

# 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, 2009**

or

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

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

**Commission File Number 1-10113**

## **Acura Pharmaceuticals, Inc.**

*(Exact name of registrant as specified in its charter)*

**New York**

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

**11-0853640**

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

**616 N. North Court, Suite 120**

**Palatine, Illinois**

*(Address of Principal Executive Offices)*

**60067**

*(Zip Code)*

**847 705 7709**

*(Registrant's telephone number, including area code)*

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is a 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

Non-accelerated filer

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 23, 2009 the registrant had 42,968,521 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**

**UNAUDITED  
(in thousands, except par values)**

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 32,729	\$ 30,398
Short term investments	—	5,039
Collaboration revenue receivable	226	3,529
Prepaid expense and other current assets	364	431
Deferred income taxes	13	2,491
Total current assets	<u>33,332</u>	<u>41,888</u>
<b>Non-current assets</b>		
Property, plant and equipment, net	1,187	1,073
Total assets	<u>\$ 34,519</u>	<u>\$ 42,961</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ —	\$ 382
Accrued expenses	906	883
Deferred program fee revenue	1,943	4,632
Total current liabilities	<u>2,849</u>	<u>5,897</u>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Common stock - \$.01 par value; 100,000 shares authorized; 42,966 and 42,723 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	430	427
Additional paid-in capital	350,377	344,023
Accumulated deficit	(319,137)	(307,386)
Total stockholders' equity	<u>31,670</u>	<u>37,064</u>
Total liabilities and stockholders' equity	<u>\$ 34,519</u>	<u>\$ 42,961</u>

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except share and per share data)

	Nine Months Ended September 30		Three Months Ended September 30,	
	2009	2008	2009	2008
<b>Revenue</b>				
Program fee revenue	\$ 2,688	\$ 23,678	\$ 583	\$ 1,263
Milestone revenue	—	5,000	—	—
Collaboration revenue	397	7,971	225	2,617
Total revenue	3,085	36,649	808	3,880
<b>Operating expenses</b>				
Research and development expenses	3,828	10,859	1,494	3,693
Marketing, general and administrative expenses	8,680	5,617	3,284	3,373
Total operating expenses	12,508	16,476	4,778	7,066
Operating (loss) income	(9,423)	20,173	(3,970)	(3,186)
<b>Other income (expense)</b>				
Interest, net	134	675	20	171
Other	(3)	1	—	(17)
Total other income	131	676	20	154
(Loss) income before income tax	(9,292)	20,849	(3,950)	(3,032)
Income tax expense (benefit)	2,459	3,382	4	(6,180)
Net (loss) income	\$ (11,751)	\$ 17,467	\$ (3,954)	\$ 3,148
<b>(Loss) earnings per share</b>				
Basic	\$ (0.26)	\$ 0.38	\$ (0.09)	\$ 0.07
Diluted	\$ (0.26)	\$ 0.35	\$ (0.09)	\$ 0.06
<b>Weighted average shares used in computation</b>				
Basic	45,839	45,670	45,992	45,680
Diluted	45,839	49,529	45,992	49,409

See accompanying notes to the consolidated financial statements.

**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

**NINE MONTHS ENDED SEPTEMBER 30, 2009**

**UNAUDITED**  
**(in thousands)**

	<b>Common Stock Shares</b>	<b>Common Stock Amount</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
Balance at December 31, 2008	42,723	\$ 427	\$ 344,023	\$ (307,386)	\$ 37,064
Net loss	—	—	—	(11,751)	(11,751)
Stock-based compensation	—	—	6,529	—	6,529
Exercise of warrants	193	2	(2)	—	—
Exercise of options	50	1	(173)	—	(172)
Balance at September 30, 2009	42,966	\$ 430	\$ 350,377	\$ (319,137)	\$ 31,670

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, except supplemental disclosures)**

	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities</b>		
Net (loss) income	\$ (11,751)	\$ 17,467
<b>Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities</b>		
Depreciation and amortization	96	108
Deferred income taxes	2,479	3,334
Non-cash share-based compensation expense	6,529	2,367
Loss (gain) on asset disposals	3	(1)
Impairment reserve against fixed assets	—	(29)
<b>Changes in assets and liabilities</b>		
Collaboration revenue receivable	3,304	361
Prepaid expenses and other current assets	91	1
Accounts payable	(382)	—
Accrued expenses	(176)	1,750
Deferred program fee revenue	(2,688)	(20,679)
<b>Net cash (used in) provided by operating activities</b>	<b>(2,495)</b>	<b>4,679</b>
<b>Cash flows from investing activities</b>		
Purchase of investments	—	(5,039)
Investment maturities	5,039	—
Capital expenditures	(213)	(135)
Proceeds from asset disposals	—	1
<b>Net cash provided by (used in) investing activities</b>	<b>4,826</b>	<b>(5,173)</b>
<b>Cash flows from financing activities – proceeds from warrant exercise</b>	<b>—</b>	<b>20</b>
<b>Increase in cash and cash equivalents</b>	<b>2,331</b>	<b>(474)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>30,398</b>	<b>31,368</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 32,729</b>	<b>\$ 30,894</b>
<b>Cash paid during the period for interest</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Cash paid during the period for income taxes</b>	<b>\$ 102</b>	<b>\$ 47</b>

**SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES**

Nine Months Ended September 30, 2009

1. Warrants to purchase 391,000 shares of common stock were exercised at an exercise price of \$3.40 per share in a series of cashless exercise transactions resulting in the issuance of 193,000 shares of common stock.
2. Options to purchase 100,000 shares of common stock were exercised at an exercise price of \$1.30 per share in a cashless exercise transaction and after withholding shares for statutory payroll taxes calculated at \$173,000, the transaction resulted in the issuance of 50,000 shares of common stock.

