SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20649

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

or

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

For the transition period from _____ to_____

Commission File Number 1-10113

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

New York	**11-0853640**
(State or other Jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
616 N. North Court, Suite 120 **Palatine, Illinois** *(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, and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 S-T (§232.405 of this charter) during the preceding 12 months (or to such shorter period that the registrant was required to submit and post such files).

Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large" filer, "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☑	Smaller reporting company ☐

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

As of October 28, 2012 the registrant had 45,864,422 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value)

	September 30, 2012 (unaudited)	December 31, 2011 (audited)
Assets		
Current assets		
Cash and cash equivalents	$ 29,320	$ 35,685
Income taxes refundable	157	153
Prepaid insurance	328	218
Prepaid expenses and other current assets	33	73
Total current assets	29,838	36,129
Property, plant and equipment, net	1,076	1,044
Total assets	$ 30,914	$ 37,173
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 228	$ 53
Accrued expenses	459	477
Total current liabilities	$ 687	$ 530
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock - $.01 par value; 100,000 shares authorized; 45,864 and 45,320 shares issued and outstanding at September 30, 2012 and December 31, 2011	458	453
Additional paid-in capital	361,964	361,733
Accumulated deficit	(332,195)	(325,543)
Total stockholders' equity	30,227	36,643
Total liabilities and stockholders' equity	$ 30,914	$ 37,173

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED
(in thousands, except per share data)

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2012	2011	2012	2011
Revenues				
Program fee revenue	$ 0	$ 466	$ 0	$ 0
Milestone revenue	0	20,000	0	0
Total revenues	0	20,466	0	0
Operating expenses				
Research and development	2,518	3,245	696	962
Marketing, general and administrative	4,164	4,840	1,453	1,185
Total operating expenses	6,682	8,085	2,149	2,147
Income (loss) from operations	(6,682)	12,381	(2,149)	(2,147)
Other income (expense), net	30	(9)	9	6
Income (loss) before income tax	(6,652)	12,372	(2,140)	(2,141)
Income tax expense	0	341	0	0
Net income (loss)	$ (6,652)	$ 12,031	$ (2,140)	$ (2,141)
Income (loss) per share				
Basic	$ (0.14)	$ 0.25	$ (0.04)	$ (0.05)
Diluted	$ (0.14)	$ 0.25	$ (0.04)	$ (0.05)
Weighted average shares				
Basic	47,520	47,392	47,522	47,802
Diluted	47,520	47,627	47,522	47,802

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

NINE MONTHS ENDED SEPTEMBER 30, 2012

UNAUDITED
(in thousands, except par value)

	Common Stock $0.01 Par Value - Shares	Common Stock $0.01 Par Value - Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2011	45,320	$ 453	$ 361,733	$ (325,543)	$ 36,643
Net loss	0	0	0	(6,652)	(6,652)
Share-based compensation	0	0	1,272	0	1,272
Net distribution of common stock pursuant to restricted stock unit award plan	827	8	(7)	0	1
Common shares withheld for withholding taxes on distribution of restricted stock units	(296)	(3)	(1,031)	0	(1,034)
Net issuance of common stock pursuant to cashless exercise of stock options	10	0	0	0	0
Common shares withheld for withholding taxes on cashless exercise of stock options	(3)	0	(12)	0	(12)
Issuance of common stock for exercise of stock options	6	0	9	0	9
Balance at September 30, 2012	45,864	$ 458	$ 361,964	$ (332,195)	$ 30,227

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30,

UNAUDITED
(in thousands)

	2012	2011
Cash flows used in operating activities:		
Net income (loss)	$ (6,652)	$ 12,031
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation	97	99
Non-cash share-based compensation expense	1,272	2,133
Loss on disposal of property and equipment	0	5
Changes in operating assets and liabilities:		
Collaboration revenue receivable	0	126
Prepaid expenses and other current assets	(70)	(156)
Accounts payable	175	45
Accrued expenses	(18)	279
Income taxes refundable	(4)	105
Deferred program fee revenue	0	(466)
Net cash (used in) provided by operating activities	(5,200)	14,201
Cash flows used in investing activities – purchase of property and equipment	(129)	(54)
Cash flows used in financing activities:		
Exercise of stock options	9	217
Distribution of restricted stock units	1	5
Net proceeds from warrant exercise	0	1,076
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(1,046)	(1,830)
Net cash used in finance activities	(1,036)	(532)
Net increase (decrease) in cash and cash equivalents	(6,365)	13,615
Cash and cash equivalents at beginning of period	35,685	24,045
Cash and cash equivalents at end of period	$ 29,320	$ 37,660
Supplemental cash flow information		
Cash paid for:		
Interest	$ 0	$ 26
Income taxes	$ 0	$ 218

Supplemental Disclosure of Noncash Financing Activities (in thousands)

For the Nine Months Ended September 30, 2012

1. 829 shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan and after withholding 2 shares for $7 in exercise costs and withholding 296 shares for $1,034 in statutory minimum payroll taxes, a net 531 shares of common stock were issued.
2. Options to purchase 17 shares of common stock were exercised utilizing various cashless exercise features of our plan and after withholding 7 shares for $22 in exercise costs and withholding 3 shares for $12 in statutory minimum payroll taxes, 7 shares of common stock were issued.

For the Nine Months Ended September 30, 2011

1. 829 shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan and after withholding 1 shares for $3 in exercise costs and withholding 288 shares for $953 in statutory minimum payroll taxes, a net 540 shares of common stock were issued.
2. Options to purchase 925 shares of common stock were exercised utilizing various cashless exercise features of our plan and after withholding 321 shares for $1,231 in exercise costs and withholding 227 shares for $ 877 in statutory minimum payroll taxes, 377 shares of common stock were issued.

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2012 AND 2011

NOTE 1 BASIS OF PRESENTATION

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the "Company", "We", or "Our") is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address medication abuse and misuse, utilizing its proprietary Aversion® and Impede™ technologies.

The accompanying unaudited consolidated financial statements of the Company were prepared in accordance with generally accepted accounting principles for interim financial information and instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments considered necessary to present fairly the Company's financial position, results of operations and cash flows have been made. The results of operations for the nine months ended September 30, 2012 are not necessarily indicative of results expected for the full year ending December 31, 2012. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto for the year ended December 31, 2011 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission. The 2011 year-end consolidated balance sheet presented in this Report was derived from the Company's 2011 year-end audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles.

NOTE 2 RESEARCH AND DEVELOPMENT

Research and Development ("R&D") expenses include internal R&D activities, external Contract Research Organization ("CRO") services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments, clinical trial studies or other contracted development services. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. We make payments to the CRO's based on agreed upon terms and may include payments in advance of a study or service starting date. We review and accrue CRO activity expenses based on services performed and rely on estimates of those costs applicable to the stage of completion as provided by the CRO. Accrued CRO activity expenses are subject to revisions as such services progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. At September 30, 2012 and December 31, 2011 we had accrued $23 thousand and $28 thousand of CRO activity expenses, respectively.

NOTE 3 REVENUE RECOGNITION AND DEFERRED PROGRAM FEE REVENUE

We recognize revenue when there is persuasive evidence that an agreement exists, performance specified in the agreement has occurred, the price is fixed and determinable, and collection is reasonably assured. In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 (the "Pfizer Agreement") with King Pharmaceuticals Research and Development, Inc. ("King"), a subsidiary of Pfizer, Inc. ("Pfizer"), we recognize program fee revenue and milestone revenue. On July 26, 2012 Pfizer provided us with notice of the exercise of its right to terminate the license to three development opioid products using our Aversion® Technology which carried a 12 month notice period. On September 26, 2012 we announced that we entered into a letter agreement with Pfizer which provides for the termination of Pfizer's license to our Aversion Technology used in the three development-stage products as of September 26, 2012 and the transfer of these products back to us. A fourth product utilizing our Aversion® Technology, Oxecta (oxycodone hydrochloride) Tablets CII, is being commercialized by Pfizer in the United States and Pfizer retains all rights and obligations relating to Oxecta® under the Pfizer Agreement.

Program fee revenue is derived from amortized upfront payments, such as the $30.0 million upfront payment under the Pfizer Agreement received in December 2007, and license fees, such as the $3.0 million option exercise fee paid to us in each of May and December 2008 upon the exercise of Pfizer's option to license a third and fourth opioid analgesic product candidate under the Pfizer Agreement. We have assigned an equal portion of the $30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. The recognition of the program fee revenue for two of the three product candidates was completed by June 2008. During the second quarter 2011, we recognized the remaining program fee revenue which was assigned to the third product candidate under the Pfizer Agreement.

Milestone revenue is contingent upon the achievement of certain pre-defined events in the Pfizer Agreement. Milestone payments received under the Pfizer Agreement are recognized as revenue upon achievement of the "at risk" milestone events. Milestone payments are triggered either by the results of our R&D efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones were substantially at risk at the inception of the Pfizer Agreement and the amounts of the revenue correspond to the milestone payments set forth in the Pfizer Agreement. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone. Milestone revenue is non-refundable and non-creditable upon payment. Under the Pfizer Agreement, we remain eligible to receive milestone payments for the achievement of a certain net sales level of Oxecta and a regulatory milestone for the approval of Oxecta in another territory, however, no assurance can be made that Pfizer will achieve these milestones.

NOTE 4 INCOME TAXES

The Company accounts for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities and are accounted for using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At both September 30, 2012 and December 31, 2011, all our remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

NOTE 5 ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	Sept 30, 2012	Dec 31, 2011
	(in thousands)	
Payroll, payroll taxes, bonus and benefits	$ 94	$ 104
Professional services	174	191
Franchise taxes	2	60
Property taxes	23	21
Clinical and regulatory services	54	59
Other fees and services	112	42
Total	$ 459	$ 477

NOTE 6 SHARE-BASED COMPENSATION

The Company has share-based compensation plans including stock options and restricted stock units ("RSUs") for its employees and directors. The Company accounts for compensation cost related to share-based payments based on fair value of the stock options and RSUs when awarded to an employee or director. The value of the portion of the award that is ultimately expected to vest is recognized as expense in the relevant accounting periods in the Company's consolidated financial statement. The Company uses the straight line amortization method for calculating share-based compensation expense. The Company determines the estimated fair value of share-based stock option awards using the Black-Scholes option pricing model. Option valuation models require the input of highly subjective assumptions including the expected volatility of the market price of the Company's common stock as determined by reviewing its historical public market closing prices, risk-free interest rate and expected dividend yields. The Company does not consider implied volatility because of a lack of an established market in option trading in our stock. The risk – free interest rate assumption is based on observed interest rates appropriate for the estimated term of the employee stock options. The dividend yield assumption is based on the Company's history and current expectation of dividend payouts on common stock. The expected term of the award represents the period that the employees and directors are expected to hold the award before exercise and issuance using historical exercise activity. The Company's accounting for share-based compensation for RSUs is also based on the fair-value method. The fair value of the RSUs is based on the closing market price of the Company's common stock on the date of the RSU award.

Our non-cash share-based compensation expense is comprised of the following:

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2012	2011	2012	2011
Research and development				
Stock options	$ 273	$ 399	$ 91	$ 44
RSUs	0	75	0	0
	273	474	91	44
General and administrative				
Stock options	999	1,431	333	206
RSUs	0	228	0	0
	999	1,659	333	206
Total	$ 1,272	$ 2,133	$ 424	$ 250

Stock Option Award Plans

At September 30, 2012, the Company has stock options issued and outstanding under three stock option plans. The Company's 1995 and 1998 Stock Option Plans have expired but stock options awarded under such plans remain outstanding under the terms of those plans. The Company's 2008 Stock Option Plan remains in effect. To date, approximately 50% of the vested non-incentive stock options ("NonISO") under the 1998 and 2008 stock option plans have been exercised. Absent a change in control, the balance of NonISOs may be exercised in equal amounts during each of calendar years 2013 and 2014.

