, respectively, of which no like debentures were issued for the payment of interest for the three month period ended September 30, 2004 and 2003, respectively. On August 13, 2004, the 1998 Debentures and 1999 Debentures, including accrued interest, held by this individual were converted into shares of preferred stock.

Indemnifications

Each of the purchase agreements for the Company's 1998 Debentures, 1999 Debentures, 2002 Debentures, 2003 Debentures and 2004 Debentures, and the Bridge Loan Agreements to which the Company was a party, contain provisions by which the Company is obligated to indemnify the purchasers of the debentures for any losses, claims, damages, liabilities, obligations, penalties, awards, judgments, expenses or disbursements arising out of or resulting from the breach of any representation, warranty or agreement of the Company related to the purchase of the debentures and bridge loans. These indemnification obligations do not include a limit on maximum potential future payments, nor are there any recourse provisions or collateral that may offset the cost. As of September 30, 2004, the Company does not believe that any liability has been incurred as a result of these indemnification obligations.

NOTE 12 - SENIOR SECURED TERM NOTE PAYABLE

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 March 31, 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 March 31, 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 2004 Debenture Offering, simultaneous with the closing of the 2004 Purchase Agreement, 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 "New Watson 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 March 31, 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 New Watson 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 New Watson Note

Simultaneous with the issuance of the New Watson Note, each of the investors in the 2004 Debentures at the initial closing of the 2004 Purchase Agreement on February 10, 2004 (collectively, the "Watson Note Purchasers") purchased the New Watson Note from Watson in consideration for a payment to Watson of $1.0 million. The new Note is 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 September 30, 2004 was 9.25%.

NOTE 13 - COMMITMENTS AND CONTINGENCIES

U.S. Department of Justice Settlement

On June 21, 1993, the Company entered into a Plea Agreement with the U.S. Department of Justice (the "DOJ") to resolve the DOJ's investigation into the manufacturing and record keeping practices at the Company's former Brooklyn, New York plant. The Plea Agreement required the Company to pay a fine of $2,500,000 over five years in quarterly installments of $125,000, commencing on or about September 15, 1993.

As of February 28, 1998, the Company was in default of the payment terms of the Plea Agreement and had made payments aggregating $350,000. On May 8, 1998, the Company and the DOJ signed the Letter Agreement serving to amend the Plea Agreement relating to the terms of the Company's satisfaction of the fine assessed under the Plea Agreement (the "Letter Agreement"). Specifically, the Letter Agreement provided that the Company will satisfy the remaining $2,150,000 of the fine through the monthly payments of $25,000 commencing June 1, 1998, plus interest on such outstanding balance (at the rate calculated pursuant to 28 U.S.C. Section 1961 (5.319%)). Such payment schedule provided for the full satisfaction of the DOJ fine in July 2005. The Letter Agreement also provides certain restrictions on the payment of salary or compensation to any individual in excess of certain amounts without the written consent of the DOJ. In addition, the Letter Agreement requires the repayment of the outstanding fine to the extent of 25% of the Company's after-tax profit or 25% of the net proceeds received by the Company on any sale of a capital asset for a sum in excess of $10,000, if not invested in another capital asset. At December 31, 2003, the Company was current in its payment obligations, with a remaining obligation of $433,000. In February 2004, the Company fully satisfied its obligation to the DOJ under the Letter Agreement.

Employment Contracts

During April 2004, the Company entered into an employment agreement with a new officer/employee of the Company. The agreement provides for, among other things: (i) an annual base salary of $260,000, and (ii) the commitment to issue an aggregate of 3,000,000 stock options to purchase the Company's stock at an exercise price of $0.13 per common share that vest 1,000,000 option shares on October 1, 2004 and the balance thereafter at a rate of 333,333 per calendar quarter, beginning January 1, 2005 with an exercise term expiring in ten years. The commitment to issue the stock option was subject to the receipt of shareholder approval to modify the Company's 1998 Stock Option Plan to (i) increase the number of shares reserved for issuance and (ii) authorize issuance of stock options having an exercise price less than fair market value of the common stock of the Company on the date of issuance. On August 13, 2004, the Company's shareholders approved the modifications to the 1998 Stock Option Plan and 3,000,000 stock options were issued. The employment agreement term is for a two year period, which automatically renews for successive one-year periods unless either the Company or the employee provides 90 days' notice of non-renewal.

During August 2003, the Company entered into an employment agreement with a new officer/employee of the Company. The agreement provides for, among other things: (i) an annual base salary of $300,000, and (ii) the commitment to issue an aggregate of 5,500,000 options to purchase the Company's stock at an exercise price of $0.34 per common share that vest 1,000,000 option shares on March 31, 2004 and the balance thereafter at a rate of 500,000 per calendar quarter, beginning June 30, 2004 which an exercise term expiring in ten years. The commitment to issue the stock option was subject to the receipt of shareholder approval to modify the Company's 1998 Stock Option Plan to (i) increase the number of shares reserved for issuance and (ii) authorize issuance of stock options having an exercise price less than fair market value of the common stock of the Company on the date of issuance. In May 2004, such employment agreement was amended, among other things, to adjust the Company's commitment to issue stock options from 5,500,000 shares to 8,750,000 shares and to provide for an exercise price of $0.13 per share. On August 13, 2004, the Company's shareholders approved the modifications to the 1998 Stock Option Plan and 8,750,000 stock options were issued. The options have a ten-year term and provide for vesting in the amount of 2,750,000 shares on June 30, 2004 and the balance thereafter at a rate of 250,000 shares per calendar month, beginning July 31, 2004. The employment agreement term is for a two year period, which automatically renews for successive one-year periods unless either the Company or the employee provides 90 days' notice of non-renewal.

During April 2004, the Company committed to issue to current employees stock options that upon grant, will be exercisable for an aggregate of 1,425,000 shares of the Company's common stock at an exercise price of $0.13 per common share and will vest 25% annually over four years and provide for immediate vesting upon change of control. The grant of these stock options was subject to the receipt of shareholder approval to modify the Company's 1998 Stock Option Plan to (i) increase the number of shares reserved for issuance and (ii) authorize issuance of stock options having an exercise price less than fair market value of the common stock of the Company on the date of issuance. On August 13, 2004, the Company's shareholders approved the modifications to the 1998 Stock Option Plan and 1,425,000 stock options were issued.

During November 2002, the Company entered into an employment contract with a new officer/employee of the Company. The contract calls for, among other things: (1) annual base salary of $180,000, and (2) an aggregate of 400,000 options to purchase the Company's stock at an exercise price of $1.15 per common share that vest evenly over a four-year period. The two year employment agreement automatically renews for successive one-year periods unless the Company provides 90 days' notice of nonrenewal. In August 2004, the Company gave notice of non renewal as required under the provisions of such employment agreement . Under the terms of a negotiated separation and general release agreement with this employee/officer, the Company will grant an option having a two-year term to this individual for the purchase of up to 200,000 shares of the Company's common stock at an exercise price of $0.13 per share, which will be fully vested upon the employee's separation date. The fair value of the option will be calculated using closing price of the Company's common stock on the date of grant.