Nine Months Ended September 30, 2008

1. The disposal of fixed assets with \$52,000 net book value resulted in a \$29,000 reduction in the impairment allowance recognized favorably in the statement of operations.
2. A \$5,022,000 valuation allowance against deferred income tax assets was removed which resulted in an equal amount recorded as a benefit against current income tax expense.
3. Deferred income tax assets of \$8,356,000 were used to offset an equal amount of current income taxes payable.

See accompanying notes to the consolidated financial statements.

**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**SEPTEMBER 30, 2009 AND 2008**

**NOTE 1 - BASIS OF PRESENTATION**

Acura Pharmaceuticals, Inc., a New York corporation, and its wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc. (the “Company” or “We”) is a specialty pharmaceutical company engaged in research, development and manufacture of product candidates providing abuse deterrent features and benefits utilizing our proprietary Aversion® Technology and other novel technologies. Our portfolio of product candidates utilizing Aversion® Technology includes opioid analgesics intended to effectively relieve pain and benzodiazepines intended to treat anxiety and related disorders. Aversion® Technology is designed to maintain the therapeutic efficacy of the product candidates while simultaneously discouraging common methods of pharmaceutical product misuse and abuse including:

- intravenous injection of dissolved tablets or capsules;
- nasal snorting of crushed tablets or capsules; and
- intentional swallowing of excess quantities of tablets or capsules.

The accompanying unaudited interim consolidated financial statements of the Company were prepared in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X and accordingly, 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, (consisting primarily of items of normal recurring nature), considered necessary to present fairly the financial position of the Company as of September 30, 2009 and results of operations and cash flows for the three and nine months ending September 30, 2009 and 2008 have been made. The results of operations for the three and nine months ending September 30, 2009 are not necessarily indicative of results that may be expected for the full year ending December 31, 2009. These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto for the year ended December 31, 2008 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”). The 2008 year-end consolidated balance sheet was derived from the audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles. Amounts presented have been rounded to the nearest thousand, where indicated, except per share data and par values. No material subsequent events have occurred since September 30, 2009 and the date of this Report that require recognition or disclosure in this Report.

**NOTE 2 – NEW ACCOUNTING PRONOUNCEMENTS**

In May 2009, the Financial Accounting Standards Board (“FASB”) issued ASC 855-10 (formerly FAS No. 165), “Subsequent Events,” which establishes general standards of accounting and disclosure for events that occur after the balance sheet date but before the financial statements are issued. This new standard was effective for interim or annual periods beginning after June 15, 2009. The Company adopted the application of this statement and has provided the new disclosures as required.

In June 2009, the FASB issued ASC 105-10 (formerly FAS No. 168), “The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles – a replacement of FASB Statement No. 162” (“ASC 105-10”). ASC 105-10 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities which are presented in conformity with generally accepted accounting principles (GAAP) in the United States (the GAAP hierarchy). It establishes the FASB Accounting Standards Codification™ as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. ASC 105-10 explicitly recognizes rules and interpretive releases of the Securities and Exchange Commission (“SEC”) under federal securities laws as authoritative GAAP for SEC registrants. ASC 105-10 is effective for interim or annual financial periods ending after September 15, 2009. The Company adopted this statement and has updated all existing GAAP references to the new codification.

### NOTE 3 – RESEARCH AND DEVELOPMENT

Research and development (“R&D”) expenses include internal R&D activities, external contract research organization (“CRO”) activities, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, depreciation, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and incentive compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include clinical trial studies, regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. The Company makes payments to CROs based on written contracts which may include advanced payments. The Company accrues CRO and clinical trial study expenses based on work performed and the stage of completion and relies upon estimates of these measures provided by the CRO. Accrued CRO expenses are subject to revisions as such work and clinical trials progress to completion. Revisions are charged or credited to R&D expense in the period in which the facts that give rise to the revision become known. Advance payments are amortized to expense based on work performed. At September 30, 2009 we had \$0.6 million of CRO contractual obligations expected to be incurred during the next two fiscal quarters. We had CRO contractual obligations of \$1.0 million at December 31, 2008 which was incurred and charged to R&D expense as the clinical studies progressed during the first quarter of 2009.

### NOTE 4 – REVENUE RECOGNITION AND DEFERRED PROGRAM FEE REVENUE

We recognize revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, “Revenue Recognition in Financial Statements” (“SAB 104”). We have also adopted the provisions of Emerging Issues Task Force, ASC 605-25 (formerly Issue No. 00-21), “Revenue Arrangements with Multiple Deliverables”. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery 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 “King Agreement”) with King Pharmaceuticals Research and Development, Inc. (“King”), we recognize program fee revenue, collaboration revenue and milestone revenue.

Program fee revenue is derived from amortized upfront payments, such as the \$30.0 million upfront payment received from King in December 2007, and license fees upon the exercise of options to license opioid analgesic product candidates under the King Agreement. We have assigned an equal portion of the King upfront payment to each of three product candidates identified in the King Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. Our development responsibilities for two of the three product candidates have been completed. We expect to recognize the remainder of the program fee revenue for the third product candidate ratably over its remaining development period which we currently estimate to extend through July, 2010. In May 2008 King paid us a \$3.0 million license fee upon the exercise of its option to license a third opioid analgesic product candidate utilizing our Aversion® Technology. We recognized program revenue fees of \$0.6 million and \$1.3 million for the three months ended September 30, 2009 and 2008, respectively, and \$2.7 million and \$23.7 million for the nine months ended September 30, 2009 and 2008, respectively.