Exercise of NonISOs by employees may require the Company to make minimum statutory withholding tax ("withholding tax") payments for such employee on any gain on such shares at the time of exercise. The employee is responsible for providing sufficient funds to the Company to make such withholding tax payments. However, under the Company's stock option plans, the employee may elect to take a partial distribution of the exercised NonISO shares and have the Company retain the balance of the exercised shares in satisfaction of the employee's withholding tax payments. In such event, the Company becomes obligated to directly pay the withholding taxes of such employee and will retain a sufficient number of exercised shares such that the fair market value of the retained shares will offset the employee's withholding taxes. The Company has not reflected this obligation as a liability in its consolidated financial statements as the withholding tax payments are contingent upon the timing and number of NonISOs exercised by employees and the closing market price of our common stock at the time of exercise. Such withholding tax will be paid and charged against additional paid in capital as the NonISOs are exercised.

During the nine months ended September 30, 2012, 24 thousand NonISOs were exercised by our employees. Our employees elected to have 10 thousand shares withheld in satisfaction of $34 thousand for both the exercise costs and the withholding tax obligations resulted in the net issuance of 14 thousand shares. During the nine months ended September 30, 2011, 1.1 million NonISOs were exercised by our employees. Our employees elected to have 0.60 million shares withheld in satisfaction of $2.1 million for both the exercise costs and the withholding tax obligations resulted in the net issuance of 0.50 million shares to them.

As of September 30, 2012 the Company had $1.0 million of unrecognized share-based compensation expense from stock option grants, which will be recognized in our consolidated financial statements over their remaining vesting periods over the next 1.25 years. Under the stock option plans, if a change in control occurs, an acceleration of unvested shares will occur and any remaining unrecognized share-based compensation expense will be recognized in our consolidated financial statements.

Our stock option award activity during the nine months ended September 30, 2012 and 2011 is as follows:

	Nine Months Ended September 30,			
	2012		2011	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, beginning	3,556	$ 6.41	4,243	$ 5.40
Granted	105	3.48	96	3.43
Exercised	(24)	1.30	(1,092)	1.33
Forfeited or expired	(703)	8.44	(69)	3.38
Outstanding, ending	2,934	$ 5.86	3,178	$ 6.78
Options exercisable	2,640	$ 6.11	2,932	$ 7.17

Assumptions used in the Black-Scholes model to determine fair value for the stock option awards granted during the nine months ended September 30, 2012 and 2011 were:

	2012	2011
Dividend yield	0.0%	0.0%
Average risk-free interest rate	1.97%	3.17%
Average volatility	114%	114%
Expected forfeitures	0.0%	0.0%
Expected holding period	10 years	10 years
Weighted average grant date fair value	$ 3.25	$ 3.23

Restricted Stock Unit Award Plan

The Company has RSUs issued and outstanding under a Restricted Stock Unit Award Plan ("2005 RSU Plan") for its employees and directors. A RSU represents the contingent obligation of the Company to deliver a share of its common stock to the holders of a vested RSU on a specified distribution date. To date, 50% of RSU awards under the 2005 RSU Plan have been distributed. Absent a change of control, the balance of the RSU awards will be distributed in equal amounts on January 1 of each of 2013 and 2014. Distribution of RSU shares to employees may require the Company to make minimum statutory withholding tax ("withholding tax") payments for such employee on any gain on such shares at the time of distribution. The employee is responsible for providing sufficient funds to the Company to make such withholding tax payments. However, under the 2005 RSU Plan, the employee may elect to take a partial distribution of shares and have the Company retain the balance of the share distribution in satisfaction of the withholding tax payments. In such event, the Company becomes obligated to directly pay the withholding taxes of such employee and will retain a sufficient number of shares such that the fair market value of the retained shares will offset the employee's withholding taxes. The Company has not reflected this obligation as a liability in its consolidated financial statements as the withholding tax payments are contingent upon the timing and number of RSU shares distributed to employees and the closing market price of our common stock at the time of distribution. Such withholding taxes will be paid and charged against additional paid-in capital as the RSU shares are distributed.

On each of January 1, 2012 and 2011, 0.83 million RSUs were distributed to our employees and directors. Our employees' elections to withhold 0.30 million shares in satisfaction of $1.0 million withholding tax obligations resulted in the net issuance of 0.53 million shares in January 2012. Our employees' elections to withhold 0.29 million shares in satisfaction of $1.0 million withholding tax obligations resulted in the net issuance of 0.54 million shares in January 2011.

A summary of the RSU Plan as of September 30, 2012 and 2011 and for the nine months then ended consisted of the following:

	Nine Months Ended September 30,			
	2012		2011	
	(in thousands)			
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	2,487	2,487	3,316	3,267
Granted	0	0	0	0
Distributed	(829)	(829)	(829)	(829)
Vested	0	0	0	49
Forfeited or expired	0	0	0	0
Outstanding, ending	1,658	1,658	2,487	2,487

NOTE 7 COMMON STOCK WARRANTS

The Company has outstanding common stock purchase warrants at September 30, 2012 exercisable for 1.9 million shares of common stock having an exercise price of $3.40 per share and expiration date of August 2014. These warrants contain a cashless exercise feature.

NOTE 8 EARNINGS (LOSS) PER SHARE

Computation of basic earnings (loss) per share of common stock is based on the sum of the weighted average number of outstanding common shares and vested RSUs during the period. Computation of diluted earnings (loss) per share is based on the sum of the common shares and vested RSUs used in the basic earnings (loss) computation, adjusted for the effect of other potentially dilutive securities. Excluded from the diluted earnings (loss) per share computations at September 30, 2012 and 2011 are potentially dilutive securities as the effect of including these securities in these computations would be antidilutive.

(in thousands, except per share data)	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011
Basic income (loss) per share computation Numerator:				
Net income (loss)	$ (6,652)	$ 12,031	$ (2,140)	$ (2,141)
Denominator:				
Common shares (weighted)	45,862	44,914	45,864	45,315
Vested RSUs (weighted)	1,658	2,478	1,658	2,487
Weighted average number of shares outstanding	47,520	47,392	47,522	47,802
Basic income (loss) per common share	$ (0.14)	$ 0.25	$ (0.04)	$ (0.05)
Diluted income per share computation Numerator:				
Net income (loss)	$ (6,652)	$ 12,031	$ (2,140)	$ (2,141)
Denominator:				
Common shares (weighted)	45,862	44,914	45,864	45,315
Vested RSUs (weighted)	1,658	2,478	1,658	2,487
Common stock options	0	142	0	0
Common stock warrants	0	93	0	0
Weighted average number of shares outstanding	47,520	47,627	47,522	47,802
Diluted income (loss) per common share	$ (0.14)	$ 0.25	$ (0.04)	$ (0.05)
Excluded potentially dilutive securities:				
Common shares issuable (1):				
Common stock options (vested and nonvested)	2,934	2,507	2,934	3,179
Common stock warrants	1,856	0	1,856	1,856
Total excluded dilutive common stock equivalents	4,790	2,507	4,790	5,035

(1) Number of shares issuable represents those securities which were either i) nonvested at period end or ii) were vested but antidilutive. The number of shares is based on maximum number of shares issuable on exercise at period end. Such amounts have not been adjusted for the treasury stock method or weighted average outstanding calculations as required if the securities were dilutive.

NOTE 9 COMMITMENTS AND CONTINGENCIES

Paragraph IV ANDA Filings

On September 20, 2012, we announced that we had received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from a generic sponsor of an ANDA for a generic drug listing Oxecta as the reference listed drug. Since such date, we have received similar Paragraph IV Notices from three other generic pharmaceutical companies that have filed ANDAs listing Oxecta as the reference drug. The Paragraph IV Notices refer to our U.S. Patent Numbers 7,201,920, 7,510,726 and 7,981,439, which cover our Aversion Technology and Oxecta. The Paragraph IV Notices state that each generic sponsor believes that such patents are invalid, unenforceable or not infringed. Pfizer has advised us that it will not exercise its first right under the Pfizer Agreement to control the enforcement of our patents licensed to Pfizer for Oxecta against these generic sponsors. As a result, we will take appropriate action to enforce our intellectual property rights and on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. - Florida, Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement of our patent no. 7,510,726 listed in the FDA's Orange Book. The commencement of such litigation prohibits the FDA from granting approval of the filed ANDAs until the earliest of 30 months from the date the FDA accepted the application for filing, or the conclusion of litigation.

Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to us, has been named along with numerous other companies as a defendant in cases filed in three separate state coordinated litigations pending in Pennsylvania, New Jersey and California, respectively captioned In re: Reglan®/Metoclopramide Mass Tort Litigation, Philadelphia County Court of Common Pleas, January Term, 2010, No. 01997; In re: Reglan® Litigation, Superior Court of New Jersey, Law Division, Atlantic County, Case No. 289, Master Docket No. ATL-L-3865-10; and Reglan®/Metoclopramide Cases, Superior Court of California, San Francisco County, Judicial Council Coordination Proceeding No. 4631, Superior Court No.: CJC-10-004631. In this product liability litigation against numerous pharmaceutical product manufacturers and distributors, including us, plaintiffs claim injuries from their use of the Reglan brand of metoclopramide and generic metoclopramide. In the Pennsylvania state court mass tort proceeding, over 200 lawsuits have been filed against us and Halsey Drug Company alleging that plaintiffs developed neurological disorders as a result of their use of the Reglan brand and/or generic metoclopramide. Plaintiffs have filed approximately 150 lawsuits against us, but have served less than 50 individual lawsuits upon us in the New Jersey action. In the California action, we were not served with any complaints until the Spring of 2011 when a single complaint including over 400 plaintiffs was served. To date, Acura has not been served with any metoclopramide lawsuits in jurisdictions other than Philadelphia, New Jersey and California state courts.

In the lawsuits filed to date, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by us. We discontinued manufacture and distribution of generic metoclopramide more than 15 years ago. In addition, we believe the June 23, 2011 decision by the U.S. Supreme Court in *PLIVA v. Mensing ("Mensing* decision") holding that state tort law failure to warn claims against generic drug companies are pre-empted by the 1984 Hatch-Waxman Act Amendments and federal drug regulations will assist us in favorably resolving these cases. We have consistently maintained the position that these claims are without merit and intend to vigorously defend these actions.

In New Jersey, Generic Defendants, including Acura, filed dispositive motions based on the *Mensing* decision, which the Court granted with a limited exception. In June 2012, the New Jersey trial court dismissed Acura with prejudice.

In Philadelphia, and California, Generic Defendants, including Acura, have filed dispositive motions based on the *Mensing* decision. On November 18, 2011, the Philadelphia trial court denied Generic Defendants' dispositive motion. In December 2011, the Generic Defendants appealed this ruling. The Pennsylvania Superior Court will hear argument on this appeal on October 31, 2012. A decision on this appeal should be issued later this year or in 2013, which could result in dismissal of all of the Philadelphia cases against Generic Defendants, although there can be no assurance in this regard.

In addition, on April 17, 2012, the California trail court also denied Generic defendants' dispositive motions and this ruling has been appealed. On September 26, 2012 the California Court of Appeal summarily denied this appeal. A further appeal to the California Supreme Court is pending. The trial court has scheduled a December 4, 2012 conference to further manage this litigation. Nonetheless, as noted above, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by us. Therefore, action will be taken in an effort to dismiss Acura from these cases, although there can be no assurance in this regard.

As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to this matter as of September 30, 2012. Legal fees related to this matter are currently covered by our insurance carrier.

Statutory Minimum Withholding Tax Obligations

Under the terms of our stock option plans and our 2005 RSU plan, our employees may elect to have shares withheld upon their option exercises and their RSU exchanges whereby requiring the Company to satisfy their statutory minimum withholding tax obligations from these transactions. During each of the nine months ended September 30, 2012 and 2011, approximately 0.3 million shares were withheld from these transactions in satisfaction of $1.0 million of withholding tax obligations.