Stock Option Grants to Board Members

On June 26, 2004, the Company committed to issue to the members of its board of directors, including the Independent Committee of the Board, stock options that upon grant or complete vesting, will be exercisable for an aggregate of 1,100,000 shares of the Company's common stock at an exercise price equal to the fair market value of the Company's Common Stock on the date of grant. With the exception of stock options to purchase an aggregate of 200,000 shares of the Company's Common Stock, all options are fully vested at the time of grant. Options to purchase an aggregate of 200,000 shares of the Company's Common Stock will vest 25% quarterly over one year. The commitment to issue all such stock options was subject to the receipt of shareholder approval to modify the Company's 1998 Stock Option Plan. On August 13, 2004, the Company's shareholders approved the modifications to the 1998 Stock Option Plan and 1,100,000 stock options were issued at an exercise price of $0.36 per common share.

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.

This Report contains "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. Such factors include, among others, the following: changes in general economic and business conditions; future operating losses and anticipated operating and capital expenditures; the anticipated results of our pre-clinical and clinical development of our product candidates, including the timing of development and any regulatory approvals; the protection of our intellectual property; expected future sources of revenue and capital; potential competitors or products; future market acceptance of our product candidates; future expectations regarding trade secretes, technological innovations, licensing agreements and outsourcing of certain business functions; the sufficiency of our current resources to fund near term operations; the development of our internal systems and infrastructure; regulatory changes in the pharmaceutical industry; difficulties encountered in the development of novel products and manufacturing techniques; regulatory obstacles to the introduction of new technologies or products that are important to the Company's growth; availability of qualified personnel; and other factors both referenced and not referenced in this Report. When used in this Report, the words "estimate," "project," "anticipate," "expect," "intend," "believe" and similar expressions are intended to identify forward-looking statements.

Such forward-looking statements involve risks and uncertainties including, without limitation, those risks and uncertainties relating to the development, testing, regulatory approval and commercialization of the Company's product candidates; the uncertainty of patent protection of the Company's intellectual property; potential infringement of intellectual property rights or trade secrets of third parties; and the Company's ability to obtain additional financing. 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

The Company is a development stage specialty pharmaceutical company engaged in research, development and manufacture of innovative abuse deterrent formulations ("ADF Technology") intended for use in orally administered opioid-containing pharmaceutical products. In addition, the Company is 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 ADF Technology, the "Technologies") intended for use in the commercial production of certain bulk opioid active pharmaceutical ingredients ("APIs"). To date, the Company has one (1) issued US patent (issued September 2004), one issued US Notice of Allowance, one (1) foreign patent application and six (6) patent applications pending with the United States Patent and Trademark Office ("PTO") relating to the Opioid Synthesis Technologies . Additionally, the Company has one (1) pending US patent application relating to the ADF Technology . One of the Company's product candidates incorporating the ADF Technology is in Phase I Clinical Trials. The Company currently retains all commercial rights to its product candidates, ADF Technology and Opioid Synthesis Technologies.

In November 2003, the Company commenced the restructuring of its operations to focus its efforts on research and development relating to the ADF 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.

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.

Company's Present Financial Condition and Commercial Focus

At September 30, 2004 the Company had cash and cash equivalents of approximately $4.6 million compared to $942,000 at December 31, 2003. The Company had working capital of $3.8 million at September 30, 2004 and a working capital deficit of approximately $3.8 million at December 31, 2003. The Company had an accumulated deficit of approximately $277.5 million and approximately $209.5 million as September 30, 2004 and December 31, 2003, respectively. The Company had an operating loss of approximately $8.0 million for the nine months ended September 30, 2004. The Company incurred a loss from operations of approximately $17.2 million and a net loss of approximately $48.5 million during the year ended December 31, 2003.

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:

- Development of the Company's ADF Technology for use in orally administered opioid finished dosage product candidates.

- Manufacture and quality assurance release of clinical trial supplies of certain finished dosage form product candidates utilizing the ADF Technology.

- Evaluation of certain finished dosage product candidates utilizing the ADF Technology in clinical trials.

- Scale-up and manufacture of commercial quantities of certain product candidates utilizing the ADF Technology for sale by the Company's licensees.

- Research, development and scale up of the Company's Opioid Synthesis Technologies.

- Prosecution of the Company's application to the U.S. Drug Enforcement Administration ("DEA") to for registration to import narcotic raw materials ("NRMs") for use in the production of opioid API's utilizing the Company's Opioid Synthesis Technologies.

- 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 ADF 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 the year ended December 31, 2003 and the nine months ended September 30, 2004 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 expects net losses to continue at least through 2005. The Company's future profitability will depend on several factors, including:

- The successful completion of the development, scale-up, clinical testing and acceptable regulatory review of the ADF Technology;

- The receipt of a notice of allowance from the PTO for the material claims in the Company's patent application relating to the ADF Technology;

- The commercialization of products incorporating the ADF Technology without infringing the patents and other intellectual property rights of third parties;

- The completion of the development, commercial scale-up and acceptable regulatory review of the Opioid Synthesis Technologies;

- The receipt of approval from the DEA to import NRMs to be used in the Company's development and manufacturing efforts; and

- 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.

In order 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 must 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. Product revenue will be derived from a share of profits and/or royalty payments relating to such collaborative partners' sale of products incorporating the Company's Technologies. Currently, the Company does not have any such collaborative agreements, nor can there be any assurance that the Company will actually 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 take a significant amount of 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 on 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 NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

In comparing results of operations for the nine months ended September 30, 2004 with those for 2003 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 activities. Net product revenues and manufacturing expenses realized in 2004 were incurred as part of an orderly phase out of all generic manufacturing activities.

NET PRODUCT REVENUES

The Company's net product revenues for the nine months ended September 30, 2004 and September 30, 2003 were as follows (in thousands):

9/30/04 NET PRODUCT REVENUES	9/30/03 NET PRODUCT REVENUES	9/30/04-9/30/03 NET PRODUCT REVENUE CHANGE ($)	9/30/04-9/30/03 NET PRODUCT REVENUE CHANGE (%)
$ 838	$ 4,210	($ 3,372)	(80%)

The decrease in net product revenues was a result of the Company's decision to restructure operations and cease the manufacture of finished dosage generic pharmaceutical products. The net product revenues for the nine months ended September 30, 2004 reflect the sale of all remaining inventories of saleable finished dosage generic pharmaceutical products during the first two quarters of 2004. No revenues were recorded for the third quarter 2004.

COST OF MANUFACTURING

The Company's cost of manufacturing for the nine months ended September 30, 2004 and September 30, 2003 were as follows (in thousands):

9/30/04 COST OF MANUFACTURING	9/30/03 COST OF MANUFACTURING	9/30/04-9/30/03 COST OF MANUFACTURING CHANGE ($)	9/30/04-9/30/03 COST OF MANUFACTURING CHANGE (%)
$ 1,437	$ 7,405	($ 5,968)	(81%)

For the nine months ending September 30, 2004 cost of manufacturing includes the fixed costs of the Company's generic finished dosage manufacturing operations in the first quarter of 2004 and residual expenses through the second quarter 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 nine months ended September 30, 2004 and September 30, 2003 were as follows (in thousands):

9/30/04 R&D EXPENSES	9/30/03 R&D EXPENSES	9/30/04-9/30/03 R&D EXPENSES CHANGE ($)	9/30/04-9/30/03 R&D EXPENSES CHANGE (%)
$ 3,179	$ 955	$ 2,224	233%

The increase in R&D expenses is primarily related to the Company's strategic decision to devote a major portion of its resources in 2004 to research and development activities relating to its ADF Technology and to a lesser extent to its Opioid Synthesis Technologies. The expenses include a non cash compensation charge of $356 recorded for the issuance of stock options and the effect of the reallocation of $997 in costs otherwise classified and charged as general and administrative expenses during the period ending 2003.