Collaboration revenue is derived from reimbursement by King to us of certain development and regulatory expenses, which are invoiced quarterly in arrears, and recognized as revenue when costs are incurred. The ongoing development and regulatory services being provided by us to King under the King Agreement are priced at our cost to provide such services without mark-up. We recognized collaboration revenue of \$0.2 million and \$2.6 million for the three months ended September 30, 2009 and 2008, respectively, and \$0.4 million and \$8.0 million for the nine months ending September 30, 2009 and 2008, respectively.

Milestone revenue is contingent upon the achievement of certain pre-defined events in the development of Acurox® Tablets and other product candidates licensed to King under the King Agreement. Milestone payments from King are recognized as revenue upon achievement of the “at risk” milestone events, which represent the culmination of the earnings process related to that milestone. Milestone payments are triggered either by the results of our research and development 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 King Agreement, and the amounts of the payments assigned thereto are dependent on the milestones being achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment. Each milestone payment is non-refundable and non-creditable when made. No milestone revenue was recognized during the nine months ended September 30, 2009 and \$5.0 million was recognized during the nine months ended September 30, 2008.



## NOTE 5 – INCOME TAXES

The Company accounts for income taxes under the liability method in accordance with ASC 740-10 (formerly FAS No. 109), "Accounting for Income Taxes" ("ASC 740-10"). 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 measured 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. ASC 740-10 requires a valuation allowance 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 September 30, 2009 and December 31, 2008, the Company determined that it was more likely than not that a portion of the Company's net operating loss carryforwards may not be realized in the near term and accordingly a valuation allowance was provided. For the second quarter 2009, the valuation allowance was increased by \$2.5 million and income tax expense was recognized. We made no change to the valuation allowance in the third quarter 2009. If in the future it is determined that amounts of our deferred income tax assets would likely be utilized, the valuation allowance would be reduced in the period in which such determination is made and a benefit from income taxes in such period would be recognized.

## NOTE 6 – ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	Sept 30, 2009	Dec 31, 2008
Payroll, bonus, payroll taxes and employee benefits	\$ 405	\$ 77
Legal services	35	35
Audit and tax professional services	99	89
State franchise taxes	30	144
Property taxes	22	39
State income taxes	—	94
Clinical, regulatory, trademark, and patent services	43	217
Other fees and services	272	188
	<u>\$ 906</u>	<u>\$ 883</u>

## NOTE 7 – SHARE-BASED COMPENSATION

The Company accounts for employee and director share-based compensation plans, including stock options and restricted stock units ("RSU"), pursuant to ASC 718-10 (formerly FAS 123R) "Share-Based Payment". The Company estimates the fair value of share-based awards on the date of grant using an option pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's Consolidated Statement of Operations. The Company uses the straight line method of attributing the value of share-based compensation. The Company selected the Black-Scholes option pricing model for determining the estimated fair value for share-based awards. The use of the Black-Scholes model requires the use of assumptions including expected volatility, risk-free interest rate and expected dividends. The Company estimated the volatility factor of the market price of its stock by reviewing its historical public market closing prices. The Company did not consider implied volatility because there are no options traded in its stock. The risk-free interest rate assumption is based on observed interest rates appropriate for the estimated term of the employee stock options and restricted stock units. The dividend yield assumption is based on the Company's history and 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. Forfeitures are accounted for as they occur. We incurred share-based compensation expense of \$2.7 million and \$1.5 million for the three months ended September 30, 2009 and 2008, respectively, and \$6.5 million and \$2.4 million for the nine months ended September 30, 2009 and 2008, respectively. As of September 30, 2009 the Company had \$10.9 million of net unrecognized share-based compensation expense related to stock option grants and RSU awards.

## Restricted Stock Unit Award Plan

The Company has a Restricted Stock Unit Award Plan (the “2005 RSU Plan”) for its employees and non-employee directors. A RSU represents the contingent obligation of the Company to deliver a share of its common stock to the holder of the RSU on a distribution date. RSUs for up to 3.5 million shares of common stock are authorized for issuance under the 2005 RSU Plan. Absent a change of control, one-fourth of vested shares of common stock underlying an RSU award will be distributed (after payment of \$0.01 par value per share) on January 1 of each of 2011, 2012, 2013 and 2014. If a change in control occurs (whether prior to or after 2011), an acceleration of unvested shares will occur and all shares underlying the RSU award will be distributed at or about the time of the change in control and any unrecognized share-based compensation expense will be recognized.