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

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

Forward-Looking Statements

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to, our and our licensee's ability to successfully launch and commercialize our products and technologies including Oxecta® Tablets and Nexafed® Tablets, the price discounting that may be offered by Pfizer for Oxecta®, the ability of us or our licensee's to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, expectations regarding potential market share for our products and the timing of first sales, our ability to enter into additional license agreements for our other product candidates, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability of our patents to protect our products from generic competition, our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation, and the ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development to meet over-the-counter, or OTC, Monograph standards as applicable, the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, whether the FDA will agree with our analysis of our clinical and laboratory studies and how it may evaluate the results of these studies or whether further studies of our product candidates will be required to support FDA approval, whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and will be able to promote the features of our abuse discouraging technologies, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede technology will disrupt the processing of pseudoephedrine into methamphetamine. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in this Report.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on such forward-looking statements.

Company Overview

We are a specialty pharmaceutical company engaged in the research, development and commercialization of products intended to address medication abuse and misuse, utilizing our proprietary Aversion® and Impede™ Technologies. Our products and product candidates are based on widely-used commercial products and do not alter the safety and efficacy of the active pharmaceutical ingredients.

Oxecta® Tablets CII, or Oxecta, was approved for marketing by the United States Food and Drug Administration, or FDA, on June 17, 2011. Oxecta represents the first immediate-release oxycodone product approved by the FDA that applies our Aversion Technology. Aversion is a mixture of inactive ingredients incorporated into pharmaceutical tablets and capsules designed to address some common methods of product tampering associated with abuse. Oxecta is being manufactured and commercialized by Pfizer under our October 2007 license agreement with a subsidiary of Pfizer and was made commercially available by Pfizer in February 2012. We are eligible to receive tiered royalties ranging from 5% to 25% on net sales of Oxecta pursuant to our agreement with Pfizer commencing in February 2013. The trademark Oxecta® is owned by Pfizer Inc.

On September 26, 2012, we announced that we entered into a letter agreement with Pfizer which provides for the termination of Pfizer's license to our Aversion® Technology used in the three development-stage products licensed to Pfizer and for the transfer of these products back to us. These development-stage products are hydrocodone by bitartrate/acetaminophen tablets, oxycodone HCl/acetaminophen tablets and an undisclosed opioid. See the discussion below under the caption "Aversion Products in Development" for further information regarding the development of these products.

We have developed Nexafed®, an OTC immediate-release pseudoephedrine HCl tablet, utilizing our proprietary Impede Technology, which we intend to launch commercially in late 2012. Pseudoephedrine HCl, or PSE, is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products, including Johnson & Johnson's Sudafed® product. Our Impede Technology is a proprietary mixture of inactive ingredients that prevents the extraction of pseudoephedrine from tablets and disrupts the direct conversion of PSE from tablets into methamphetamine. The addition of the Impede Technology ingredients does not impact the efficacy of Nexafed.

Oxecta®

Oxecta is a Schedule II narcotic indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. The safety and efficacy of Oxecta 5 mg and 7.5 mg tablets was established by demonstrating bioequivalence to commercially available oxycodone immediate-release tablets in the fasted state. Oxecta differs from oxycodone tablets when taken with a high fat meal though these differences are not considered clinically relevant, and Oxecta can be taken without regard to food. The FDA-approved label for Oxecta describes elements unique to our Aversion Technology, which differs from current commercially available oxycodone immediate-release tablets. The label for Oxecta includes the results from a clinical study that evaluated the effects of nasally snorting crushed Oxecta and commercially available oxycodone tablets, and limitations on exposing Oxecta tablets to water and other solvents and administration through feeding tubes. The clinical study evaluated 40 non-dependent recreational opioid users, who self-administered the equivalent of 15mg of oxycodone. After accounting for a first sequence effect, the study demonstrated:

- 30% of subjects exposed to Oxecta responded that they would not take the drug again compared to 5% of subjects exposed to immediate-release oxycodone;
- subjects taking Oxecta reported a higher incidence of nasopharyngeal and facial adverse events compared to immediate-release oxycodone;
- a decreased ability to completely insufflate two crushed Oxecta tablets within a fixed time period (21 of 40 subjects), while all subjects were able to completely insufflate the entire dose of immediate-release oxycodone; and
- small numeric differences in the median and mean drug liking scores, which were lower in response to Oxecta than immediate-release oxycodone.

Although we believe these abuse deterrent characteristics differentiate Oxecta from immediate-release oxycodone products currently on the market, consistent with FDA guidance which requires epidemiology studies to support a claim of abuse deterrence, the clinical significance of the difference in drug liking and difference in response to taking the drug again in this study has not been established. There is no evidence that Oxecta has a reduced liability compared to immediate release oxycodone. Pfizer has agreed to a post-approval commitment with the FDA to perform an epidemiology study to assess the actual impact on abuse of Oxecta tablets.

Further, the Oxecta product label guides patients not to crush and dissolve the tablets or pre-soak, lick or otherwise wet the tablets prior to administration. Similarly, caregivers are advised not to crush and dissolve the tablets or otherwise use Oxecta for administration via nasogastric, gastric or other feeding tubes as it may cause an obstruction. Our laboratory studies demonstrated that the Oxecta tablet characteristics may change when Oxecta is exposed to certain solvents, including water.

The market for IR oxycodone products is primarily serviced by generic manufacturers with an average price per tablet shipped from distribution centers to healthcare providers of $0.10 for a 5 mg tablet. Pfizer's price to drug wholesalers and other direct customers for Oxecta is many fold the generic market price. We believe that Pfizer will have to enter into price discounting contracts with managed care and other end purchasers of IR oxycodone products, of which no assurance can be given.

Pfizer License, Development and Commercialization Agreement

In October 2007, we entered into a License, Development and Commercialization Agreement, or the Pfizer Agreement, with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer, covering the United States, Canada and Mexico. Under the Pfizer Agreement, Pfizer will manufacture and commercialize Oxecta in the United States. The Pfizer Agreement also provided for Pfizer to develop and commercialize three additional opioid analgesic products utilizing our proprietary Aversion Technology, including hydrocodone / acetaminophen tablets, oxycodone/acetaminophen tablets and an undisclosed opioid (the "Development-Stage Products"). Our lead product, Oxecta® Tablets CII, or Oxecta, was approved for marketing by the United States Food and Drug Administration, or FDA, on June 17, 2011. Oxecta was made commercially available by Pfizer in February 2012. Commencing in February 2013 we are eligible to receive tiered royalties of 5%-25% on the annual net sales of Oxecta.

On July 27, 2012 we announced that Pfizer had provided us with notice of the exercise of its right to terminate the license to the Development-Stage Products and return such products to us. Oxecta is not subject to Pfizer's termination notice and Pfizer will retain all rights and obligations relating to Oxecta under the Pfizer Agreement. On September 26, 2012 we further announced we entered into a letter agreement with Pfizer which provides for the termination of Pfizer's license to our Aversion Technology used in three Development-Stage Products.

Aversion Products in Development

Effective upon the execution of our letter agreement with Pfizer on September 26, 2012, we have the right to engage in the development of the products returned to us by Pfizer.

Our Aversion hydrocodone/acetaminophen product is the most advanced in development, with Pfizer having completed in February 2012 an open label, single dose, randomized, two period, two-way crossover study comparing such product to its reference listed drug. Such study demonstrated that the hydrocodone/acetaminophen product utilizing our Aversion Technology was bioequivalent to its reference listed drug. Such product was also the subject of a pre-IND meeting held with the FDA in May 2012.

We expect our clinical development program for our hydrocodone/acetaminophen product to consist of:

- A pharmacokinetic study to establish a bridge to a new contract manufacturer and safety compared to the reference listed drugs tramadol/acetaminophen (for acetaminophen) and hydrocodone bitartrate/ibuprofen (for hydrocodone);
- A pharmacokinetic study demonstrating dose proportionality and evaluating the food effect of our product;
- A nasal abuse liability liking study against a reference drug;
- Laboratory studies demonstrating extraction, syringing and particle size characteristics of our product; and
- An assessment of the routes of abuse of hydrocodone products.

We are assessing the documents and studies transferred to us by Pfizer and currently expect to submit an IND for our hydrocodone/acetaminophen product with the FDA by the end of 2012 which, if accepted by the FDA, will allow the commencement of clinical development in early 2013. Based on the development program outlined above, we anticipate preparing and submitting a 505(b)(2) NDA for our hydrocodone/acetaminophen product in the first half of 2014.

We continue to evaluate possible partnering of our Aversion development products with alternative strategic partners.

Paragraph IV ANDA Filings

On or about September 17, 2012, we believe the FDA internally changed the status of Oxecta to be considered a Reference Listed Drug (RLD). An RLD is the standard to which all generic versions must be shown to be bioequivalent and a drug company seeking approval to market a generic equivalent must refer to the RLD. By designated Oxecta as an RLD, the FDA was allowed to accept ANDAs referencing Oxecta.

On September 20, 2012, we announced that we had received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from a generic sponsor of an ANDA for a generic drug listing Oxecta as the reference listed drug. Since such date, we have received similar Paragraph IV Notices from three other generic pharmaceutical companies that have filed ANDAs listing Oxecta as the reference drug. The Paragraph IV Notices refer to our U.S. Patent Numbers 7,201,920, 7,510,726 and 7,981,439, which cover our Aversion Technology and Oxecta. The Paragraph IV Notices state that each generic sponsor believes that such patents are invalid, unenforceable or not infringed. Pfizer has advised us that they will not exercise their first right under the Pfizer Agreement to control the enforcement of our patents licensed to Pfizer for Oxecta against these generic sponsors. As a result, we will take appropriate action to enforce our intellectual property rights and on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. - Florida, Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement of our patent no. 7,510,726 listed in the FDA's Orange Book. The commencement of such litigation prohibits the FDA from granting approval of the filed ANDAs until the earliest of 30 months from the date the FDA accepted the application for filing, or the conclusion of litigation. The above actions are referred to as the "Paragraph IV Proceedings."

Litigation is inherently uncertain and we cannot predict the outcome of the Paragraph IV Proceedings. If any of these generic companies prevails its respective lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of Oxecta prior to the expiration of our patents in 2025. Additionally, it is possible that other generic manufacturers may also seek to launch a generic version of Oxecta and challenge our patents. Any determination in the Paragraph IV Proceedings that our patents covering our Aversion Technology and Oxecta are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents could have a material adverse affect on our operations and financial condition.

Citizen's Petition filing with FDA

By designating Oxecta as an RLD, we believe the FDA has acknowledged that Oxecta contains unique properties and/or a unique label that is different from other FDA approved immediate-release oxycodone HCl tablets that do not contain abuse resistant characteristics. The Food and Drug Administration Safety and Innovation Act of July 2012, requires the FDA to promulgate guidance on the development of abuse-deterrent drug products. As such, we believe the ANDA applicants that refer to Oxecta as an RLD will have to have substantially equivalent, if not identical, abuse deterrent characteristics to be considered by the FDA as therapeutically equivalent to Oxecta. There can be no assurance, however, that the FDA's guidance, once promulgated, will contain such requirements.

On September 21, 2012, Pfizer, as licensee of our Aversion Technology used in Oxecta under the Pfizer Agreement, filed a Citizen's Petition with the FDA requesting that the FDA: (1) refrain from permitting an ANDA applicant to rely on Oxecta as a reference listed drug unless the ANDA applicant demonstrates that its product uses the same inactive ingredients as those in Oxecta; (ii) require an ANDA applicant seeking approval of a product that relies on Oxecta as the reference listed drug and uses inactive ingredients different from those in Oxecta to submit an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetics Act; and (iii) refrain from rating a product as therapeutically equivalent to Oxecta unless it has the same inactive ingredients as Oxecta. The FDA has not yet responded to this Citizen's Petition and there can be no assurance that the FDA will take some or all of the actions requested.