SELLING, MARKETING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, marketing, general and administrative expenses for the nine months ended September 30, 2004 and 2003 were as follows (in thousands):

9/30/04 SELLING, MARKETING, G&A EXPENSES	9/30/03 SELLING, MARKETING, G&A EXPENSES	9/30/04-9/30/03 SELLING, MARKETING, G&A EXPENSES CHANGE ($)	9/30/04-9/30/03 SELLING, MARKETING, G&A EXPENSES CHANGE (%)
$ 4,236	$ 6,114	($ 1,878)	(31%)

The decrease in selling, marketing, general and administrative expenses resulted from the Company's decision to restructure operations by discontinuing the marketing and sale of generic finished dosage products and reducing its administrative and manufacturing support staff. The decrease includes the effect from the reallocation and reclassification of $997 in costs charged to research and development which were otherwise classified as general and administrative expenses during the period ended 2003, a nonrecurring benefit for settlement of trade payables at a discount of $194 and a non cash compensation charge of $1,085 recorded for the issuance of stock options. ENVIRONMENTAL COMPLIANCE EXPENSES

During the nine months ended September 30, 2004 and September 30, 2003, the Company incurred the following expenses in connection with environmental compliance (in thousands):

9/30/04 ENVIRONMENTAL COMPLIANCE EXPENSES	9/30/03 ENVIRONMENTAL COMPLIANCE EXPENSES	9/30/04-9/30/03 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE ($)	9/30/04-9/30/03 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE (%)
$ 180	$ 268	($ 88)	(33%)

The environmental compliance expenses related primarily to disposal of hazardous and controlled substances waste and related personnel costs for environmental compliance during the period the Company maintained its manufacturing operations.

INTEREST EXPENSE, NET OF INTEREST INCOME

The Company's interest expense, net of interest income for the nine months ended September 30, 2004 and September 30, 2003 was as follows (in thousands):

9/30/04 INTEREST EXPENSE, NET OF INTEREST INCOME	9/30/03 INTEREST EXPENSE, NET OF INTEREST INCOME	9/30/04-9/30/03 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE ($)	9/30/04-9/30/03 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (%)
$ 2,799	$ 4,414	($ 1,615)	(37%)

The change in the interest expense, net of interest income reflects the interest savings from the restructuring of the Company's term note indebtedness to Watson Pharmaceuticals as well as the conversion of the Company's 5% convertible debentures into convertible preferred stock on August 13, 2004.

AMORTIZATION OF DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS

The Company's deferred debt discount and private debt offering costs for the nine months ended September 30, 2004 and September 30, 2003 were as follows (in thousands):

9/30/04 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	9/30/03 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	9/30/04-9/30/03 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE ($)	9/30/04-9/30/03 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE (%)
$ 72,491, consisting of o $ 1,030 private debt offering costs o $ 71,461 deferred debt discount	$ 18,050, consisting of o $ 698 private debt offering costs o $ 17,352 deferred debt discount	$ 54,441	302%

The change in the deferred debt discount and private debt offering costs reflects the amortization of the remaining deferred debt discount and private debt offering costs incurred from all of the Company's debenture and bridge loan financings. As a result of the conversion of all convertible debentures into preferred stock at August 13, 2004, 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 nine months ended September 30, 2004 and September 30, 2003 was as follows (in thousands):

9/30/04 NET LOSS	9/30/03 NET LOSS	9/30/04-9/30/03 NET LOSS CHANGE ($)	9/30/04-9/30/03 NET LOSS CHANGE (%)
($ 67,912)	($ 33,192)	$ 34,720	105%

Included in the net loss for the nine months ending September 30, 2004 is the full amortization of the remaining deferred debt discount and private offering costs of $72,491, gains on debt restructuring of $12,401 and asset sales of $2,388, net interest expense of $2,799 and other income of $603 relating to settlements of a liabilities at discount.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

In comparing results of operations for the three months ended September 30, 2004 with those for 2003 it is important to consider that in 2004 the Company, as restructured, has focused the entirety of its efforts and resources on research and development activities and, unlike for the same three month period in 2003, no longer maintained any generic manufacturing facilities or conducted any finished dosage manufacturing activities.

NET PRODUCT REVENUES

The Company's net product revenues for the three months ended September 30, 2004 and September 30, 2003 were as follows (in thousands):

3 MONTHS ENDED 9/30/04 NET PRODUCT REVENUES	3 MONTHS ENDED 9/30/03 NET PRODUCT REVENUES	3 MONTHS ENDED 9/30/04- 9/30/03 NET PRODUCT REVENUE CHANGE ($)	3 MONTHS ENDED 9/30/04-9/30/03 NET PRODUCT REVENUE CHANGE (%)
$ --	$ 1,478	($ 1,478)	(100%)

The Company had no revenue or cost of goods sold during the three months ended September 30, 2004 as a result of the Company's restructuring of operations and cessation of the manufacturing finished dosage generic pharmaceutical products. All remaining inventories of saleable finished dosage products had been sold during the first two quarters of 2004.

COST OF MANUFACTURING

The Company's cost of manufacturing for the three months ended September 30, 2004 and September 30, 2003 were as follows (in thousands):

3 MONTHS ENDED 9/30/04 COST OF MANUFACTURING	3 MONTHS ENDED 9/30/03 COST OF MANUFACTURING	3 MONTHS ENDED 9/30/04-9/30/03 COST OF MANUFACTURING CHANGE ($)	3 MONTHS ENDED 9/30/04-9/30/03 COST OF MANUFACTURING CHANGE (%)
$ --	$ 2,267	($ 2,267)	(100%)

The Company had no revenue or cost of goods sold during the three months ended September 30, 2004. The generic finished dosage manufacturing operations were discontinued in March 2004.

RESEARCH AND DEVELOPMENT EXPENSES

The Company's research and development expenses for the three months ended September 30, 2004 and September 30, 2003 were as follows (in thousands):

3 MONTHS ENDED 9/30/04 R&D EXPENSES	3 MONTHS ENDED 9/30/03 R&D EXPENSES	3 MONTHS ENDED 9/30/04-9/30/03 R&D EXPENSES CHANGE ($)	3 MONTHS ENDED 9/30/04-9/30/03 R&D EXPENSES CHANGE (%)
$ 1,937	$ 339	$ 1,598	471%

The increase in R&D expenses is primarily related to the Company' strategic decision to devote a large portion of its resources in 2004 to research and development activities relating to its ADF Technology and to a lesser extent to its Opioid Synthesis Technologies. The expenses of the period ended 2004 also include a non cash compensation charge of $356 recorded for the issuance of stock options and the effect of the reallocation of $570 in costs otherwise classified and charged as general and administrative expenses during the period ending 2003.