RSU awards of 3.3 million and 3.0 million shares were outstanding at September 30, 2009 and December 31, 2008, respectively, and 3.1 million and 2.95 million shares were vested, respectively. No awards were granted during either of the three months ended September 30, 2009 or 2008. During the nine months ended September 30, 2009 and 2008, RSU awards of 0.33 million and 0.05 million were granted, respectively. The Black-Scholes values of these awards were \$2.1 million and \$0.4 million respectively, which will be recognized as share-based compensation expense over the vesting period of the awards under straight-line amortization methods. We incurred share-based compensation expense from all RSU awards of \$0.3 million and \$0.1 million for the three months ended September 30, 2009 and 2008, respectively, and \$0.6 million and \$0.1 million for the nine months ended September 30, 2009 and 2008, respectively. Assumptions used in the Black-Scholes model to determine fair value for the 2009 RSU awards were:

	2009
Dividend yield	0.00%
Risk-free interest rate	1.30% to 1.50%
Volatility	102% to 108%
Forfeitures	0.00%
Expected life of RSU award	3.4 years
Grant date fair value	\$ 5.69 to \$7.10

As of September 30, 2009 the Company had \$1.7 million of net unrecognized share-based compensation expense related to RSU awards. The unrecognized share-based compensation expense will be recognized ratably over each of the various remaining vesting periods of the unvested RSU awards, whose furthest period extends for twenty months. The weighted average fair value of all RSU grants is \$3.77 per share of common stock underlying each RSU. As of September 30, 2009 and December 31, 2008, the aggregate intrinsic value of the RSU awards outstanding and vested was \$15.6 million and \$21.8 million, respectively.

## Stock Option Plans

The Company has stock options outstanding under three stock option plans. Our 1995 and 1998 Stock Option Plans have expired but options granted under such plans remain outstanding under the terms of those plans. On April 30, 2008 our shareholders approved a 2008 Stock Option Plan authorizing the granting of options to purchase up to 6.0 million shares of the Company’s common stock.

Stock options to purchase 4.2 million and 3.0 million shares with a weighted-average exercise price of \$5.45 and \$6.95 were outstanding at September 30, 2009 and December 31, 2008, respectively, of which 2.8 million and 2.2 million options were vested at September 30, 2009 and December 31, 2008, respectively. There was no stock option activity during the three months ending September 30, 2009 and 2008. During the nine months ended September 30, 2009 and 2008, stock options to purchase 1.3 million and 1.2 million shares of common stock having a weighted average exercise price of \$6.38 and \$9.58, respectively, were granted; during the nine months ended September 30, 2009, 0.1 million stock options were exercised at a price of \$1.30 per share; and during the nine months ended September 30, 2009 and 2008, 0.02 million and 0.05 million stock options expired, respectively. We incurred share-based compensation expense from all stock option awards of \$2.4 million and \$1.4 million for the three months ended September 30, 2009 and 2008, respectively, and \$5.9 million and \$2.3 million for the nine months ended September 30, 2009 and 2008, respectively. Assumptions used in the Black-Scholes model to determine fair value for the 2009 stock option grants were:

	2009
Dividend yield	0.0%
Risk-free interest rate	2.4% to 3.1%
Average volatility	124%
Forfeitures	0.0%
Expected life of option	10 years
Weighted average grant date fair value	\$ 6.06

As of September 30, 2009 the Company had \$9.2 million of net unrecognized share-based compensation expense related to stock option grants. The unrecognized share-based compensation expense will be recognized ratably over each of the various remaining vesting periods of the unvested stock options, whose furthest period extends for twenty months. Total intrinsic value of stock options outstanding and exercisable at September 30, 2009 and December 31, 2008 was \$6.1 million and \$10.5 million, respectively.

#### **NOTE 8 – COMMON STOCK WARRANTS**

At September 30, 2009, the Company had outstanding common stock purchase warrants, exercisable for an aggregate of approximately 3.5 million shares of common stock, all of which, under certain conditions, contain cashless exercise features. During the nine month period ended September 30, 2009, warrants to purchase 0.4 million shares of common stock were exercised at \$3.40 per share in a series of cashless exercise transactions resulting in the issuance of 0.2 million shares of common stock. At September 30, 2009, outstanding warrants to acquire 0.1 million, 1.1 million and 2.3 million common shares will expire if unexercised before the end of years 2010, 2013 and 2014, respectively, and have a weighted average remaining term of 4.6 years. The exercise prices of these warrants range from \$1.29 to \$3.40 per share, with a weighted average exercise price of \$3.15.

#### **NOTE 9 – EARNINGS (LOSS) PER SHARE**

Computation of basic earnings or loss per share of common stock is based upon the sum of the weighted average number of common shares outstanding and vested RSUs outstanding during the period. Computation of diluted earnings or loss per share is based on the same denominator used in the basic earning or loss computation, adjusted for the effect of additional potentially dilutive securities. Excluded from the diluted earnings or loss per share computations for the three and nine months ending September 30, 2009 are 8.0 million of potentially dilutive securities, as the effect of including these securities in the computation would be antidilutive. Accordingly, in the table below, the denominator used in 2009 is the same for both basic and diluted computations.

(in thousands, except per share data)	Nine Months Ended September 30,		Three Months Ended September 30,	
	2009	2008	2009	2008
<b>Basic earnings (loss) per share</b>				
Numerator:				
Net income (loss) allocable to common shareholder	\$ (11,751)	\$ 17,467	\$ (3,954)	\$ 3,148
Denominator:				
Common shares (weighted)	42,841	42,717	42,958	42,723
Vested RSUs (weighted)	2,998	2,953	3,034	2,957
Weighted average shares used in computing basic earnings (loss) per share allocable to common shareholder	45,839	45,670	45,992	45,680
Basic earnings (loss) per share allocable to common shareholder	\$ (0.26)	\$ 0.38	\$ (0.09)	\$ 0.07
<b>Diluted earnings (loss) per share</b>				
Denominator:				
Common shares (weighted)	42,841	42,717	42,958	42,723
Vested RSUs (weighted)	2,998	2,953	3,034	2,957
Common stock options	—	1,461	—	1,438
Common stock warrants	—	2,398	—	2,291
Weighted average shares used in computing diluted earnings (loss) per share allocable to common shareholder	45,839	49,529	45,992	49,409
Diluted earnings (loss) per share allocable to common shareholder	\$ (0.26)	\$ 0.35	\$ (0.09)	\$ 0.06
<b>Excluded potentially dilutive securities:</b>				
Common shares issuable (see #1 below):				
Nonvested RSUs	270	37	270	37
Common stock options (vested and nonvested)	4,164	1,173	4,164	1,173
Common stock warrants	3,517	—	3,517	—
Total excluded dilutive common stock equivalents	7,951	1,210	7,951	1,210

(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.