Nexafed®

Our Nexafed product is an immediate-release pseudoephedrine HCl tablet which utilizes our patent pending Impede Technology. In addition to being a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products, PSE is also the starting material in the illicit manufacture of methamphetamine. Our Impede Technology, a proprietary mixture of inactive ingredients, prevents the extraction of PSE from tablets and disrupts the direct conversion of PSE from tablets into methamphetamine without affecting the effectiveness of Nexafed to provide the expected relief of nasal and sinus congestion. We have demonstrated that an initial formulation of Nexafed 30 mg tablets is bioequivalent to Johnson & Johnson's Sudafed® 30 mg tablets and a leading generic store brand's 30 mg tablets. Studies, sponsored by us at an independent laboratory and confirmed by a law enforcement agency, demonstrated our Impede Technology prevents the extraction of PSE from tablets for conversion into methamphetamine using what we believe are the two most common manufacturing methods, each requiring extraction of PSE as an initial step. A third, newer method of methamphetamine production known as the "one-pot" method involves the direct conversion of PSE from tablets into methamphetamine without first extracting and purifying the PSE. Laboratory tests conducted on our behalf by an independent CRO using the "one-pot" method demonstrated that our Impede Technology disrupted the direct conversion of PSE into methamphetamine. The study compared the amount of pure methamphetamine hydrochloride produced from Nexafed and Sudafed® tablets. Conducting multiple "one-pot" tests with a variety of commonly used solvents, and starting with one hundred 30 mg tablets of each product, the study demonstrated an average of 38% of the maximum possible yield of 2.7 grams of pure methamphetamine hydrochloride was recovered from Nexafed. Comparatively, approximately twice as much pure methamphetamine hydrochloride was recovered from Sudafed® tablets. Both products yielded a substantial amount of additional solids such that the purity of the total powder provided contained approximately 65% methamphetamine hydrochloride.

The completed scale-up of our manufacturing process to approximately 700,000 tablets per batch required a change to our formulation's inactive ingredients to improve manufacturability and new stability data is being collected. Due to this change, another bioequivalence study is being conducted. We have already confirmed that this formulation change does not impact Nexafed's properties of preventing extraction or disruption of the conversion of PSE into methamphetamine. We have commenced manufacturing process validation and expect to make Nexafed commercially available to pharmacies later this year. We intend to market Nexafed pursuant to the FDA's OTC Monograph regulations that do not require the submission an ANDA or NDA with the FDA.

We expect our Impede Technology products containing PSE to compete in the highly competitive market for cold, sinus and allergy products generally available to consumers without a prescription. In 2009, AC Nielsen reported approximately $1.0 billion in sales of non-prescription products containing either PSE or phenylephrine as a nasal decongestant, of which approximately 47% contained PSE. Products in this category consist of many different formulations containing different active ingredients such as analgesics, cough suppressants and antihistamines and have strong consumer brand recognition. Commencing in 2006, the Federal Combat Methamphetamine Epidemic Act, or CMEA, has required all non-prescription PSE products to be held securely behind the pharmacy counter, has set monthly consumer purchase volume limits, and has necessitated consumer interaction with pharmacy personnel to purchase PSE-containing products. We intend to capitalize on this consumer-pharmacist interaction at the point of sale by soliciting distribution to pharmacies and educating and encouraging pharmacists to recommend Nexafed to their customers. In our 2012 survey of 215 chain and independent pharmacists, 164 indicated they had influence over the pharmacies' product offerings. Of such pharmacists, 70% indicated they were likely to stock or recommend stocking Nexafed in their pharmacies. The 215 surveyed pharmacists also indicated a willingness to recommend Nexafed to over 50% of their customers who seek a pharmacist's advice for a single ingredient nasal decongestant. We are establishing vendor relationships with several national and regional wholesalers who have verbally committed to stocking Nexafed which would provide distribution and product availability throughout the U.S. We have begun executing a plan to generate awareness of Nexafed with pharmacists to support stocking of Nexafed in pharmacies and generate consumer recommendations by the pharmacist. We expect to offer Nexafed in 24-count cartons at a price comparable to other branded 30 mg PSE tablet 24-count products.

Company's Present Financial Condition

At October 28, 2012, we had cash and cash equivalents of approximately $28.8 million. We estimate that our current cash reserves will be sufficient to fund operations through at least the next 12 months.

We have yet to generate any product sales or royalty revenues from product sales. To fund our continued operations, we expect to rely on our current cash resources, royalty payments that may be made under Pfizer Agreement and under future license agreements with other pharmaceutical company partners, of which there can be no assurance of obtaining, and revenues, if any, from our commercialization of Nexafed. Our cash requirements for operating activities will increase in the future as we undertake the development of the three development-stage products returned to us by Pfizer under the Pfizer Agreement, maintain, defend, if necessary and expand the scope of our intellectual property, including the prosecution of the Paragraph IV Proceedings, hire additional personnel, scale up commercial supply of Nexafed, commercialize Nexafed, or invest in other areas.

Results of Operations for the Nine Months Ended September 30, 2012 and 2011

	September 30,		Increase (Decrease)	
	2012	2011	Dollars	%
Revenues				
Program fee revenue	$ 0	$ 466	$ (466)	(100)%
Milestone revenue	0	20,000	(20,000)	(100)
Total revenues	0	20,466	(20,466)	(100)
Operating expenses				
Research and development	2,518	3,245	(727)	(23)
Marketing, general and administrative	4,164	4,840	(676)	(14)
Total operating expenses	6,682	8,085	(1,403)	(17)
Income (loss) from operations	(6,682)	12,381	(19,063)	(154)
Other income (expense), net	30	(9)	39	433
Income (loss) before income tax	(6,652)	12,372	(19,024)	(154)
Income tax expense	0	341	(341)	(100)
Net income (loss)	$ (6,652)	$ 12,031	$ (18,683)	(155)%

Revenues

Pfizer paid us a $30.0 million upfront fee in connection with the closing of the Pfizer Agreement in December 2007. We assigned an equal portion of Pfizer's $30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognized the upfront payment as program fee revenue ratably over the development period for each identified product candidate, all which was completed in June 2011. On June 17, 2011 the Oxecta NDA was approved and we recognized $20.0 million milestone revenue. On July 26, 2012 Pfizer provided us with notice of the exercise of its right to terminate the license to three development opioid products using our Aversion® Technology. On September 26, 2012 we announced that we entered into a letter agreement with Pfizer which provides for the termination of Pfizer's license to our Aversion Technology used in the three development-stage products as of September 26, 2012 and the transfer of such products back to us. Under the Pfizer Agreement, we remain eligible to receive milestone payments for the achievement of a certain net sales level of Oxecta and a regulatory milestone for the approval of Oxecta in another territory, however, no assurance can be made that Pfizer will achieve these milestones.

Operating Expenses

R&D expense during the nine months ended September 30, 2012 and 2011 were for product candidates utilizing our Aversion ® and Impede™ Technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2012 and 2011 results are non-cash share-based compensation expenses of $0.3 million and $0.5 million, respectively. Excluding the share-based compensation expense, our development expenses decreased approximately $0.5 million between reporting periods primarily on our Nexafed development expenses as we have shifted towards Nexafed commercialization. We expect to make Nexafed commercially available to pharmacies later this year.

Marketing expenses during the nine months ended September 30, 2012 and 2011 primarily consisted of market research studies on our Aversion and Impede™ Technologies but also included various advertising and marketing activities we initiated on Nexafed® during the third quarter of 2012. Our Nexafed advertising and marketing activities will continue in the fourth quarter of 2012 and we expect similar activities in 2013. Our G&A expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in the 2012 and 2011 results are non-cash share-based compensation expenses of $1.0 million and $1.7 million, respectively. Excluding the share-based compensation expense and the $0.2 million U.S. government research grants under the Qualifying Therapeutic Discovery Project Program received by us during 2011, our marketing, general and administrative expenses decreased approximately $0.2 million, primarily for professional services and payroll, between reporting periods.

Other Income (Expense)

During the nine months ended September 30, 2012 and 2011, other income consisted principally of interest income derived from our cash reserves being invested in accordance with a Board of Director approved investment policy.

Net Income (Loss)

The net loss for the nine months ended September 30, 2012 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Results of Operations for the Three Months Ended September 30, 2012 and 2011

	September 30,		Increase (Decrease)	
	2012	2011	Dollars	%
Revenues				
Program fee revenue	$ 0	$ 0	$ 0	0%
Milestone revenue	0	0	0	0
Total revenues	0	0	0	0
Operating expenses				
Research and development	696	962	(266)	(28)
Marketing, general and administrative	1,453	1,185	268	23
Total operating expenses	2,149	2,147	2	0
Loss from operations	(2,149)	(2,147)	2	0
Other income, net	9	6	3	50
Loss before income tax	(2,140)	(2,141)	(1)	(0)
Income tax expense	0	0	0	0
Net loss	$ (2,140)	$ (2,141)	$ (1)	(0)%

Revenues

Pfizer paid us a $30.0 million upfront fee in connection with the closing of the Pfizer Agreement in December 2007. We assigned an equal portion of Pfizer's $30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognized the upfront payment as program fee revenue ratably over the development period for each identified product candidate, all which was completed in June 2011. On June 17, 2011 the Oxecta NDA was approved and we recognized $20.0 million milestone revenue. On July 26, 2012 Pfizer provided us with notice of the exercise of its right to terminate the license to three development-opioid products using our Aversion® Technology. On September 26, 2012 we announced we entered into a letter agreement with Pfizer which provides for the termination of Pfizer's license to our Aversion Technology used in the three development-stage products as of September 26, 2012 and the transfer of such products back to us. Under the Pfizer Agreement, we remain eligible to receive milestone payments for the achievement of a certain net sales level of Oxecta and a regulatory milestone for the approval of Oxecta in another territory, however, no assurance can be made that Pfizer will achieve these milestones.

Operating Expenses

R&D expense during the three months ended September 30, 2012 and 2011 were for product candidates utilizing our Aversion and Impede™ Technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in each of the 2012 and 2011 results are non-cash share-based compensation expenses of $0.1 million. Excluding the share-based compensation expense, our development expenses decreased approximately $0.3 million between reporting periods primarily on our Nexafed development expenses as we have shifted towards Nexafed commercialization. We expect to make Nexafed commercially available to pharmacies later this year.

Marketing expenses during the three months ended September 30, 2012 primarily consisted of advertising and marketing activities we initiated on Nexafed. Marketing expenses during the three months ended September 30, 2011 primarily consisted of market research studies on our Aversion and Impede™ Technologies. Our Nexafed advertising and marketing activities will continue in the fourth quarter of 2012 and we expect similar activities in 2013. Our G&A expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in the 2012 and 2011 results are non-cash share-based compensation expenses of $0.3 million and $0.2 million, respectively. Excluding the share-based compensation expense our marketing, general and administrative expenses increased approximately $0.1 million, primarily for professional services, between reporting periods.

Other Income (Expense)

During the three months ended September 30, 2012 and 2011, other income consisted principally of interest income derived from our cash reserves being invested in accordance with a Board of Director approved investment policy.

Net Income (Loss)

The net loss for the three months ended September 30, 2012 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Liquidity and Capital Resources

At September 30, 2012, the Company had unrestricted cash and cash equivalents of $29.3 million compared to $35.7 million at December 31, 2011. The Company had working capital of $29.2 million at September 30, 2012 compared to $35.6 million at December 31, 2011. The decrease in our cash position is primarily due to the period's net loss and the payment of employees' withholding taxes approximating $1.0 million associated with their option exercises and RSU exchanges during such period, adjusted for the non-cash share-based compensation expenses.

At October 28, 2012, the Company had cash and cash equivalents of approximately $28.8 million. We estimate that our current cash reserves will be sufficient to fund operations through at least the next 12 months.

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company's 2011 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's critical accounting policies described in the 2011 Annual Report are also applicable to 2012.

Item 4. Controls and Procedures

(a) *Disclosure Controls and Procedures*. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined on Rules 13a – 13(e) and 15(d) – 15(e) under the Exchange Act) as of the end of the period covered by this Report. The Company's disclosure controls and procedures are designed to provide reasonable assurance that information is recorded, processed, summarized and reported accurately and on a timely basis in the Company's periodic reports filed with the SEC. Based upon such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures are effective to provide reasonable assurance. Notwithstanding the foregoing, a control system, no matter how well designed and operated, can provide only reasonable, not absolute assurance that it will detect or uncover failures within the Company to disclose material information otherwise require to be set forth in the Company's periodic reports.

(b) *Changes in Internal Controls over Financial Reporting*. There were no changes in our internal controls over financial reporting during the third fiscal quarter of 2012 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information required by this Item is incorporated by reference to Note 9, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

ITEM 1A. RISK FACTORS

Our future operating results may vary substantially from anticipated results due to a number of factors, many of which are beyond our control.