SELLING, MARKETING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, marketing, general and administrative expenses for the three months ended September 30, 2004 and 2003 were as follows (in thousands):

3 MONTHS ENDED 9/30/04 SELLING, MARKETING, G&A EXPENSES	3 MONTHS ENDED 9/30/03 SELLING, MARKETING, G&A EXPENSES	3 MONTHS ENDED 9/30/04-9/30/03 SELLING, MARKETING, G&A EXPENSES CHANGE ($)	3 MONTHS ENDED 9/30/04-9/30/03 SELLING, MARKETING, G&A EXPENSES CHANGE (%)
$ 1,873	$ 2,197	($ 324)	(15%)

The decrease in selling, marketing, general and administrative expenses results from the Company's decision to restructure operations by discontinuing the marketing and sale of generic finished dosage products and reducing its administrative and manufacturing support staff. The decrease includes the effect from the reallocation and reclassification of $570 in costs charged to research and development which were otherwise classified as general and administrative expenses during the period ended 2003, offset by a non cash compensation charge of $1,085 recorded for the issuance of stock options.

ENVIRONMENTAL COMPLIANCE EXPENSES

During the three months ended September 30, 2004 and September 30, 2003, the Company incurred the following expenses in connection with environmental compliance (in thousands):

3 MONTHS ENDED 9/30/04 ENVIRONMENTAL COMPLIANCE EXPENSES	3 MONTHS ENDED 9/30/03 ENVIRONMENTAL COMPLIANCE EXPENSES	3 MONTHS ENDED 9/30/04-9/30/03 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE ($)	3 MONTHS ENDED 9/30/04-9/30/03 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE (%)
$ --	$ 148	($ 148)	(100%)

The environmental compliance expenses related to disposal of hazardous and controlled substances waste and related personnel costs for environmental compliance during the period 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 September 30, 2004 and September 30, 2003 was as follows (in thousands):

3 MONTHS ENDED 9/30/04 INTEREST EXPENSE, NET OF INTEREST INCOME	3 MONTHS ENDED 9/30/03 INTEREST EXPENSE, NET OF INTEREST INCOME	3 MONTHS ENDED 9/30/04-9/30/03 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE ($)	3 MONTHS ENDED 9/30/04-9/30/03 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (%)
$ 669	$ 1,531	($ 863)	(56%)

The change in the interest expense, net of interest income reflects the interest savings from the restructuring of the Company's term note indebtedness to Watson Pharmaceutical as well as the conversion of the Company's 5% convertible debentures into convertible preferred stock on August 13, 2004.

AMORTIZATION OF DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS

The Company's deferred debt discount and private debt offering costs or the three months ended September 30, 2004 and September 30, 2003 were as follows (in thousands):

3 MONTHS ENDED 9/30/04 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	3 MONTHS ENDED 9/30/03 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	3 MONTHS ENDED 9/30/04-9/30/03 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE ($)	3 MONTHS ENDED 9/30/04-9/30/03 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE (%)
$ 47,836, consisting of o $ 796 private debt offering costs o $ 47,040 deferred debt discount	$ 6,367, consisting of o $ 392 private debt offering costs o $ 5,975 deferred debt discount	$ 41,469	651%

The change in the deferred debt discount and private debt offering costs reflects the amortization of the remaining deferred debt discount and private debt offering costs incurred from all of the Company's debenture and bridge loan financings. As a result of the conversion of all convertible debentures into preferred stock at August 13, 2004, 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 September 30, 2004 and September 30, 2003 was as follows (in thousands):

3 MONTHS ENDED 9/30/04 NET LOSS	3 MONTHS ENDED 9/30/03 NET LOSS	3 MONTHS ENDED 9/30/04-9/30/03 NET LOSS CHANGE ($)	3 MONTHS ENDED 9/30/04-9/30/03 NET LOSS CHANGE (%)
($ 51,480)	($ 11,590)	$ 39,890	344%

Included in the net loss for the three months ending September 30, 2004 is the full amortization of the remaining deferred debt discount and private offering costs of $47,836, gains on asset sales of $633, net interest expense of $669 and other income of $202 relating to settlement of a liability at a discount.

LIQUIDITY AND CAPITAL RESOURCES

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 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 (see "Conversion of 2004 Debentures into Series A Preferred Stock" below).

Source and Amount of Funding under 2004 Purchase Agreement

Of the $14.0 million in 2004 Debentures issued in the 2004 Debenture Offering, approximately $2.0 million of 2004 Debentures were issued in exchange for the surrender of like amount of principal plus accrued interest outstanding under Company's 5% convertible senior secured debentures issued pursuant to working capital bridge loan transactions with Care Capital, Essex and Galen during November and December, 2003.

Conversion of 2004 Debentures into Series A Preferred Stock

The 2004 Debentures (including the principal amount plus interest accrued) converted automatically into the Company's Series A convertible preferred stock (the "Series A Preferred") on August 13, 2004, the business day following the Company's receipt of shareholder approval to restate the Company's Certificate of Incorporation (the "Charter Amendment") to authorize the Series A Preferred and the Junior Preferred Shares (as described below) and the filing of the Charter Amendment with the Office of the New York Department of State, as provided in the 2004 Purchase Agreement. The 2004 Debentures converted into an aggregate of 21,963,757 Series A Preferred shares based on a $0.6425 per share conversion price.

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.

Impact of Conversion of the Company's Outstanding Debentures

As of February 10, 2004, the date of the initial closing of the 2004 Purchase Agreement, the Company had issued and outstanding and aggregate of approximately $86.6 million in principal amount of 5% convertible senior secured debentures maturing March 31, 2006 issued pursuant to three separate Debenture Purchase Agreements dated March 10, 1998, as amended (the "1998 Debentures"), May 26, 1999, as amended (the "1999 Debentures") and December 20, 2002 (the "2002 Debentures"), respectively. The 1998 Debentures, 1999 Debentures and 2002 Debentures are referred to collectively as the "1998-2002 Debentures". After giving effect to the Company's issuance of additional 5% convertible senior secured debentures in satisfaction of interest payments on the 1998-2002 Debentures, as of February 10, 2004, the 1998-2002 Debentures were convertible into an aggregate of approximately 190.4 million shares of the Company's Common Stock.

Conversion Agreement of Holders of 1998-2002 Debentures

Simultaneous with the execution of the 2004 Purchase Agreement, and as a condition to the initial closing of the 2004 Purchase Agreement, the Company, the 2004 Debenture Investor Group and each of the holders of the 1998-2002 Debentures executed a certain Debenture Conversion Agreement, dated as of February 6, 2004 (the "Conversion Agreement"). In accordance with the terms of the Conversion Agreement, effective August 13, 2004, each holder of 1998-2002 Debentures converted the 1998-2002 Debentures held by such holder into the Company's Series B convertible preferred stock (the "Series B Preferred") and/or Series C-1, C-2 and/or C-3 convertible 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".

Under the Conversion Agreement, the holders of approximately $6.6 million in principal amount of 2002 Debentures issued during 2003 converted such 2002 Debentures (plus accrued and unpaid interest) into Series B Preferred Shares. Of the remaining approximate $80 million in principal amount of the 1998-2002 Debentures, approximately $31.2 million was comprised of 1998 Debentures, approximately $21.5 million was comprised of 1999 Debentures and approximately $27.3 million was comprised of 2002 Debentures. Effective August 13, 2004, the 1998 Debentures were converted into Series C-1 Preferred shares, the 1999 Debentures were converted into Series C-2 Preferred shares and the remaining balance of the 2002 Debentures were converted into Series C-3 Preferred shares.