## **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 in our Annual Report on Form 10-K for the year ended December 31, 2008 as filed with the SEC (the "2008 Annual Report") and the 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. The most significant of such factors include, but are not limited to, our ability and the ability of King Pharmaceuticals Research and Development, Inc. ("King") (to whom we have licensed our Aversion<sup>®</sup> Technology for certain opioid analgesic products in the United States, Canada and Mexico) and the ability of other pharmaceutical companies, if any, to whom we may license our Aversion<sup>®</sup> Technology, to obtain necessary regulatory approvals and commercialize products utilizing Aversion<sup>®</sup> Technology, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability to fulfill the U.S. Food and Drug Administration's ("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 intended to support FDA approval of our product candidates, the adequacy of the development program for our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, the risk that the FDA may not agree with our analysis of our clinical studies and may evaluate the results of these studies by different methods or conclude that the results of the studies are not statistically significant, clinically meaningful or that there were human errors in the conduct of the studies or the risk that further studies of our product candidates are not positive or otherwise do not support FDA approval or commercially viable product labeling, and the uncertainties inherent in scientific research, drug development, clinical trials and the regulatory approval process. Other important factors that may also affect future results include, but are not limited to: our ability to attract and retain qualified personnel; our ability to secure and protect our patents, trademarks and other proprietary rights; litigation or regulatory action that could require us to pay significant damages or change the way we conduct our business; our ability to compete successfully against current and future competitors; our dependence on third-party suppliers of raw materials; our ability to secure U.S. Drug Enforcement Administration ("DEA") quotas and source the active ingredients for our products in development; difficulties or delays in clinical trials for our product candidates or in the commercial manufacture and supply of our products; and other risks and uncertainties detailed in this Report and in our 2008 Annual Report and our quarterly reports on Form 10-Q for the first and second quarters of 2009, each as filed with the Securities and Exchange Commission. When used in this Report, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions identify forward-looking statements.

## Company Overview

We are a specialty pharmaceutical company engaged in research, development and manufacture of product candidates intended to provide abuse deterrent features and benefits utilizing our proprietary Aversion<sup>®</sup> and Impede<sup>™</sup> Technologies. Our opioid analgesic product candidates are intended to effectively relieve pain while simultaneously discouraging common methods of opioid product misuse and abuse, including:

- intravenous injection of dissolved tablets or capsules;
- nasal snorting of crushed tablets or capsules; and
- intentional swallowing of excess quantities of tablets or capsules.

In addition to Acurox<sup>®</sup>, our lead product candidate, we (and/or our licensee, King Pharmaceuticals Research and Development, Inc.) are developing Vycavert<sup>®</sup> (hydrocodone bitartrate, niacin and acetaminophen), Acuracet<sup>®</sup> (oxycodone HCl, niacin and acetaminophen) and additional undisclosed opioid product candidates utilizing Aversion<sup>®</sup> Technology. Four opioid product candidates are licensed to King. We are also developing an undisclosed benzodiazepine tablet product candidate utilizing our Aversion<sup>®</sup> Technology.

Our research efforts continue to investigate and develop novel mechanisms to incorporate abuse deterrent characteristics into abused and misused pharmaceutical products. In this regard we have begun initial laboratory testing of a new product candidate developed with our novel Impede<sup>™</sup> Technology. Impede<sup>™</sup> Technology is primarily intended to inhibit the conversion of pseudoephedrine HCl (a legally available nasal decongestant) into methamphetamine (an illicit and frequently abused drug).

## Acurox<sup>®</sup> Tablets

Acurox<sup>®</sup> is an orally administered immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient. On December 30, 2008, we submitted a 505(b)(2) NDA for Acurox<sup>®</sup> Tablets to the FDA and on June 30, 2009 we received from the FDA a Complete Response Letter ("CRL") for the Acurox<sup>®</sup> Tablets NDA. The CRL raised issues regarding the potential abuse deterrent benefits of Acurox<sup>®</sup>. On September 2, 2009 we and King met with the FDA and agreed that the data and evidence supporting the Acurox<sup>®</sup> Tablets NDA would be presented to an FDA Advisory Committee. Although the FDA stated that no new Acurox<sup>®</sup> clinical trials are required at this time, we and King plan to initiate and complete an additional clinical study to further assess the abuse deterrent features of Acurox<sup>®</sup>. The FDA has not yet established a date for the Acurox<sup>®</sup> Advisory Committee meeting and we do not expect the meeting will be convened in 2009.

## King License Agreement

We have entered into a license agreement (the "King Agreement") with King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc., to develop and commercialize in the United States, Canada and Mexico (the "King Territory") Acurox<sup>®</sup> Tablets, Acuracet<sup>®</sup> Tablets, Vycavert<sup>®</sup> Tablets and a fourth undisclosed opioid analgesic product candidate utilizing our proprietary Aversion<sup>®</sup> Technology. King has an option to license in the King Territory certain future opioid analgesic products developed utilizing our Aversion<sup>®</sup> Technology.