The following risk factors replace and supersede our risk factors set forth in our 2011 Form 10-K:

Risks Related to Our Business and Industry

We are largely dependent on the commercial success of Oxecta and we have not generated any revenue from sales of Oxecta.

We anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend in large part on the commercial success of our only FDA approved product, Oxecta, which in turn, will depend on several factors, including:

- the successful launch of Oxecta in the United States by Pfizer, to whom we have licensed Oxecta;
- Pfizer's obtaining and increasing market demand for, and sales of, Oxecta;
- obtaining acceptance of Oxecta by physicians and patients;
- obtaining and maintaining adequate levels of coverage and reimbursement for Oxecta from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;
- maintaining compliance with regulatory requirements;
- Pfizer's list price for Oxecta and its willingness to enter into price discounting contracts with managed care and other end purchasers of IR oxycodone products;
- Pfizer's establishing and maintaining agreements with wholesalers and distributors on commercially reasonable terms;
- Pfizer's manufacture and supply of adequate supplies of Oxecta to meet commercial demand; and
- maintaining intellectual property protection for Oxecta and obtaining favorable drug listing treatment by the FDA to minimize generic competition.

There can be no assurance that Pfizer will devote sufficient resources to the marketing and commercialization of Oxecta. Pfizer's marketing of Oxecta may result in low market acceptance and insufficient demand for, and sales of, the product. If Pfizer fails to successfully commercialize Oxecta and increase sales, we may be unable to generate sufficient revenues to sustain or grow our business and we may never become profitable, and our business, financial condition and results of operations will be materially affected.

If Pfizer is not successful in commercializing Oxecta our revenues and our business will suffer.

Pursuant to our license, development and commercialization agreement with a subsidiary of Pfizer, or the Pfizer Agreement, Pfizer is responsible for manufacturing, marketing, pricing, promoting, selling, and distributing Oxecta in the United States, Canada and Mexico, or the Pfizer Territory. If such agreement is terminated in accordance with its terms, including due to a party's failure to perform its obligations or responsibilities under the agreement, then we would need to commercialize Oxecta ourselves for which we currently have no infrastructure, or alternatively enter into a new agreement with another pharmaceutical company, of which no assurance can be given. If we are unable to build the necessary infrastructure to commercialize Oxecta ourselves, which would substantially increase our expenses and capital requirements that we might not be able to fund, or are unable to find a suitable replacement commercialization partner, we would be unable to generate any revenue from Oxecta. Even if we are successful at replacing the commercialization capabilities of Pfizer, our revenues and/or royalties from Oxecta could be adversely impacted.

Pfizer's manufacturing facility is currently the sole commercial source of supply for Oxecta. If Pfizer's manufacturing facility fails to obtain sufficient DEA quotas for oxycodone, fails to source adequate quantities of active and inactive ingredients, fails to comply with regulatory requirements, or otherwise experiences disruptions in commercial supply of Oxecta, product revenue and our royalties could be adversely impacted.

Pfizer has a diversified product line for which Oxecta Tablets will vie for Pfizer's promotional, marketing, and selling resources. If Pfizer fails to commit sufficient promotional, marketing and selling resources to Oxecta, product revenue and our royalties could be adversely impacted. Additionally, in view of Pfizer's recent acquisition of King Pharmaceuticals in February 2011, there can be no assurance that Pfizer will commit the resources required for the successful commercialization of Oxecta Tablets.

The market for our opioid product candidates is highly competitive with many marketed non-abuse deterrent brand and generic products and other abuse deterrent product candidates in development. If Pfizer prices Oxecta inappropriately, fails to position Oxecta properly, targets inappropriate physician specialties, or otherwise does not provide sufficient promotional support, product revenue and our royalties could be adversely impacted.

Pfizer's promotional, marketing and sales activities in connection with Oxecta are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program. The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. If Pfizer's activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, Pfizer may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its activities with regard to the commercialization of our products, which could harm the commercial success of Oxecta and materially affect our business, financial condition and results of operations.

Our failure to continue the development of the three development stage products terminated by Pfizer under the Pfizer Agreement, or to successfully establish a license agreement with a pharmaceutical company for the development and commercialization of such products, will adversely impact our ability to develop, market and sell such products and our revenues and business will suffer.

In July 2012 Pfizer exercised its right to terminate the license to the three products in development, or the returned products, under the Pfizer Agreement. The termination of such license provides for the return to us of oxycodone hydrochloride with acetaminophen, hydrocodone bitartrate with acetaminophen and another undisclosed opioid product. Pursuant to a letter agreement between us and Pfizer dated September 24, 2012, the effective date of such termination was accelerated from the 12-month period provided in the Pfizer Agreement to the date of the letter agreement. As of such date, we have the right to develop the returned products on our own or in partnership with a third party. Our plan for developing, manufacturing and commercialize the returned products includes entering into an agreement similar to the Pfizer Agreement with a strategically focused pharmaceutical company. However, there can be no assurance that we will be successful in entering into such an agreement. Pending any such agreement, we expect to continue the development of our hydrocodone bitartrate with acetaminophen product on our own. Although we believe we have sufficient cash resources to fund the development of such product and submit a corresponding NDA to the FDA, there can be no assurance that this will be the case. The continued development of our hydrocodone bitartrate with acetaminophen product and the other returned products may require additional financing, which may not be available on acceptable terms, or at all. In the absence of available financing, or our failure to successfully enter into a license agreement with a pharmaceutical company to develop and commercialize the returned products, we may have to limit the size or scope of, or delay or abandon the development of the returned products, which would adversely impact our financial condition and results of operations.

We have a history of operating losses and may not achieve profitability sufficient to generate a positive return on shareholders' investment.

We had net income of $10.4 million for the year ended December 31, 2011 and a net loss of $12.7 million and $15.8 million for the years ended December 31, 2010 and 2009, respectively. Our future profitability will depend on several factors, including:

- our receipt of milestone payments and royalties relating to our FDA approved Oxecta Tablets, for which we only receive royalties on sales occurring on and following February 2, 2013, the one year anniversary of the first commercial sale of Oxecta Tablets;
- our receipt of milestone payments and royalties relating to our Aversion Technology products in development, including the products returned by Pfizer, from future licensees, of which no assurance can be given;
- the receipt of FDA approval and the successful commercialization by future licensees (if any) of products utilizing our Aversion Technology and our ability to commercialize our Impede Technology without infringing the patents and other intellectual property rights of third parties; and
- our successful development, launch and marketing of Nexafed and other products utilizing our Impede Technology, and market acceptance, increased demand for and sales of Nexafed.

We cannot assure you that our Oxecta or Nexafed products will be successfully commercialized or our Aversion Technology products in development will be successfully developed or be approved for commercialization by the FDA.

We recognized revenues of $20.5 million, $3.3 million and $3.8 million in the years ended December 31, 2011, 2010 and 2009, respectively, from payments received under the Pfizer Agreement. However, we have not yet generated any revenues from Aversion Technology or Impede Technology product sales. Even if we or Pfizer succeed in commercializing one or more of our Aversion Technology products or if we are successful in commercializing our Impede Technology products, we expect to continue using cash reserves for the foreseeable future. Our expenses may increase in the foreseeable future as a result of continued research and development of our product candidates, including the three products returned to us by Pfizer under the Pfizer Agreement, maintaining and expanding the scope of our intellectual property, commercializing our Nexafed product, and hiring of additional research and development staff.

We will need to generate revenues from direct product sales or indirectly from royalties on sales to achieve and maintain profitability. If we cannot successfully commercialize Nexafed, if Pfizer does not successfully commercialize Oxecta, or if we or our licensee (if any) cannot successfully develop, obtain regulatory approval and commercialize our products in development, we will not be able to generate such royalty revenues or achieve future profitability. Our failure to achieve or maintain profitability would have a material adverse impact on the market price of our common stock.

We must rely on current cash reserves, technology licensing fees and third party financing to fund operations.

Pending the receipt of royalties, if any, under the Pfizer Agreement or milestone payments and royalties under similar license agreements that we may enter into with other pharmaceutical companies in the future, of which no assurance can be given, we must rely on our current cash reserves, revenues from sales of Nexafed, if any, and third-party financing to fund operations and product development activities. No assurance can be given that current cash reserves or revenues from Nexafed product sales will be sufficient to fund the continued operations and development of our product candidates until such time as we generate additional revenue from the Pfizer Agreement or any similar future license agreements. Moreover, no assurance can be given that we will be successful in raising additional financing or, if funding is obtained, that such funding will be sufficient to fund operations until product candidates utilizing our Aversion and Impede Technologies may be commercialized.

Our and our licensees' ability to market and promote Oxecta and other Aversion Technology products by describing the abuse deterrent features of such products will be determined by the FDA approved label for such products.

The commercial success of our Aversion Technology products will depend upon our and our licensees' ability to obtain FDA approved labeling describing such products' abuse deterrent features or benefits. Our or our licensees' failure to achieve FDA approval of product labeling containing such information will prevent or substantiality limit our and our licensees' advertising and promotion of such abuse deterrent features in order to differentiate Aversion Technology products from other immediate release opioid products containing the same active ingredients, and would have a material adverse impact on our business and results of operations. The FDA has publicly stated that explicit indications or claims of abuse deterrence will not be permitted unless such indications or claims are supported by double blind controlled clinical studies demonstrating an actual reduction in product abuse by patients or drug abusers. Because the cost, time and practicality of designing and implementing clinical studies adequate to support explicit claims of abuse deterrence are prohibitive, we and Pfizer are not pursuing and have not conducted the clinical trials necessary to include an explicit product label claim of abuse deterrence. Instead, we will rely on certain clinical and laboratory studies to support product labeling describing the relative difficulty of abusing or misusing our products and such products' abuse deterrent features. However, the extent to which such information is included in the FDA approved product label is the subject of our and our licensees' discussions with, and agreement by, the FDA as part of the NDA review process for each of our product candidates. The outcome of those discussions with the FDA will determine whether we or our licensees will be able to market our products with labeling that sufficiently differentiates them from other products that have comparable therapeutic profiles. While the FDA approved label for Oxecta includes the results from a clinical study which evaluated the effects of nasally snorting crushed Oxecta and commercially available oxycodone tablets and limitations on wetting or dissolving Oxecta, it does not, however, include the results of our laboratory studies intended to evaluate Oxecta's potential to limit extraction of oxycodone HCl from dissolved Oxecta Tablets and resist conversion into an injectable, or IV solution. The absence of the results of these extraction and syringe studies in the FDA approved label for Oxecta may substantially limit Pfizer's ability to differentiate Oxecta from other immediate release oxycodone products, which would have a material adverse effect on market acceptance of Oxecta and on our business and results of operations.

Notwithstanding the FDA approved labeling for Oxecta, there can be no assurance that our Aversion Technology products in development will receive FDA approved labeling that describes the abuse deterrent features of such products. If the FDA does not approve labeling containing such information, we or our licensees will not be able to promote such products based on their abuse deterrent features, may not be able to differentiate such products from other immediate release opioid products containing the same active ingredients, and may not be able to charge a premium above the price of such other products which could materially adversely affect our business and results of operations.

Because the FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse deterrent characteristics of our product, as in the case of Oxecta, the FDA may object to our or our licensee's marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of Oxecta from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution, which could harm the commercial success of our product and materially affect our business, financial condition and results of operations.

Our product candidates are unproven and may not be approved by the FDA.

We are committing a majority of our resources to the development of product candidates utilizing our Aversion and Impede Technologies. Notwithstanding the receipt of FDA approval of Oxecta Tablets, there can be no assurance that the FDA will approve any other product candidate utilizing Aversion Technology for commercial distribution. Further there can be no assurance that other product candidates that may be developed using Aversion Technology or Impede Technology will achieve the targeted end points in the required clinical studies or perform as intended in other pre-clinical and clinical studies or lead to an NDA submission or filing acceptance. Our failure to successfully develop and achieve final FDA approval of our product candidates in development utilizing Aversion Technology will have a material adverse effect on our financial condition.