The number of Junior Preferred Shares issued by the Company to by each holder of 1998-2002 Debentures was based on the respective prices at which the 1998-2002 Debentures were convertible into Common Stock. The 2002 Debentures issued in 2003 had a conversion price of $0.3420 per share. The 1998 Debentures, 1999 Debentures and the remaining balance of the 2002 Debentures had conversion prices of $0.5776, $0.5993 and $0.3481 per share, respectively. Upon the automatic conversion of the 1998-2002 Debentures on August 13, 2004, the Company issued an aggregate of 20,246,506 million Series B Preferred shares, 56,422,558 million Series C-1 Preferred shares, 37,433,096 million Series C-2 Preferred shares and 81,907,069 million Series C-3 Preferred shares.

Liquidation Preference of Junior Preferred Shares

In general, the Junior Preferred Shares have a liquidation preference equal to one (1) time the principal amount plus accrued and unpaid interest of the 1998-2002 Debentures 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.

Amendment to Watson Term Loan Agreement

The Company was a party to a certain loan agreement with Watson Pharmaceuticals ("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 March 31, 2006 to June 30, 2007, to provide for satisfaction of future interest payments under the Watson Notes in the form of the Company's Common Stock, 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 "New Watson Note"). Simultaneous with the issuance of the New Watson Note, each of Care Capital, Essex Woodlands, Galen Partners and the other investors in the 2004 Debentures as of February 10, 2004 (collectively, the "Watson Note Purchasers") purchased the New Watson 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 New Watson Note

The New Watson Note in the principal amount of $5.0 million as purchased by the Watson Note Purchasers is 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% and matures on September 30, 2007.

Sale of Certain Company Assets to IVAX

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 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 $500,000 from IVAX.

ADF Technology Research and Development

The Company's primary business focus is the research and development of proprietary abuse deterrent formulation technologies (the "ADF Technology") intended to deter the abuse of opioid-containing orally administered prescription products. A patent application relating to the ADF Technology was filed with the PTO in the fourth quarter of 2003 (see discussion below under the caption "Patent Applications"). The Company's first product candidate ("Product Candidate #1") incorporating the ADF Technology is a tablet formulation intended for oral administration. The Company received regulatory clearance to initiate its clinical trial program for Product Candidate #1 following the acceptance by the FDA of an Investigational New Drug application in October 2004. The clinical development program for Product Candidate #1 will focus on optimizing the product's formulation to most effectively deter opioid abuse while minimizing the potential for any new adverse events compared to non-ADF formulated products.

To date, the Company has performed pre-clinical research and development on Product Candidate #1 through a combination of internal and external collaborative research programs. The Company has and will continue to rely on contract research organizations ("CROs") to perform key components of its product development activities. Such development efforts include the completion of studies demonstrating the effectiveness of the ADF Technology compared to selected currently marketed opioid products in deterring potential intravenous injection. Through the use of CROs, the Company has submitted an investigational new drug application ("IND") relating to Product Candidate #1. Such IND was reviewed by the FDA and in October 2004, after amending such IND, the Company was cleared by the FDA to begin phase I clinical trials for Product Candidate #1. Also through the use of CROs, the Company has evaluated Product Candidate #1 in a single dose clinical study to assess the bioavailability and bioequivalence ("BA/BE") of such product candidate in comparison to a frequently prescribed, commercially marketed drug product with the same opioid active ingredient but without abuse deterrent properties. The results of the BA/BE study indicate that Product Candidate #1 is sufficiently bio-available but not bio-equivalent to the reference commercially marketed opioid product. The Company has subsequently developed a revised formulation of Product Candidate #1 and plans to test such revised formulation in a pilot BA/BE study to confirm that the revised formulation is both bioavailable and bioequilavent to the commercially marketed product without the abuse deterrent properties. There can be no assurance, however, that Product Candidate #1 will be bioavailable and bioequivalent to the extent required to justify continued clinical testing or that, even if it demonstrates acceptable bioequivalence, that it will result in a commercially acceptable drug product. To receive marketing authorization for commercial distribution in the United States, all drug products formulated with the ADF Technology will require the development, submission and filing of a new drug application ("NDA") and approval of such application by the FDA. In the event that Product Candidate #1 is stable and demonstrates acceptable bioequivalence, then substantial additional clinical and non-clinical testing will be required prior to the submission of an NDA. There can be no assurances that Product Candidate #1 will lead to an NDA submission or that if an NDA is filed, that the FDA will approve such regulatory application for commercial distribution.

Opioid Synthesis Technologies Research and Development

The Company is also engaged in the research, development and scale-up of a variety of proprietary manufacturing processes for opioid active pharmaceutical ingredients (the "Opioid Synthesis Technologies") as generally described in the table below.

OPIOID SYNTHESIS TECHNOLOGY	STARTING MATERIAL	ESTIMATED YIELD	APPLICABLE DEA REGISTRATIONS REQUIRED	STATUS OF PATENT APPLICATION
Oxycodone HCl Process #1	Codeine Phosphate	40 - 50%	a) Research b) Manufacturing	One (1) patent issued, US 6,790,959 One (1) Notice of Allowance issued
Hydrocodone Bitartrate Process #1	Codeine Phosphate	85%	a) Manufacturing	Patent Application filed in the second quarter of 2004
Oxycodone HCl Process #2	NRMs	68 - 72%	a) Research b) Manufacturing c) Import	Patent Application filed in July, 2004
Codeine Phosphate Process #1	NRMs	90 - 100%	a) Research b) Manufacturing c) Import	Patent Application filed in the second quarter of 2004
Codeine Phosphate Process #2	NRMs	80-90%	a) Research b) Manufacturing c) Import	Patent Application filed in the second quarter of 2004
Codeine Phosphate Process #3	NRMs	65-85%	a) Research b) Manufacturing c) Import	Patent Application filed in the fourth quarter of 2003
Hydrocodone Bitartrate Process #2	Codeine Base	85 - 95%	a) Research b) Manufacturing	Patent Application filed in the second quarter of 2004
Morphine Sulfate	NRMs	96%	a) Research b) Manufacturing c) Import	Patent Application expected to be filed in the second quarter of 2005
Dihydrocodeine Bitartrate	Codeine Phosphate	>90%	a) Research b) Manufacturing	Patent Application filed in the second quarter of 2004
Hydrocodone Derivatives	Dihydrocodeine	90%	a) Research b) Manufacturing	Patent Application drafted

The Company believes at this stage of development that, except for oxycodone hydrochloride process #1, the Opioid Synthesis Technologies are efficient and cost-effective methods of manufacturing opioid APIs. The Company believes that the primary advantages of these processes include a substantial reduction in the time and number of processing steps required to produce the desired opioid APIs and reduction of the quantity and/or toxicity of the waste products relating to such production. The Company believes that at the current manufacturing scale Hydrocodone Bitartrate Process #1 meets all USP release testing specifications, provides high yields and high levels of purity compared to competitive manufacturing processes used for this active ingredient. The development and documentation of Hydrocodone Bitartrate Process #1 has been completed and the Company believes such process is ready to be tested at full commercial scale.