We are responsible, using commercially reasonable efforts, for all Acurox<sup>®</sup> Tablet development activities through FDA approval of a 505(b)(2) NDA, for which certain expenses are reimbursed to us by King. After NDA approval King will be responsible for manufacturing and commercializing Acurox<sup>®</sup> Tablets in the U.S. With respect to all other products licensed by King pursuant to the King Agreement in all King Territories, King will be responsible, at its own expense, for development, regulatory, manufacturing and commercialization activities.

As of September 30, 2009, we have received aggregate payments of \$55.5 million from King, consisting of a \$30.0 million non-refundable upfront cash payment, \$14.5 million in reimbursed research and development expenses relating to Acurox<sup>®</sup> Tablets, \$6.0 million in fees relating to King's exercise of its option to license the undisclosed opioid analgesic tablet product and Vycavert<sup>®</sup> Tablets, and a \$5.0 million milestone fee for successful achievement of the primary endpoints for our pivotal Phase III clinical study for Acurox<sup>®</sup> Tablets. The King Agreement provides for King to pay us: (a) a \$3.0 million option exercise fee for each future opioid product candidate King licenses, (b) up to \$23 million in regulatory milestone payments for each King licensed product candidate, including Acurox<sup>®</sup> Tablets, in specific countries in the King Territory, and (c) a one-time \$50 million sales milestone payment upon the first attainment of an aggregate of \$750 million in net sales of all of our licensed products combined in all King Territories. In addition, for sales occurring following the one year anniversary of the first commercial sale of the first licensed product sold, King will pay us a royalty at one of 6 rates ranging from 5% to 25% based on the level of combined annual net sales for all products licensed by us to King in all King Territories, with the highest applicable royalty rate applied to such combined annual sales. No minimum annual fees are payable by either party under the King Agreement.

The foregoing description of the King Agreement contains forward-looking statements about Acurox<sup>®</sup> Tablets, and other product candidates pursuant to the King Agreement. As with any pharmaceutical products under development or proposed to be developed, substantial risks and uncertainties exist in development, regulatory review and commercialization process. There can be no assurance that any product developed, in whole or in part, pursuant to the King Agreement will receive regulatory approval or prove to be commercially successful. Accordingly, investors in the Company should recognize that there is no assurance that the Company will receive the milestone payments or royalty revenues described in the King Agreement or even if such milestones are achieved, that the related products will be successfully commercialized and that any royalty revenues payable to us by King will materialize.

## Patents and Patent Applications

In April 2007, the United States Patent and Trademark Office ("USPTO"), issued to us a patent titled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms" (the "920 Patent"). The 54 allowed claims in the 920 Patent encompass certain pharmaceutical compositions intended to deter the most common methods of prescription opioid analgesic product misuse and abuse. These patented pharmaceutical compositions include specific opioid analgesics such as oxycodone HCl and hydrocodone bitartrate among others.

In January 2009, the USPTO issued to us a patent (the "402 Patent") with 18 allowed claims. The 402 Patent encompasses certain combinations of *kappa* and *mu* opioid receptor agonists and other ingredients intended to deter opioid analgesic product misuse and abuse.

In March 2009, the USPTO issued to us a patent (the "726 Patent") with 20 allowed claims. The 726 Patent encompasses a wider range of abuse deterrent compositions than our 920 Patent. The USPTO previously issued to us a Notice of Allowance for a 21<sup>st</sup> claim in our then pending 726 Patent application. Upon consideration of a potential interference proceeding between the then pending 726 Patent application and a third party pending patent application, we filed with the USPTO a Request for Continued Examination of the 726 Patent application and cancelled one of the 21 claims in the pending application. Subsequently the 726 Patent was issued with 20 allowed claims.

In addition to our issued U.S. patents, we have filed multiple U.S. patent applications and international patent applications relating to compositions containing abuseable active pharmaceutical ingredients. Except for those rights conferred in the King Agreement, we have retained all intellectual property rights to our Aversion® Technology, Impede Technology™ and related product candidates.

### Company's Present Financial Condition

At October 26, 2009, we had cash and cash equivalents of approximately \$32.0 million and estimate that our current cash reserves will be sufficient to fund operations and development of Aversion® Technology and related product candidates through at least the next 12 months. In December, 2007, we and King Research and Development Inc., ("King") closed a License, Development and Commercialization Agreement (the "King Agreement") to develop and commercialize certain opioid analgesic products utilizing our proprietary Aversion® Technology in the United States, Canada and Mexico. During the nine months ended September 30, 2009, we recognized \$2.7 million of the \$30.0 million upfront cash payment received from King in December 2007 as program fee revenue and \$0.4 million of collaboration revenue for reimbursement by King for our Acurox® Tablet development and regulatory expenses. We have yet to generate any royalty revenues from product sales. We expect to rely on our current cash resources and additional payments that may be made under the King Agreement and under similar license agreements with other pharmaceutical company partners, of which there can be no assurance, in funding our continued operations. Our cash requirements for operating activities may increase in the future as we continue to conduct pre-clinical studies and clinical trials for our product candidates, maintain, defend if necessary, and expand the scope of our intellectual property, hire additional personnel, or invest in other areas related to abuse deterrence.