If the FDA disagrees with our determination that certain of our products meet the over-the-counter, or OTC, requirements, once those products are commercialized, they may be removed from the market; the FDA or the U.S. Federal Trade Commission, or FTC, may object to our advertisement and promotion of the extraction characteristics and benefits of Nexafed.

Drugs that have been deemed safe and effective by the FDA for use by the general public without a prescription are classified as OTC drug products. Certain OTC drug products may be commercialized without premarket review by the FDA if the standards set forth in the applicable regulatory monograph are met. An OTC monograph provides the marketing conditions for the applicable OTC drug product, including active ingredients, labeling, and other general requirements such as compliance with cGMP and establishment registration. Any product which fails to conform to each of the general conditions and a monograph is subject to regulatory action. Further, although the FDA regulates OTC drug product labeling, the FTC regulates the advertising and marketing of OTC drug products. We believe that Nexafed is classified for OTC sale under an FDA OTC monograph which will allow us to commercialize them without submitting an NDA or ANDA to the FDA. We have also determined that, provided we adhere to the FDA's requirements for OTC monograph products, including product labeling, we can advertise and promote the extraction characteristics and benefits of Nexafed which are supported by our research studies. No assurance can be given, however, that the FDA will agree that Nexafed may be sold under the FDA's OTC monograph product regulations or that the FDA or FTC will not object to our advertisement and promotion of Nexafed's extraction characteristics and benefits. If the FDA determines that Nexafed does not conform to the OTC monograph or if we fail to meet the general conditions, once commercialized, the product may be removed from the market and we may face various actions including, but not limited to, restrictions on the marketing or distribution of such products, warning letters, fines, product seizure, or injunctions or the imposition of civil or criminal penalties. Any of these actions may materially and adversely affect our financial condition and operations. If the FDA requires that we submit a NDA or ANDA to obtain marketing approval for Nexafed, this would result in substantial additional costs, delay or suspend the commercialization of Nexafed and require FDA approval prior to sale, of which no assurance can be provided. In such case, the label for Nexafed would be subject to FDA review and approval and there can be no assurance that we will be able to market Nexafed with labeling sufficient to differentiate it from products that have comparable therapeutic profiles. If we are unable to advertise and promote the extraction characteristics of Nexafed, we may be unable to compete with national brands and pharmacy chain store brands.

Our Aversion and Impede Technology products may not be successful in limiting or impeding abuse or misuse upon commercialization.

We are committing a majority of our resources to the development of products utilizing our Aversion and Impede Technologies. Notwithstanding the receipt of FDA approval of Oxecta Tablets and the results of our numerous clinical and laboratory studies for Oxecta and our Aversion and Impede Technology products in development, there can be no assurance that Oxecta or any other product utilizing our Aversion or Impede Technologies will perform as tested and limit or impede the actual abuse or misuse of such products in commercial settings. Moreover, there can be no assurance that the post-approval epidemiological study required by the FDA as a condition of approval of Oxecta will show a reduction in the consequences of abuse and misuse by patients for whom Oxecta is prescribed. The failure of Oxecta or other products utilizing our Aversion and Impede Technologies to limit or impede actual abuse or misuse in practice will have a material adverse impact on market acceptance for such products and on our financial condition and results of operations.

Relying on third party CROs may result in delays in our pre-clinical, clinical or laboratory testing. If pre-clinical, clinical or laboratory testing for our product candidates are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines.

To obtain FDA approval to commercially sell and distribute in the United States any of our prescription product candidates, we or our licensees must submit to the FDA an NDA demonstrating, among other things, that the product candidate is safe and effective for its intended use. As we do not possess the resources or employ all the personnel necessary to conduct such testing, we rely on CROs for the majority of this testing with our product candidates. As a result, we have less control over our development program than if we performed the testing entirely on our own. Third parties may not perform their responsibilities on our anticipated schedule. Delays in our development programs could significantly increase our product development costs and delay product commercialization.

The commencement of clinical trials with our product candidates may be delayed for several reasons, including but not limited to delays in demonstrating sufficient pre-clinical safety required to obtain regulatory approval to commence a clinical trial, reaching agreements on acceptable terms with prospective CROs, clinical trial sites and licensees, manufacturing and quality assurance release of a sufficient supply of a product candidate for use in our clinical trials and/or obtaining institutional review board approval to conduct a clinical trial at a prospective clinical site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or regulatory authorities due to several factors, including ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials, a determination by us or regulatory authorities that continuing a trial presents an unreasonable health risk to participants, 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 regulatory authorities, the imposition of a clinical hold by FDA, lack of adequate funding to continue clinical trials, and/or negative or unanticipated results of clinical trials.

Clinical trials required by the FDA for commercial approval may not demonstrate safety or efficacy of our product candidates. Success in pre-clinical testing and early clinical trials does not assure 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 licensees may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we or our licensees can submit NDAs or obtain regulatory approval for our product candidates.

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

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

We have no commercial manufacturing capacity and rely on third-party contract manufacturers to produce commercial quantities of our products.

We do not have the facilities, equipment or personnel to manufacture commercial quantities of our products and therefore must rely on our licensees or other qualified third-party contract manufactures with appropriate facilities and equipment to contract manufacture commercial quantities of products utilizing our Aversion and Impede Technologies. These licensees and third- party contract manufacturers are also subject to current good manufacturing practice or cGMP regulations, which impose extensive procedural and documentation requirements. Any performance failure on the part of our licensees or contract manufacturers could delay commercialization of any approved products, depriving us of potential product revenue.

Our drug products, including Nexafed, require precise, high quality manufacturing. Failure by our contract manufacturers to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could materially adversely affect our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMP and other applicable government regulations; however, beyond contractual remedies that may be available to us, we do not have control over third-party manufacturers' compliance with these regulations and standards.

If for some reason our contract manufacturers cannot perform as agreed, we may be required to replace them. Although we believe there are a number of potential replacements, we may incur added costs and delays in identifying and qualifying any such replacements. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drug candidates.

We or our licensees 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 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 our operations are subject to compliance with FDA regulations. Failure to adhere to applicable FDA regulations by us or our licensees would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive.

We or our licensees may encounter delays or rejections during any stage of the regulatory review and approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the product candidates 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 an NDA the FDA may refuse to file the application, deny approval of the application, require additional testing or data and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. For instance, the FDA's approval of Oxecta is conditioned on Pfizer conducting a post-approval epidemiological study to assess the actual abuse levels and consequences of Oxecta in the market. The Prescription Drug User Fee Act, or PDUFA, sets time standards for the FDA's review of NDA's. The FDA's timelines described in the PDUFA guidance are flexible and subject to change based on workload and other potential review issues and may delay the FDA's review of an NDA. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we or our licensees desire and could affect the marketability of our products.

Even if we comply with all the FDA regulatory requirements, we or our licensees may never obtain regulatory approval for any of our product candidates in development. For example, we previously submitted an NDA to the FDA for an Aversion Technology product containing niacin, intended to provide impediments to over-ingesting the product. Such niacin containing product was not approved by the FDA. If we or our licensees fail to obtain regulatory approval for any of our product candidates in development, we will have fewer commercialized products and correspondingly lower revenues. Even if regulatory approval of our products in development is received, such approval may involve limitations on the indicated uses or promotional claims we or our licensees may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles but without abuse deterrent features (see risk factor above entitled "Our and our licensees ability to market and promote Oxecta and other Aversion Technology products by describing the abuse deterrent features of such products will be determined by the FDA approved label for such products"). Such events would have a material adverse effect on our operations and financial condition. We may market certain of our products without the prior application to and approval by the FDA. The FDA may subsequently require us to withdraw such products and submit NDA's for approval prior to re-marketing.

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 cGMP and to stop shipments of allegedly violative products. In the event the FDA takes any such action relating to our products (if any are approved by the FDA), such actions would have a material adverse effect on our operations and financial condition.

We must maintain FDA approval to manufacture clinical supplies of our product candidates at our facility; failure to maintain compliance with FDA requirements may prevent or delay the manufacture of our product candidates and costs of manufacture may be higher than expected.

We have installed the equipment necessary to manufacture clinical trial supplies of our Aversion and Impede Technology product candidates in tablet formulations at our Culver, Indiana facility. To be used in clinical trials, all of our product candidates must be manufactured in conformity with cGMP regulations. All such product candidates must be manufactured, packaged, and labeled and stored in accordance with cGMPs. Modifications, enhancements or changes in manufacturing sites of marketed products are, in many circumstances, subject to FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain. Our Culver, Indiana facility, and those of any third-party manufacturers that we or our licensees 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 the FDA deems 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 product candidates, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution.

We develop our products, and manufacture clinical supplies, at a single location. Any disruption at this facility could adversely affect our business and results of operations.

We rely on our Culver, Indiana facility for developing our product candidates and the manufacture of clinical supplies of our product candidates. If the Culver, Indiana facility were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to repair or replace. If our Culver facility were affected by a disaster, we would be forced to rely entirely on CROs and third-party contract manufacturers for an indefinite period of time. Although we believe we possess adequate insurance for damage to our property and for the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. Moreover, any disruptions or delays at our Culver, Indiana facility could impair our ability to develop our product candidates utilizing the Aversion or Impede Technologies, which could adversely affect our business and results of operations.

Our operations are subject to environmental, health and safety, and other laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

Our business, properties and product candidates are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage and disposal of hazardous substances, waste and other regulated materials. Because we own and operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or may be altered in the future, could adversely affect our financial condition and results of operations.

Our failure to successfully establish new license agreements with pharmaceutical companies for the development and commercialization of our other products in development may adversely impair our ability to develop, market and sell such products.

The Pfizer Agreement grants Pfizer an exclusive license to develop and commercialize Oxecta. We believe that opportunities exist to enter into agreements similar to the Pfizer Agreement with other partners for the commercialization of Oxecta outside the Pfizer Territory, for the development and commercialization of our other opioid analgesic products (including the products returned to us by Pfizer under the Pfizer Agreement) in the United States and worldwide, and for the development and commercialization of additional Aversion Technology and Impede Technology product candidates for other abused and misused drugs, such as tranquilizers, stimulants, sedatives and nasal decongestants in the United States and worldwide. However, there can be no assurance that we will be successful in entering into such license agreements in the future. If we are unable to enter into such agreements, our ability to develop and commercialize our product candidates, and our financial condition and results of operations, would be adversely affected.

If our licensees do not satisfy their obligations, we will be unable to develop our licensed product candidates.

As part of our Pfizer Agreement or other future similar license agreements (if any), we do not and will not have day-to-day control over the activities of our licensees with respect to any product candidate. If a licensee fails to fulfill its obligations under an agreement with us, we may be unable to assume the development of the product candidate covered by that agreement or to enter into alternative arrangements with another third party. In addition, we may encounter delays in the commercialization of the product candidate that is the subject of a license agreement. Accordingly, our ability to receive any revenue from the product candidates covered by such agreements will be dependent on the efforts of our licensee. We could be involved in disputes with a licensee, which could lead to delays in or termination of, our development and commercialization programs and result in time consuming and expensive litigation or arbitration. In addition, any such dispute could diminish our licensee's commitment to us and reduce the resources they devote to developing and commercializing our products. If any licensee 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 adversely effected. Additionally, due to the nature of the market for our product candidates, it may be necessary for us to license all or a significant portion of our product candidates to a single company thereby eliminating our opportunity to commercialize other product candidates with other licensees.

If we fail to maintain our license agreement with Pfizer, we may have to commercialize Oxecta on our own.

Our plan for manufacturing and commercializing Oxecta Tablets currently requires us to maintain our license agreement with Pfizer. In addition to other customary termination provisions, the Pfizer Agreement provides that Pfizer may terminate the Pfizer Agreement at any time upon written notice to us. If Pfizer elects to terminate the Pfizer Agreement, or if we are otherwise unable to maintain our existing relationship with Pfizer, we would have to commercialize Oxecta ourselves for which we currently have no infrastructure, or alternatively enter into a new agreement with another pharmaceutical company, of which no assurance can be given. Our ability to commercialize Oxecta on our own may require additional financing, which may not be available on acceptable terms, or at all.