The Company estimates that to scale up its Hydrocodone Bitartrate Process #1 Opioid Synthesis Technology to desirable commercial scale at its Culver Facility, additional funding of approximately $7.0 million will be required for facility improvements, the purchase, installation and validation of new API manufacturing equipment, environmental waste management compliance, the preparation of the drug master files for the API to be produced at the facility, and related direct labor expenses (collectively, the "API Scale Up Expenses"). No portion of the net proceeds received by the Company from the 2004 Debenture Offering or from the sale of the assets used in the operation of the Congers Facilities to IVAX is budgeted for the API Scale Up Expenses. Until such time, if any, as the Company secures third-party financing dedicated to the API Scale Up Expenses, the Company will be unable to complete the commercial scale up of the Hydrocodone Bitartrate Process #1 or the other Opioid Synthesis Technologies described in the above table. No assurance can be given that the Company will obtain the third-party financing necessary to scale-up the Opioid Synthesis Technologies or that if such financing is obtained, that any one or more of the Opioid Synthesis Technologies will be capable of commercial scale up. As an alternative to scaling-up the Opioid Synthesis Technologies in its own facility, the Company may license-out such Technology to third parties, on an exclusive or non-exclusive basis. There can be no assurance, however, that the Company will actually enter into any license agreements relating to the Opioid Synthesis Technologies or derive any licensing fees, milestone payments or royalties from such arrangements.

Patent Applications

To date, the Company has one (1) issued US patent, one (1) issued US Notice of Allowance, one (1) foreign patent application and six (6) patent applications pending with the United States Patent and Trademark Office ("PTO") relating to the Opioid Synthesis Technologies. Additionally, the Company has one (1) pending US patent application relating to the ADF Technology. The typical review time of a U.S. patent application varies. The initial review generally occurs approximately 12 to 18 months from date of patent filing. At the completion of the initial review, the patent examiner will issue an Office Action letter, which will detail any necessary amendments, supplements or reasons for the rejection. Subsequent processing of the patent application will depend on the number of Office Action letters issued and the speed of review of the Company's responses thereto. If an application is granted, a Notice of Allowance will be issued, requiring a payment of the issue fee within three (3) months from the date of the notice. Upon the payment of the fee, the patent would be issued.

In September 2004, the Company received from the PTO an issued patent relating to one of the oxycodone HCI Opioid Synthesis Technologies. In October 2004, the Company received from the PTO a Notice of Allowance for a second patent application relating to one of the oxycodone HCI Opioid Synthesis Technologies. The Company has paid the issuing fee relating to the Notice of Allowance and expects that the corresponding US patent will be issued for the second oxycodone HCI patent. No assurance can be given, however, that any other currently pending patent applications or future patent applications relating to the Opioid Synthesis Technologies will be granted. In addition, the Company is currently unable to provide any assurance that the U.S. patent application associated with the ADF Technology will issue, or if such patent issues, that the claims granted will be sufficiently broad to provide economic value. Moreover, even if such patents issue, there can be no assurance that the commercialization of products incorporating the ADF Technology will not infringe the patents or other intellectual property rights of third parties. The Company's success depends in significant part on the Company's ability to obtain protection for the ADF Technology, both in the United States and in other countries, to enforce these patents and to avoid infringing third-party patent and intellectual property rights.

Import License Registration

To provide for an economical source of raw materials for the commercial manufacture of opioids utilizing certain of the Opioid Synthesis Technologies, the Company filed with the U.S. Drug Enforcement Agency (the "DEA") an application for registration to import certain narcotic raw materials ("NRMs"). The Company filed its application for registration to import NRMs on January 31, 2001 (the "Import Registration"). Notice of the Company's application was published in the Federal Register on September 6, 2001. Within the 30 day period provided under DEA guidelines, three parties, including two companies that the Company believes are the largest U.S. importers of NRMs requested a hearing to formally object to the Company's request for an Import Registration. Pursuant to established procedures, an evidentiary hearing relating to the Company's Import Registration application was held before a DEA Administrative Law Judge ("ALJ") in August 2003. The ALJ later re-opened the administrative record, at the request of opposing parties, to consider the Company's November and December 2003 announcements concerning the Company restructuring and financing activities. After submission of additional testimony by the Company and certain of the opposing parties, the ALJ closed the evidentiary record on May 25, 2004. As of August 31, 2004, the Company and the opposing parties have prepared and submitted to the ALJ briefing documents based on the evidentiary record and replies to the opposing parties' briefing documents. With the evidentiary record closed and the briefing documents and reply briefing documents submitted, the Company estimates that within 18 months from September 1, 2004, the ALJ will make findings of fact, draw legal conclusions and recommend a specific recommendation on the Company's Import Registration application to the DEA Deputy Administrator. Historically, within 14 months after receiving the ALJ's recommendation, the DEA deputy administrator will issue an order relating to the Company's application. Assuming DEA grants the Company's application, of which no assurance can be given, the Company would be permitted to import NRMs upon appropriate notice in the Federal Register. However, the opposing parties may challenge the DEA decision to grant the Company's application in an appropriate Court of Appeals. In such a case, assuming the Company opposes an appellate challenge, the Company would likely incur additional time delays and legal expenses prior to the issuance of a final decision by the U.S. Court of Appeals. Provided the Company continues to seek the Import Registration, it is expected that the proceedings will continue through 2005 and beyond. No assurance can be given that the Company's Import Registration application will be granted by the DEA or that if granted by DEA, the Import Registration would be upheld following an appellate challenge. Furthermore, the Company's cash flow and limited sources of available financing make it uncertain that the Company will have sufficient capital to continue to fund the development of the Opioid Synthesis Technologies, to obtain required DEA approvals and to fund the capital improvements necessary for the manufacture of APIs and finished dosage products incorporating the Opioid Synthesis Technologies.

Commercial Focus, Cash Reserves and Funding Requirements of the Restructured Company

As of November 11, 2004, the Company had cash and cash equivalents of approximately $3.8 million. All of such cash reserves will be dedicated to the development of the Company's ADF Technology, the Opioid Synthesis Technologies, the prosecution of the Company's patent applications and Import Registration and for administrative and related operating expenses.

Subsequent to the completed restructuring of its operations, 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 ADF Technology, the Opioid Synthesis Technologies and related ongoing administrative and operating expenses. The Company's future sources of revenue, if any, will be derived from the sale of API manufactured using its Opioid Synthesis Technologies and from contract signing fees, milestone payments and royalties and/or profit sharing payments from licensees for the Company's ADF Technology or Opioid Synthesis Technologies. The Company estimates that its current cash reserves will be sufficient to fund the development of the ADF Technology, the Opioid Synthesis Technologies and related operating expenses through April, 2005. To fund operations through December 2005, the Company estimates that it must raise additional financing, or enter into alliances or collaboration agreements with third parties providing for net proceeds to the Company of at least $5 million. 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 ADF Technology or the Opioid Synthesis Technologies, or otherwise enters into alliances or collaborative agreements relating to such technologies, 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 ADF Technology in a timely manner, to obtain an issued U.S. patent relating to such 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.