### Results of Operations for the Nine Month Period Ended September 30, 2009 and 2008

(\$ in thousands):	September 30,		Change	
	2009	2008	Dollars	%
<b>Revenue</b>				
Program fee revenue	\$ 2,688	\$ 23,678	\$ (20,990)	(89) %
Milestone revenue	—	5,000	(5,000)	(100)
Collaboration revenue	397	7,971	(7,574)	(95)
<b>Total revenue</b>	<b>3,085</b>	<b>36,694</b>	<b>(33,564)</b>	<b>(92)</b>
<b>Operating expenses</b>				
Research and development expenses	3,828	10,859	(7,031)	(65)
Marketing, general and administrative expenses	8,680	5,617	3,063	55
<b>Total operating expenses</b>	<b>12,508</b>	<b>16,476</b>	<b>(3,968)</b>	<b>(24)</b>
<b>Operating (loss) income</b>	<b>(9,423)</b>	<b>20,173</b>	<b>(29,596)</b>	<b>(147)</b>
<b>Other income (expense)</b>				
Interest, net	134	675	(541)	(80)
Other	(3)	1	(4)	(400)
<b>Total other income</b>	<b>131</b>	<b>676</b>	<b>(545)</b>	<b>(81)</b>
<b>(Loss) income before income tax</b>	<b>(9,292)</b>	<b>20,849</b>	<b>(30,141)</b>	<b>(145)</b>
<b>Income tax expense</b>	<b>2,459</b>	<b>3,382</b>	<b>(923)</b>	<b>(27)</b>
<b>Net (loss) income</b>	<b>\$ (11,751)</b>	<b>\$ 17,467</b>	<b>\$ (29,218)</b>	<b>(167) %</b>

### Revenue

King paid us a \$30.0 million upfront fee in connection with the closing of the King Agreement in December 2007. Revenue recognized in the nine months ended September 30, 2009 and 2008 from amortization of this upfront fee was \$2.7 million and \$23.7 million, respectively. We assigned a portion of the program fee revenue to each of three product candidates identified under the King Agreement. Our development responsibilities for two of the three product candidates are complete. We expect to recognize the remainder of the program fee revenue for the third product candidate ratably over its remaining development period which we currently estimate to extend through July, 2010.

Collaboration revenue recognized in the nine months ending September 30, 2009 and 2008 was \$0.4 million and \$8.0 million, respectively, for reimbursement of our Acurox® Tablet development and regulatory expenses incurred pursuant to the King Agreement. We invoice King in arrears on a calendar quarter basis for our reimbursable development and regulatory expenses under the King Agreement. We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying development and regulatory expenses.

### Operating Expenses

Research and development expense during the nine months ending September 30, 2009 and 2008 were for developing our product candidates and related technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. We incurred \$1.3 million and \$0.6 million of share-based compensation expense attributable to research and development staff for the nine months ended September 30, 2009 and 2008, respectively. Excluding this share-based compensation expense, we spent \$7.8 million less in the nine months ended September 30, 2009 compared to the same period in 2008 on development, primarily attributable to fewer clinical study costs for Acurox® Tablets.

Marketing expenses during the nine months ending September 30, 2009 and 2008 consisted of Aversion® Technology primary market data research studies. Our general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll. We incurred \$5.2 million and \$1.8 million share-based compensation expense attributable to general and administrative staff for the nine months ended September 30, 2009 and 2008, respectively.

### Other Income (Expense)

Other Income is principally derived from interest on cash investments and has declined due to lower interest rates. During the nine months ending September 30, 2009 and 2008, interest income was \$0.1 million and \$0.7 million, respectively.

### Net Income (Loss)

We record our tax provision using an assumed 40% effective tax rate. During the second quarter 2009 we increased our deferred tax asset valuation reserve by \$2.5 million and recorded a like amount as income tax expense because we were unable to reliably predict achieving future taxable income and to utilize such tax benefit. We sustained a loss before taxes for the nine months ended September 30, 2009 which could give rise to a tax benefit if these losses can be utilized to offset future earnings. However because we are unable to reliably predict achieving future taxable income we are precluded under generally accepted accounting principles from recognizing such tax benefit and recording a deferred tax asset on our balance sheet. Our net income for the nine month period ended September 30, 2008 includes a tax provision of \$3.4 million.

### Results of Operations for the Three Month Period Ended September 30, 2009 and 2008

(\$ in thousands):	September 30,		Change	
	2009	2008	Dollars	%
<b>Revenue</b>				
Program fee revenue	\$ 583	\$ 1,263	\$ (680)	(54) %
Milestone revenue	—	—	(5,000)	(100)
Collaboration revenue	225	2,617	(2,392)	(91)
<b>Total revenue</b>	<b>808</b>	<b>3,880</b>	<b>(3,072)</b>	<b>(79)</b>
<b>Operating expenses</b>				
Research and development expenses	1,494	3,693	(2,199)	(60)
Marketing, general and administrative expenses	3,284	3,373	(89)	(3)
<b>Total operating expenses</b>	<b>4,778</b>	<b>7,066</b>	<b>(2,288)</b>	<b>(32)</b>
<b>Operating (loss) income</b>	<b>(3,970)</b>	<b>(3,186)</b>	<b>784</b>	<b>25</b>
<b>Other income (expense)</b>				
Interest, net	20	171	(151)	(88)
Other	—	(17)	(17)	(100)
<b>Total other income</b>	<b>20</b>	<b>154</b>	<b>(134)</b>	<b>(87)</b>
(Loss) income before income tax	(3,950)	(3,032)	918	30
Income tax expense (benefit)	4	(6,180)	(6,184)	(100)
<b>Net (loss) income</b>	<b>\$ (3,954)</b>	<b>\$ 3,148</b>	<b>\$ (7,102)</b>	<b>(226) %</b>



### **Revenue**

King paid us a \$30.0 million upfront fee in connection with the closing of the King Agreement in December 2007. Revenue recognized in the three months ending September 30, 2009 and 2008 from amortization of this upfront fee was \$0.6 million and \$1.3 million, respectively. We assigned a portion of the program fee revenue to each of three product candidates identified under the King Agreement. Our development responsibilities for two of the three product candidates are complete. We expect to recognize the remainder of the program fee revenue for the third product candidate ratably over its remaining development period which we currently estimate to extend through July, 2010.