The market may not be receptive to products incorporating our Aversion or Impede Technologies.

The commercial success of our products will depend on acceptance by health care providers and others that such products are clinically useful, cost-effective and safe. There can be no assurance given that our products utilizing the Aversion or Impede Technologies would be accepted by health care providers and others. Factors that may materially affect market acceptance of our product candidates include but are not limited to:

- the relative advantages and disadvantages of our products compared to competitive products;
- the relative timing to commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products;
- the perception of health care providers of their role in helping to prevent abuse and their willingness to prescribe abuse-deterrent products to do so;
- the willingness of third party payers to reimburse for our prescription products;
- the willingness of pharmacy chains to stock our Impede Technology products; and
- the willingness of consumers to pay for our products.

Oxecta and our product candidates, if successfully developed and commercially launched, will compete with both currently marketed and new products launched in the future by other companies. Health care providers may not accept or utilize any of our products. Physicians and other prescribers may not be inclined to prescribe our prescription products unless our products demonstrate commercially viable advantages over other products currently marketed for the same indications. Pharmacy chains may not be willing to stock our Impede Technology products and pharmacists may not recommend such products to consumers. Further, consumers may not be willing to purchase our products. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

If we are not successful in commercializing Nexafed and other Impede Technology products our revenues and business will suffer.

We intend to market and sell Nexafed to pharmacies. Nexafed will compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in marketing their competing products. Category leading brands are often supported by regional and national advertising and promotional efforts. Nexafed will compete with national brands as well as pharmacy store brands that are offered at a lower price. There can be no assurance that we will launch or succeed in commercializing Nexafed, or that even if commercialized, that the pricing of Nexafed will allow us to generate significant revenues or profit. Regulations have been enacted in several state or local jurisdictions requiring a doctor's prescription to obtain pseudoephedrine products. An expansion of such restrictions to other jurisdictions or even nationally will adversely impact our ability to market Nexafed as an OTC product and generate revenue from Nexafed product sales.

If we, our licensees or others identify serious adverse events or deaths relating to any of our products once on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues.

We or our licensees are required to report to relevant regulatory authorities all serious adverse events or deaths involving our product candidates or approved products. If we, our licensees, or others identify such events, regulatory authorities may withdraw their approvals of such products; we or our licensees may be required to reformulate our products; we or our licensees may have to recall the affected products from the market and may not be able to reintroduce them onto the market; our reputation in the marketplace may suffer; and we may become the target of lawsuits, including class actions suits. Any of these events could harm or prevent sales of the affected products and could materially adversely affect our business and financial condition.

In the event that we or our licensees are successful in bringing any products to market, our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers.

The ability of our licensees to successfully commercialize our products may depend in part on the availability of reimbursement for our prescription products from government health administration authorities, private health insurers, and other third-party payers and administrators, including Medicaid and Medicare. We cannot predict the availability of reimbursement for newly-approved products utilizing our Aversion Technology. Third-party payers and administrators, including state Medicaid programs and Medicare, are challenging the prices charged for pharmaceutical products. Government and other third-party payers 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 candidates. The continuing efforts of government and third-party payers to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payers do not provide adequate coverage and reimbursement for any product utilizing our Aversion Technology, health care providers may not prescribe them or patients may ask their health care providers to prescribe competing products with more favorable reimbursement. In some foreign markets, pricing and profitability of pharmaceutical products are subject to government control. In the United States, we expect there may 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 or our licensees charge for any of our products in the future. Further, cost control initiatives could impair our ability or the ability of our licensees to commercialize our products and our ability to earn revenues from commercialization.

In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could impact our or our licensees' ability to sell our products profitably. In particular, in 2010, the Patient Protection Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the Healthcare Reform Law of greatest importance to the pharmaceutical industry are the following:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, beginning in 2011;
- An increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- A new Medicare Part D coverage gap discount program, under which manufacturers must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in 2011;
- Extension of manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010; and
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research.

At this time, it remains uncertain what the full impact of these provisions will be on the pharmaceutical industry generally or our business in particular.

Consolidation in the healthcare industry could lead to demands for price concessions or for the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations.

Because healthcare costs have risen significantly, numerous initiatives and reforms by legislatures, regulators and third-party payers to curb these cost increases have resulted in a trend in the healthcare industry to consolidate product suppliers and purchasers. As the healthcare industry consolidates, competition among suppliers to provide products to purchasers has become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, and large single accounts continue to use their market power to influence product pricing and purchasing decisions. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to influence the worldwide healthcare industry, resulting in further business consolidations, which may exert further downward pressure on the prices of our anticipated products. This downward pricing pressure may adversely impact our business, financial condition or results of operations. Under our agreement with Pfizer, Pfizer controls the price of Oxecta and other licensed products and may provide price discounts and price reductions in its discretion. Such price discounts and reductions will reduce the net sales of our licensed products and, correspondingly, our royalty payments, if any, under the Pfizer Agreement.

Our success depends on our ability to protect our intellectual property.

Our success depends on our ability to obtain and maintain patent protection for products developed utilizing our technologies, 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. Notwithstanding our receipt of U.S. Patent No. 7,201,920 and U.S. Patent No. 7,510,726 from the USPTO encompassing our opioid products utilizing our Aversion Technology, and U.S. Patent No. 7,981,439 encompassing certain non-opioid products utilizing our Aversion Technology, there is no assurance that any of our patent claims in our other pending non-provisional and provisional patent applications relating to our technologies will issue or if issued, that any of our existing and future patent claims will be held valid and enforceable against third-party infringement or that our products will not infringe any third-party patent or intellectual property. Moreover, any patent claims relating to our technologies may not be sufficiently broad to protect our products. In addition, issued patent claims may be challenged, potentially invalidated or potentially circumvented. Our patent claims 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 others. We may become aware of patents belonging to competitors and others that could require us to obtain licenses to such patents or alter our technologies. Obtaining such licenses or altering our technology 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 or our licensees require to manufacture or market one or more of our products. Even if we can obtain a license, the financial and other terms may be disadvantageous.

Our success also depends on maintaining the confidentiality of our trade secrets and know-how. We seek to protect such information by entering into confidentiality agreements with employees, potential licensees, raw material suppliers, contract research organizations, contract manufacturers, consultants and other parties. 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 affect on our operations and financial condition.

We also rely on or intend to rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks, or we may not have adequate resources to enforce our trademarks.

We may become involved in patent litigation or other intellectual property proceedings relating to our Aversion or Impede Technologies or product candidates 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 situations in which we may become parties to such litigation or proceedings may include:

- litigation or other proceedings we or our licensee(s) may initiate against third parties to enforce our patent rights or other intellectual property rights, including the Paragraph IV Proceedings described below;
- litigation or other proceedings we or our licensee(s) may initiate against third parties seeking to invalidate the patents held by such third parties or to obtain a judgment that our products do not infringe such third parties' patents;
- litigation or other proceedings third parties may initiate against us or our licensee(s) to seek to invalidate our patents or to obtain a judgment that third party products do not infringe our patents;
- if our competitors file patent applications that claim technology also claimed by us, we may be forced to participate in interference or opposition proceedings to determine the priority of invention and whether we are entitled to patent rights on such invention; and
- if third parties initiate litigation claiming that our products infringe their patent or other intellectual property rights, we will need to defend against such proceedings.

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

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could harm our business. In certain circumstances, our licensee Pfizer has the first right to control the enforcement of certain of our patents against third party infringers. Pfizer may not put adequate resources or effort into such enforcement actions or otherwise fail to restrain infringing products. In addition, in an infringement proceeding, including the Paragraph IV Proceedings, a court may decide that a patent of ours is invalid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation, including the Paragraph IV Proceedings, or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Our technologies or products may be found to infringe claims of patents owned by others. If we determine that we are, or if we are found to be infringing a patent held by another party, we, our suppliers or our licensees might have to seek a license to make, use, and sell the patented technologies and products. In that case, we, our suppliers or our licensees might not be able to obtain such license on acceptable terms, or at all. The failure to obtain a license to any third party technology that may be required would materially harm our business, financial condition and results of operations. If a legal action is brought against us or our licensee(s), 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 use of our technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited. Even prior to resolution of such a dispute, use of our technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited.

We are aware of certain United States and international pending patent applications owned by third parties with claims potentially encompassing Oxecta and our Aversion products in development. While we do not expect the claims contained in such pending patent applications will issue in their present form, there can be no assurance that such patent applications will not issue as patents with claims encompassing one or more of our product candidates. If such patent applications result in valid and enforceable issued patents, containing claims in their current form or otherwise encompassing our products we or our licensees may be required to obtain a license to such patents, should one be available, or alternatively, alter our products so as to avoid infringing such third-party patents. If we or our licensees are unable to obtain a license on commercially reasonable terms, or at all, we or our licensees could be restricted or prevented from commercializing our products. Additionally, any alterations to our products or our technologies could be time consuming and costly and may not result in technologies or products that are non-infringing or commercially viable.

We are aware of an issued United States patent owned by a third party having claims encompassing the use of one of our Aversion inactive ingredients in a controlled release pharmaceutical preparation. We are also aware of an issued United States patent owned by a third party having claims encompassing a pharmaceutical preparation containing viscosity producing ingredients that can be drawn into a syringe when dissolved in 10mL's or less of aqueous solution. While we believe that our Aversion products do not infringe these patents, or that such patents are otherwise invalid, there can be no assurance that we or Pfizer will not be sued for infringing these patents, and if sued, there can be no assurance that we or Pfizer will prevail in any such litigation. If we or Pfizer are found to infringe either or both of these patents, we or Pfizer may seek a license to use the patented technology. If we are unable to obtain such a license, of which no assurance can be given, we or Pfizer may be restricted or prevented from commercializing our Aversion products.

We are aware of certain issued United States patents owned by a third party having claims encompassing a process used to manufacture oxycodone HCl of high purity and pharmaceutical products resulting therefrom. As required by the FDA, Oxecta contains a similar high purity oxycodone HCl manufactured by a supplier that is not the owner or licensee of such patents. The owner of these patents has filed patent infringement actions relating to these patents against companies that have filed abbreviated new drug applications with the FDA for extended-release versions of oxycodone HCl. To our knowledge, the patent owner has not initiated any patent infringement actions against the sellers of immediate-release oxycodone HCl products or their suppliers of oxycodone HCl, however, we cannot be certain that these immediate-release products actually utilize a high purity oxycodone. We cannot provide assurance that Pfizer or its oxycodone HCl supplier will not be sued for infringing these patents. In the event of an infringement action, Pfizer and their oxycodone HCl supplier would have to either: (a) demonstrate that the manufacture of the oxycodone HCl used in Oxecta does not infringe the patent claims, (b) demonstrate the patents are invalid or unenforceable, or (c) enter into a license with the patent owner. If Pfizer or their oxycodone HCl supplier is unable to demonstrate the foregoing, or obtain a license to these patients, Pfizer may be required or choose to withdraw Oxecta from the market.

We cannot assure you that our technologies, products and/or actions in developing our products will not infringe third-party patents. Our failure to avoid infringing third-party patents and intellectual property rights in the development and commercialization of our products would have a material adverse affect on our operations and financial condition.

Generic manufacturers are using litigation and regulatory means to seek approval for generic versions of Oxecta, which could cause our and our licensee's sales to suffer.

Under the Hatch-Waxman Act, the FDA can approve an ANDA for a generic version of a branded drug and what is referred to as a Section 505(b)(2) NDA, for a branded variation of an existing branded drug, without requiring such applicant to undertake the full clinical testing necessary to obtain approval to market a new drug. An ANDA applicant usually needs to only submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

The Hatch-Waxman Act requires an applicant for a drug that references one of our branded drugs to notify us of their application if they assert in their application that the patents we have listed in the Orange Book will not be infringed or otherwise are invalid or unenforceable (a Paragraph IV Certification). Upon receipt of this notice we have 45 days to bring a patent infringement suit in federal district court against such applicant. If such a suit is commenced, the FDA is generally prohibited from granting approval of the ANDA or Section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor or expiration of the patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) NDAs. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove this uncertainty. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the applicant for the patents subject to the litigation.