RISK FACTORS RELATING TO THE COMPANY

THE COMPANY RECEIVED A "GOING CONCERN" OPINION FROM ITS INDEPENDENT AUDITORS, 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 $67.9 million in the nine months ended September 30, 2004 and $48.5, $59.6 and $12.5 million during fiscal 2003, 2002 and 2001, respectively. As of September 30, 2004 our accumulated deficit was approximately $277.5 million. The Company's consolidated financial statements for the year ended December 31, 2003 and the nine months ended September 30, 2004 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 opioid abuse deterrent formulation technology (the "ADF Technology");
- the receipt of a notice of allowance and issued patent from the US Patent and Trademark Office ("PTO") for the material claims in our patent application relating to the ADF Technology;
- the ADF Technology not infringing third-party patents or other intellectual property rights;
- the completion of the development, commercial scale up and acceptable regulatory review of our opioid active pharmaceutical ingredient manufacturing process technology (the "Opioid Synthesis Technologies");
- the receipt of approval from the U.S. Drug Enforcement Administration ("DEA") to import narcotic raw materials to be used in our development and manufacturing efforts; and
- the interest of qualified third parties in our ADF Technology 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 are substantial and will depend on many factors, including:

- the expenses incurred in the development and commercialization of products incorporating our Technologies;
- the structure of any future collaborative or development agreements relating to the 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 Technologies;
- our ability to negotiate agreements with third parties for development, marketing, sale and distribution of products utilizing our Technologies;
- the prosecution, defense and enforcement of patent claims and other intellectual property rights relating to the Technologies; and
- the commercialization of products incorporating our 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 April, 2005. To fund operations through December, 2005, the Company estimates that it must raise additional financing, or enter into alliances or collaborative agreements with third parties providing for net proceeds to the Company of at least $5 million. 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 Technologies, or otherwise enters into alliances or collaborative agreements relating to the 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 Technologies, and the receipt of regulatory approval of products incorporating our Technologies, 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 a consequence of the restructuring of our operations, including the cessation of our finished dosage manufacturing and packaging operations at our former Congers, NY facilities and the sale of such assets and related generic products to third parties , we have no ability to generate revenues from the sale of generic products. As of September 30 , 2004, we had cash and cash equivalents of approximately $4.6 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 Technologies, or products incorporating such Technologies, may be commercialized.

OUR PRODUCT CANDIDATES ARE BASED ON TECHNOLOGIES THAT COULD ULTIMATELY PROVE INEFFECTIVE

In accordance with the restructuring of the Company's operations, the Company has transitioned to a single operations facility located in Culver, Indiana. At such site, the Company will seek to develop its proprietary ADF Technology and Opioid Synthesis Technologies. With respect to the ADF Technology, the first product candidate ("ADF Product Candidate #1") resulting from the ADF Technology is a tablet formulation intended for oral administration. Such product candidate is currently undergoing stability testing. Six month real time stability data for Product Candidate #1 appear to be satisfactory. However, the Company can provide no assurance that the stability of ADF Product Candidate #1 will result in a commercially acceptable drug product with at least 24 months of acceptable stability data. In addition, ADF Product Candidate #1 has been evaluated in a single dose clinical study to assess the bio-availability and bio-equivalence ("BA/BE") of such product candidate in comparison to a frequently prescribed commercially marketed drug product with the same opioid active ingredient but without abuse deterrent properties. The results of the BA/BE study indicate that ADF Product Candidate #1 is sufficiently bio-available but not bioequivalent to the reference commercially marketed opioid product. The Company has subsequently developed a more discriminating dissolution test methodology and a revised formulation of Product Candidate #1 (Product Candidate #1R) and plan to test such revised formulation in a second BA/BE study to confirm that the revised formulation is both bio-available and bio-equivalent to the commercially marketed product without the abuse deterrent properties. Even if ADF Product Candidate #1R is stable and demonstrates acceptable bio-availability, substantial additional clinical and non-clinical testing will required to continue development and for the preparation and submission of an NDA filing with the FDA. There can be no assurance that ADF Product Candidate #1R or any other product developed using the ADF Technology will lead to an NDA submission to the FDA and that if an NDA is filed, that the FDA will approve such regulatory application to allow for commercial distribution of the product.

With respect to the Opioid Synthesis Technologies, while the Company believes that such technologies are effective and cost-effective methods of manufacturing opioid APIs, such technologies will need to be scaled up to commercial scale to have economic value, of which no assurance can be given. Additionally, unless the Company secures third-party financing dedicated to the scale up expenses relating to the Opioid Synthesis Technologies (estimated by the Company to be approximately $7.0 million), the Company will be unable to complete the commercial scale up of the Opioid Synthesis Technologies. No assurance can be given that the Company will obtain the third-party financing necessary to scale up the Opioid Synthesis Technologies or, if such financing is obtained, that any one or more of the Opioid Synthesis Technologies will be capable of commercial scale up.

The Company is committing substantially all of its resources and available capital to the development of the ADF Technology, the Opioid Synthesis Technologies and the prosecution of its patent applications for such Technologies. The failure of the Company to successfully develop the ADF Technology, to successfully obtain an issued patent from the PTO relating to the ADF Technologies and ADF Product Candidates, and to avoid infringing third-party patents and other intellectual property rights in the commercialization of such ADF Products will have a material adverse effect on the Company's operations and financial condition.

IF PRE-CLINICAL TESTING OR CLINICAL TRIALS FOR OUR PRODUCT CANDIDATES ARE UNSUCCESSFUL OR DELAYED, WE WILL BE UNABLE TO MEET OUR ANTICIPATED DEVELOPMENT AND COMMERCIALIZATION TIMELINES.

To obtain FDA approval for any of our product candidates, we must submit to the FDA a new drug application ("NDA") demonstrating, among other things, that the product candidate is safe and effective in humans for its intended use. This demonstration requires significant research and animal tests, which are referred to pre-clinical studies, as well as human tests, which are referred to as clinical trials. As we do not possess the resources or employ all the personnel necessary to conduct clinical trial studies, it is our intention to rely on collaborative partners to conduct Phase II and Phase III clinical trials on our product candidates. As a result, we will have less control over the timing and other aspects of these clinical trials than if we performed the monitoring and supervision of clinical trials entirely on our own. Third parties may not perform their responsibilities for our pre-clinical testing or clinical trials on our anticipated schedule or, for clinical trials, consistent with a clinical trial protocol. Delays in pre-clinical and clinical testing 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 clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient pre-clinical safety required to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective collaborative partners;
- manufacturing and quality assurance releasing a sufficient supply of a product candidate for use in our clinical trials; and
- 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; or
- negative results of clinical trials.

Phase III clinical trials 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 Phase III 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 Technologies and further develop, register 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 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 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 pain management products, it may be necessary for us to license all or significant portion of our product candidates to a single collaborator, thereby eliminating our opportunity to commercialize other pain management products 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
- 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 ADF 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 ADF Technology, both 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. Although we have filed a patent application with the PTO on our ADF Technology, there is no assurance that a patent will issue or, if issued, that such patent will be valid and enforceable against third party infringement or that such patent will not infringe any third party patent or intellectual property. Moreover, even if patents do issue on our ADF Technology, the claims allowed may not be sufficiently broad to protect the products incorporating the ADF 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 of 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 Company's ADF Technology. For example, the Company has recently become aware of certain United States and European patent applications owned by third parties that claim multiple-form abuse deterrent technologies. If such patent applications result in issued patents, with claims encompassing our ADF Technology or products, the Company may need to obtain a license in order to commercialize products incorporating the ADF Technology, should one be available or, alternatively, alter the ADF 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 incorporating the ADF Technology. Additionally, any alterations to the Company's ADF Technology in view of such 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 Company's ADF 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 ADF Technology will not infringe such 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 would have a material adverse effect on the Company's operations and financial condition. In addition, in the event the Company is successful in developing product candidates for sale in other countries, the Company would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive.