Collaboration revenue recognized in the three months ending September 30, 2009 and 2008 was \$0.2 million and \$2.6 million, respectively, for billed reimbursement of our Acurox® Tablet development and regulatory expenses incurred pursuant to the King Agreement. We invoice King in arrears on a calendar quarter basis for our reimbursable development and regulatory expenses under the King Agreement. We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying research and regulatory development expenses.

### **Operating Expenses**

Research and development expense during the three months ending September 30, 2009 and 2008 were for developing our product candidates and related technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. We incurred \$0.6 million and \$0.4 million of share-based compensation expense attributable to research and development staff for the three months ended September 30, 2009 and 2008, respectively. Excluding this share-based compensation expense, we spent \$2.3 million less in the three months ended September 30, 2009 than in the same period in 2008 on development, primarily attributable to fewer clinical study costs for Acurox® Tablets.

Marketing expenses during the three months ending September 30, 2009 and 2008 consisted of Aversion® Technology primary market data research studies. Our general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll. We incurred \$2.1 million and \$1.1 million of general and administrative share-based compensation expense for the three months ended September 30, 2009 and 2008, respectively. Excluding this share-based compensation expense, we spent \$1.1 million less in the three months ended September 30, 2009 than in the same period in 2008 in all general, administrative and marketing expenses.

### **Other Income (Expense)**

Other Income is principally derived from interest on cash investments and has declined due to lower interest rates. During the three months ending September 30, 2009 and 2008 earnings from invested cash were \$0.02 million and \$0.2 million, respectively.

### **Net Income (Loss)**

We record our tax provision using an assumed 40% effective tax rate. We sustained a loss before taxes for the three months ended September 30, 2009 which could give rise to a tax benefit if these losses can be utilized to offset future earnings. However, because we are unable to reliably predict achieving future taxable income we are precluded under generally accepted accounting principles from recognizing such tax benefit in the three month statement of operations and recording a deferred tax asset on our balance sheet. Our net loss for the three month period ended September 30, 2008 includes a recorded tax benefit of \$6.2 million.

### **Liquidity and Capital Resources**

At September 30, 2009, the Company had unrestricted cash and cash equivalents of \$32.7 million compared to \$35.4 million in cash, cash equivalents and short-term investments at December 31, 2008. The Company had working capital of \$30.5 million at September 30, 2009 compared to \$36.0 million at December 31, 2008. Cash flow used in operating activities was \$2.5 million for the nine month period ended September 30, 2009 primarily representing the period's net loss and the recognition of deferred program fee revenue adjusted for certain non-cash items such as deferred income taxes and charges for stock compensation, and from the collection of the collaboration revenue receivable. Cash flow generated by operating activities of \$4.7 million for the nine months ending September 30, 2008 primarily represented the period's net income and changes in deferred program fee revenue, deferred income taxes, and charges for stock compensation. The cash flow from investing activities for both periods resulted from our short term investment purchases and maturities.

At October 26, 2009, we had cash and cash equivalents of approximately \$32.0 million and estimate that such cash reserves will be sufficient to fund development of Aversion® Technology product candidates and related operating expenses at least through the next 12 months.

### ***Critical Accounting Policies***

Note A of the Notes to Consolidated Financial Statements, in the Company's 2008 Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company does not believe there is a consequential likelihood that materially different amounts would be reported under different conditions or using different assumptions. The Company's critical accounting policies described in the 2008 Annual Report are also applicable to 2009.

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

*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 in Rules 13a-15(e) and 15d-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 in providing such 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 required to be set forth in the Company's periodic reports.

*Changes in Internal Controls over Financial Reporting.* There were no changes in our internal controls over financial reporting during the third fiscal quarter of 2009 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## **PART II - OTHER INFORMATION**

### ***Item 6. Exhibits***

The exhibits required to be filed as part of this Report 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.

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 26, 2009

ACURA PHARMACEUTICALS, INC.

/s/ Andrew D. Reddick

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Andrew D. Reddick  
*President & Chief Executive Officer*

/s/ Peter A. Clemens

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

1. I have reviewed this quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying 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 registrant's 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 26, 2009

/s/ Andrew D. Reddick

Andrew D. Reddick  
Chief Executive Officer

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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-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 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 registrant's 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 26, 2009

/s/ Peter A. Clemens

Peter A. Clemens

Chief Financial Officer

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CERTIFICATIONS OF THE CHIEF EXECUTIVE 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, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew D. Reddick, the Chief Executive Officer of the Company, 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 26, 2009

/s/ Andrew D. Reddick

Andrew D. Reddick  
*Chief Executive Officer*

/s/ Peter A. Clemens

Peter A. Clemens  
*Chief Financial Officer*

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