On September 20, 2012, we announced that we had received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from a generic sponsor of an ANDA for a generic drug listing Oxecta as the reference listed drug. Since such date, we have received similar Paragraph IV Notices from three other generic pharmaceutical companies that have filed ANDAs listing Oxecta as the reference drug. The Paragraph IV Notices refer to our U.S. Patent Numbers 7,201,920, 7,510,726 and 7,981,439, which cover our Aversion Technology and Oxecta. The Paragraph IV Notices state that each generic sponsor believes that such patents are invalid, unenforceable or not infringed. Pfizer has advised us that it will not exercise its first right under our license agreement to control the enforcement of our patents licensed to Pfizer for Oxecta against these generic sponsors. As a result, we will take appropriate action to enforce our intellectual property rights and on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. - Florida, Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement of our patent no. 7,510,726 listed in the FDA's Orange Book. The commencement of such litigation prohibits the FDA from granting approval of the filed ANDAs until the earliest of 30 months from the date the FDA accepted the application for filing, or the conclusion of litigation. The above actions are referred to as the "Paragraph IV Proceedings."

Litigation is inherently uncertain and we cannot predict the outcome of the Paragraph IV Proceedings. If any of these generic companies prevails its respective lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of Oxecta prior to the expiration of our patents in 2025. Additionally, it is possible that other generic manufacturers may also seek to launch a generic version of Oxecta and challenge our patents. Any determination in the Paragraph IV Proceedings that our patents covering our Aversion Technology and Oxecta are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents, could have a material adverse affect on our operations and financial condition.

We may be exposed to product liability claims and may not be able to obtain or maintain 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 patients, or health care providers or others that sell or consume our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale. We are currently covered by clinical trial product liability insurance on a claims-made basis and expect to expand such coverage to cover Nexafed, if commercialized. 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 obtain coverage for Nexafed or, if obtained, maintain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to product 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. Reference is made to the discussion under the caption "Item 3, Legal Proceedings – Reglan®/Metoclopramide Litigation" for a discussion of pending product liability litigation filed against the Company in each of Pennsylvania, New Jersey and California.

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 future litigation, in addition to the ongoing Reglan/Metoclopramide mass tort litigation. Such litigation may have material adverse consequences to our financial condition and results of operations.

We face significant competition which may result in others developing or commercializing products before or more successfully than we do.

Our products and technologies will, if marketed, compete to varying degrees against both brand and generic products offering similar therapeutic benefits and being developed and marketed by small and large pharmaceutical (for prescription products) and consumer packaged goods (for OTC products) companies. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in research, development and commercialization of their competitive technologies and products. Prescription generic products and OTC store brand products will offer cost savings to third party payers and/or consumers that will create pricing pressure on our products. Also, these competitors may have a substantial sales volume advantage over our products which may result in our costs of manufacturing being higher than our competitors' costs. If our products are unable to capture and maintain market share, we or our licensees may not achieve significant product revenues and our financial condition and results of operations will be materially adversely affected.

We believe potential competitors may be developing opioid abuse deterrent technologies and products. Such potential competitors include, but may not be limited to, Pain Therapeutics, in collaboration with Pfizer, Purdue Pharma, Atlantic Pharmaceuticals, Egalet a/s, KemPharm and Collegium Pharmaceuticals, Inc. These companies appear to be focusing their development efforts on ER Opioid Products, except for Atlantic Pharmaceuticals, while the majority of our Aversion Technology opioid analgesic product candidates under development are IR Opioid Products. Pfizer, our partner in commercializing Oxecta, is also developing and/or marketing ER Opioid Products, other analgesic products and non-analgesic products, all of which will compete for development and commercialization resources with our products, which may delay development or adversely impact the sales of our products.

Our Impede Technology products containing PSE will compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Some of our competitors will have multiple consumer product offerings both within and outside the cold, allergy and sinus category providing them with substantial leverage in dealing with a highly consolidated pharmacy distribution network. The competing products may have well established brand names and may be supported by national or regional advertising. Nexafed will compete directly with Johnson & Johnson's Sudafed® brand as well as generic formulations manufactured by Perrigo Company and others.

We are concentrating a substantial majority of our efforts and resources on developing product candidates utilizing our Aversion and Impede Technologies. The commercial success of products utilizing such technologies will depend, in large part, on the intensity of competition, FDA approved product labeling for our products compared to competitive products, and the relative timing and sequence for commercial launch of new products by other companies developing, marketing, selling and distributing products that compete with the products utilizing our Aversion and Impede Technologies. Alternative technologies and non-opioid products are being developed to improve or replace the use of opioid analgesics. In the event that such alternatives to opioid analgesics are widely adopted, then the market for products utilizing our Aversion and Impede Technologies may be substantially decreased thus reducing our ability to generate future profits.

Key personnel are critical to our business and our success depends on our ability to retain them.

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

Our products are subject in regulation by the U.S. Drug Enforcement Administration, or DEA, and such regulation may affect the development and sale of our products.

The DEA regulates certain finished drug products and active pharmaceutical ingredients, including certain opioid active pharmaceutical ingredients and pseudoephedrine HCl that are contained in our products. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of regulation. Furthermore, the amount of active ingredients we can obtain for our clinical trials is limited by the DEA and our quota may not be sufficient to complete clinical trials. There is a risk that DEA regulations may interfere with the supply of the products used in our clinical trials.

In addition, we and our contract manufacturers are subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be a rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain FDA approval and adverse scheduling could have a material adverse effect on the attractiveness of such product. We or our licensees must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

Prior ownership changes limit our ability to use our tax net operating loss carryforwards.

Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of Net Operating Loss, or NOL, carryforwards and other tax attributes. We have determined that an ownership change (as defined by Section 382 of the Internal Revenue Code) did occur as a result of restructuring that occurred in 2004. Neither the amount of our NOL carryforwards nor the amount of limitation of such carryforwards claimed by us have been audited or otherwise validated by the Internal Revenue Service, which could challenge the amount we have calculated. The recognition and measurement of our tax benefit includes estimates and judgment by our management, which includes subjectivity. Changes in estimates may create volatility in our tax rate in future periods based on new information about particular tax positions that may cause management to change its estimates.

Risks Relating to our Common Stock

Our quarterly results of operations will fluctuate, and these fluctuations could cause our stock price to decline.

Our quarterly and annual 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 launch and market acceptance of our products, and the timing of the research, development and regulatory submissions of our products in development that could cause our operating results to fluctuate. The forecasting of the timing and amount of sales of our products is difficult due to market uncertainty and the uncertainty inherent in seeking FDA and other necessary approvals for our product candidates. As a result, in some future quarters or years our clinical, financial or operating results may not meet the expectations of securities analysts and investors which could result in a decline in the price of our stock.

Volatility in stock prices of other companies may contribute to volatility in our stock price.

The market price of our common stock, like the market price for securities of pharmaceutical and biotechnology companies, has historically been highly volatile. The stock market from time to time experiences significant price and volume fluctuations unrelated to the operating performance of particular companies. Factors, such as fluctuations in our operating results, future sales of our common stock, announcements of the timing and amount of product sales, of our products, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements, laboratory or clinical trial results, government regulation, FDA determinations on the approval of a product candidate NDA submission, 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 substantial 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 and shareholder derivative litigation has often been instituted. A securities class action suit or shareholder derivative suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources and result in a material adverse affect on our financial condition and results of operations. Reference is made to the discussion under "Item 3, Legal Proceedings – Securities Class Action and Derivative Litigation" for a discussion of a pending securities class action litigation filed against us in the United States District Court for the Northern District of Illinois, Eastern Division, and three shareholder derivative suits filed in the Circuit Court of Cook County, Illinois, Chancery Division.

Our stock price has been volatile and there may not be an active, liquid trading market for our common stock.

Our stock price has experienced significant price and volume fluctuations and may continue to experience volatility in the future. Factors that may have a material impact on the price of our common stock, in addition to the other issues described herein, include the launch and commercial success of Oxecta and Nexafed, results of or delays in our pre-clinical and clinical studies, any delays in, or failure to receive FDA approval of our product candidates, the entry into collaboration or license agreements relating to our products in development, announcements of technological innovations or new commercial products by us or others, developments in patents and other proprietary rights by us or others, future sales of our common stock by existing stockholders, regulatory developments or changes in regulatory guidance, the departure of our officers, directors or key employees, and period-to-period fluctuations in our financial results. Also, you may not be able to sell your shares at the best market price if trading in our stock is not active or if the volume is low. There is no assurance that an active trading market for our common stock will be maintained on the NASDAQ Capital Market.

The National Association of Securities Dealers, Inc., or NASD, and the Securities and Exchange Commission, or SEC, have adopted rules relating to the listing of publicly traded stock. If we were unable to continue to comply with such rules, we could be delisted from trading on the NASDAQ Capital Market and thereafter trading in our common stock, if any, would be conducted through the Over-the-Counter Bulletin Board of the NASD. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock from the NASDAQ Capital Market could also result in lower prices per share of our common stock than would otherwise prevail.

We do not have a history of paying dividends on our common stock.

Historically we have not declared and paid any cash dividends on our common stock. We intend to retain all of our earnings for the foreseeable future to finance the operation and expansion of our business. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases.

Because Our Principal Shareholders Control A Large Percentage Of Our Voting Power, Other Stockholders' Voting Power May Be Limited

Our principal shareholders, Galen Partners III, L.P and its affiliates, Care Capital Investments II, LP and its affiliate and Essex Woodlands Health Ventures V, beneficially own approximately 29.8%, 23.0% and _22.2%, respectively, of our outstanding common stock (calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended). Accordingly, these shareholders, individually or if they were to act as a group or vote in the same manner, may be able to influence the outcome of shareholder votes, including the adoption or amendment of provisions in our Certificate of Incorporation or By-Laws and the approval of mergers and other significant corporate transactions, including a sale of substantially all of our assets. These shareholders may make decisions that are adverse to other shareholders' interests. This ownership concentration may also adversely affect the market price of our common stock.

Any future sale of a substantial number of shares included in our current registration statement could depress the trading price of our stock, lower our value and make it more difficult for us to raise capital.

In accordance with the terms of the Securities Purchase Agreement dated August 20, 2007 between us and the investors named therein, we filed a registration statement with and declared effective by the SEC, to register the shares included in our Units issued pursuant to the Securities Purchase Agreement, including shares underlying warrants included in the Units. In addition, pursuant to the exercise of previously granted piggyback registration rights, each of Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP and Essex Woodlands Health Ventures V, L.P. have exercised their piggyback registration rights to include an aggregate of 26,584,016 shares in such registration statement. As a result, 34,243,273 shares (representing approximately 65% of our shares outstanding on a fully-diluted basis – including all derivative securities, whether or not currently exercisable) are available for resale by selling stockholders under the registration statement. If some or all of the shares included in such registration statement are sold by our affiliates and others it may have the effect of depressing the trading price of our common stock. In addition, such sales could lower our value and make it more difficult for us to raise capital if needed in the future.

Item 6. Exhibits

The exhibits required by this Item are listed below.

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 the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase

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.

October 31, 2012

ACURA PHARMACEUTICALS, INC.

/s/ Robert B. Jones
Robert B. Jones
Chief Executive Officer

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

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

I, Robert B. Jones, the President & 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 officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d – 15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with general accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrants most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer 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.

October 31, 2012

/s/ Robert B. Jones
Robert B. Jones
President & Chief Executive Officer

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

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

1. I have reviewed this quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrants most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.

5. The registrant's other certifying officer 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.

October 31, 2012

/s/ Peter A. Clemens
Peter A. Clemens
Chief Financial Officer

CERTIFICATIONS OF THE CHIEF EXEUTIVE OFFICER AND THE CHIEF FINANCIAL OFFICER
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, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert B. Jones, the Chief Executive Officer of the Company, and Peter A. Clemens, Chief Financial Officer 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.

October 31, 2012

/s/ Robert B. Jones
Robert B. Jones
Chief Executive Officer

/s/ Peter A. Clemens
Peter A. Clemens
Chief Financial Officer