We may encounter delays or rejections during any stage of the regulatory approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the products to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of a marketing application, in the form of a New Drug Application ("NDA"), a 502(b)(2) application, 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) 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 Company's 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 (GMP) 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 chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Certain opioid active ingredients in our current product candidates are classified by the DEA as Schedule II or III 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. These regulations require, for example, that all Schedule II product prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. 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

Our business strategy focuses on the development of opioid containing products incorporating the Technologies. The development, marketing and sale of products incorporating the Technologies is subject to extensive regulation by the DEA and FDA. At present, the Company's facility located in Culver, Indiana is approved by the DEA to manufacture Schedule II to V controlled substance active pharmaceutical ingredients ("APIs") and finished dosage products incorporating such API's. To continue the development and commercialization of the Opioid Synthesis Technologies, 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 NMRs 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 continue to fund 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 ADF 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 (cGMPs) regulations as interrupted 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 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 then 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.

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

WE 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 in the amount of $1.0 million per occurrence and $3.0 million annually in the aggregate 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 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.

In addition, since the Company's delisting from the American Stock Exchange in September 2000, the Company's common stock has been traded 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 guaranty 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 46.3% 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 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 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 aversely 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 $5.0 million senior term loan 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.

ACCOUNTING POLICIES

Note A of the Notes to Consolidated Financial Statements, as contained in the Company's Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. 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 great likelihood that materially different amounts would be reported under different conditions or using different assumptions. The Company's critical accounting policies are as follows:

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"). 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 results from the issuance of stock warrants and beneficial conversion features in connection with the issuance of subordinated debt 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.

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 September 30, 2004 the Company issued 211,918 shares of the Company's common stock as payment of $106,000 accrued interest due June 30, 2004 on the Company's senior secured term note . In October 2004, the Company issued an additional 261,309 shares of the Company's common stock as payment of $112,000 accrued interest due September 30, 2004 on the Company's senior secured term note .

Conversion of the Company's Debentures

On August 13, 2004, the business day following the Company's receipt of shareholder approval to restate the Company's Certificate of Incorporation (the "Charter Amendment") to authorize Series A Convertible Preferred Stock ("Series A Preferred"), Series B Convertible Preferred Stock ("Series B Preferred"), Series C-1 Convertible Preferred Stock, Series C-2 Convertible Preferred Stock and Series C-3 Convertible Preferred Stock (collectively, "Series C Preferred" and collectively with Series A Preferred and Series B Preferred, the "Preferred Stock"), all of the Company's outstanding convertible senior secured debentures (the "Debentures") automatically converted into the Preferred Stock. As a result of such automatic conversion of the Debentures, the Company issued an aggregate of 21,963,757 million Series A Preferred shares, 20,246,506 million Series B Preferred shares, 56,422,558 million Series C-1 Preferred shares, 37,433,096 million Series C-2 Preferred shares and 81,907,069 million Series C-3 Preferred shares. The Company received no additional consideration as a result of the automatic conversion of the Debentures into the Preferred Stock

Preferred Stock

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) 3.125 (five (5) times the initial $0.6425 Series A conversion price) by (ii) Series A conversion price of $0.6425, as such conversion price may be adjusted, from time to time, pursuant to the dilution protections of such shares.

Each of the Series B Preferred shares and Series C Preferred shares are convertible into the Company's Common Stock, with each Series B Preferred share and Series C Preferred share convertible into one share of Common Stock.

Exemption from Registration

The Company issued the Preferred 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 Debentures, senior secured term note and shares of common stock issued during the Quarter ended September 30, 2004, 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 Debentures and any securities issued pursuant thereto were being acquired for investment purposes.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

The Company's 2004 Annual Meeting of Shareholders was held on August 12, 2004 (the "Annual Meeting"). In connection with the Annual Meeting proxies were solicited by management pursuant to Regulation 14A under the Securities Exchange Act of 1934. On the record date for the Annual Meeting, the Company's outstanding voting securities consisted of 66,453,861 shares of common stock, of which 60,841,517 shares were represented in person or by proxy at the Annual Meeting.

At the Annual Meeting, the following matters were submitted to a vote of the company's voting security holders, with the results indicated below:

1. Election of Directors.

The following five (5) incumbent directors and one (1) new director were elected to serve until the next Annual Meeting of Shareholders. The tabulation of votes was as follows:

Nominee	For	Withheld
Jerry Karabelas	60,617,128	224,389
Immanuel Thangaraj	60,616,204	225,313
Bruce F. Wesson	60,617,028	224,489
Andrew D. Reddick	60,616,304	225,213
William A.Sumner	60,658,074	183,443
William Skelly	60,658,204	183,313

2. Proposal to Restate the Company's Certificate of Incorporation to Increase its Authorized Capital Stock.

The tabulation of votes was as follows:

For	Against	Abstained	Not Voted
51,199,369	347,528	9,664	9,284,956

3. Proposal to Approve the Amendment to the Company's Certificate of Incorporation to Change the Name of the Company.

The tabulation of votes was as follows:

For	Against	Abstained
60,794,914	37,548	9,055

4. Proposal to Approve the Sale of Substantially All of the Assets used in Manufacture and Sale of Finished Dosage Pharmaceutical Products at the Company's Former Congers, New York Locations.

The tabulation of votes was as follows:

For	Against	Abstained	Not Voted
51,347,419	199,562	9,580	9,284,956

5. Proposal to Approve the Amendment to the Company's 1998 Stock Option Plan.

The tabulation of votes was as follows:

For	Against	Abstained	Not Voted
50,979,253	543,769	33,539	9,284,956

6. Proposal to Ratify the Company's Independent Accountants for the Current Fiscal Year.

The tabulation of votes was as follows:

For	Against	Abstained
60,777,144	55,874	8,499

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.

Date: November 12, 2004 ACURA PHARMACEUTICALS, INC.

By: /s/ Andrew D. Reddick

Andrew D. Reddick
President & Chief Executive Officer

By: /s/ Peter A. Clemens

Peter A. Clemens
Senior Vice President & 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.

EXHIBIT 31.1

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: November 12, 2004

/s/ Andrew D. Reddick

Andrew D. Reddick
Chief Executive Officer

EXHIBIT 31.2

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: November 12, 2004

/s/ Peter A. Clemens

Peter A. Clemens
Chief Financial Officer

EXHIBIT 32.1

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 September 30, 2004 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: November 12, 2004

/s/ Andrew D. Reddick

Andrew D. Reddick
Chief Executive Officer

EXHIBIT 32.2

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 September 30, 2004 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: November 12, 2004

/s/ Peter A. Clemens

Peter A. Clemens
Chief Financial Officer