ACURA PHARMACEUTICALS, INC
Form 10-Q
May 01, 2009

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20649

Form 10-Q

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

For the quarterly period ended March 31, 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 þ No o

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 o	Accelerated filer þ
Non-accelerated filer o	Smaller reporting company o

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

As of April 29, 2009 the registrant had 42,742,532 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

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PART 1. FINANCIAL INFORMATION

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

UNAUDITED
(in thousands, except par values)

	March 31, 2009	December 31, 2008
Assets		
Current assets		
Cash and cash equivalents	$ 37,013	$ 30,398
Short term investments	-	5,039
Collaboration revenue receivable	117	3,529
Prepaid expense and other current assets	231	431
Deferred income taxes	3,323	2,491
Total current assets	40,684	41,888
Non-current assets		
Property, plant and equipment, net	1,069	1,073
Total assets	$ 41,753	$ 42,961
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ -	$ 382
Accrued expenses	1,052	883
Deferred program fee revenue	3,368	4,632
Total liabilities	4,420	5,897
Commitments and contingencies (Note 10)		
Stockholders' equity		
Common stock - $.01 par value; 650,000 shares authorized; 42,740 and 42,723 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	427	427
Additional paid-in capital	345,569	344,023
Accumulated deficit	(308,663)	(307,386)
Total stockholders' equity	37,333	37,064
Total liabilities and stockholders' equity	$ 41,753	$ 42,961

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)

	Three Months Ended March 31,	
	2009	2008
Revenue		
Program fee revenue	$ 1,263	$ 13,707
Collaboration revenue	117	3,377
Total revenue	1,380	17,084
Operating expenses		
Research and development expenses	1,129	4,082
Marketing, general and administrative expenses	2,448	870
Total operating expenses	3,577	4,952
Operating (loss) income	(2,197)	12,132
Other income – interest, net	69	297
(Loss) income before income tax	(2,128)	12,429
Income tax (benefit) expense	(851)	4,980
Net (loss) income	$ (1,277)	$ 7,449
(Loss) earnings per share		
Basic	$ (0.03)	$ 0.16
Diluted	$ (0.03)	$ 0.15
Weighted average shares used in computation		
Basic	45,708	45,657
Diluted	45,708	49,439

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

THREE MONTHS ENDED MARCH 30, 2009

UNAUDITED
(in thousands, except par values)

	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, 2008	42,723	$ 427	$ 344,023	$ (307,386)	$ 37,064
Net loss	-	-	-	(1,277)	(1,277)
Stock based compensation	-	-	1,546	-	1,546
Exercise of warrants	17	-	-	-	-
Balance at March 31, 2009	42,740	$ 427	$ 345,569	$ (308,663)	$ 37,333

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31,

UNAUDITED
(in thousands, except supplemental disclosures)

	2009	2008
Cash flows from operating activities		
Net (loss) income	$ (1,277)	$ 7,449
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities		
Depreciation and amortization	32	42
Deferred income taxes	(832)	4,980
Non-cash stock compensation expense	1,546	121
Impairment reserve against fixed assets	-	(51)
Changes in assets and liabilities		
Collaboration revenue receivable	3,413	(400)
Prepaid expenses and other current assets	198	232
Accounts payable	(382)	-
Accrued expenses	168	(24)
Deferred program fee revenue	(1,263)	(13,708)
Net cash provided by (used in) operating activities	1,603	(1,359)
Cash flows from investing activities		
Purchase of investments	-	(4,000)
Investment maturities	5,039	-
Capital expenditures	(27)	(7)
Net cash provided by (used in) investing activities	5,012	(4,007)
Increase (decrease) in cash and cash equivalents	6,615	(5,366)
Cash and cash equivalents at beginning of period	30,398	31,368
Cash and cash equivalents at end of period	$ 37,013	$ 26,002
Cash paid for income taxes	$ 74	$ -

SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES

Three Months Ended March 31, 2009

1. Warrants to purchase 38,000 shares of common stock were exercised at exercise price of $3.40 per share in a series of cashless exercise transactions resulting in the issuance of 17,000 shares of common stock.

Three Months Ended March 31, 2008

1. Fixed assets having a net book value of $51,000 were disposed under the impairment reserve.

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 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. Our portfolio of product candidates includes opioid analgesics intended to effectively relieve pain 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 consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accrual adjustments, considered necessary to present fairly the financial position as of March 31, 2009 and results of operations and cash flows for the three month periods ended March 31, 2009 and 2008 have been made. The results of operations for the three month period ended March 31, 2009 are not necessarily indicative of results that may be expected for the full year ending December 31, 2009. The unaudited 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. The 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.

NOTE 2 – NEW ACCOUNTING PRONOUNCEMENTS

Derivative Instruments and Hedging Activities

In March 2008, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 161 "Disclosures about Derivative Instruments and Hedging Activities" ("SFAS 161"). SFAS 161 is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. SFAS No. 161 also improves transparency about the location and amounts of derivative instruments in an entity's financial statements; how derivative instruments and related hedged items are accounted for under Statement 133; and how derivative instruments and related hedged items affect its financial position, financial performance, and cash flows. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. The Company's adoption of SFAS 161 at January 1, 2009 had no effect on the Company's consolidated financial statements as we had no derivative or

hedging activities.

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 and regulatory consulting, and regulatory counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. The Company makes payments to the CROs based on agreed upon terms and may include payments in advance of the study starting date. The Company reviews and accrues CRO expenses and clinical trial study expenses based on work performed and relies upon estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Advance payments are amortized to expense based on work performed. At March 31, 2009 we have less than $0.1 million of unfunded CRO obligations which is expected to be incurred during our second quarter 2009. We had unfunded CRO obligations of $1.0 million at December 31, 2008 which was incurred and charged to R&D expenses as the clinical studies progressed during the three month period ended March 31, 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, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). 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 from King received in December 2007, and license fees upon the exercise of options to license a 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. We recognized $1.3 million and $13.7 million of program fee revenue for the three months ended March 31, 2009 and 2008, respectively.

Collaboration revenue is derived from reimbursement of development expenses, which are invoiced quarterly in arrears, and are recognized when costs are incurred pursuant to the King Agreement. The ongoing research and development services being provided to King under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with King. We recognized $0.1 million and $3.4 million of collaboration revenue during the three months ended March 31, 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 are substantially at risk at the inception of the King Agreement, and the amounts of the payments assigned thereto are commensurate with the milestone 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 for the three months ended March 31, 2009.

NOTE 5 – INCOME TAXES

The Company accounts for income taxes under the liability method in accordance with Statement of Financial Accounting Standards No. 109 ("SFAS No. 109"), "Accounting for Income Taxes." Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and 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. SFAS 109 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 both March 31, 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 and accordingly a valuation allowance was provided. If in the future it is determined that additional 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 an additional benefit from income taxes in such period would be recognized.

NOTE 6 – ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	Mar 31, 2009	Dec 31, 2008
Payroll, bonus, taxes and benefits	$ 326	$ 77
Legal fees	43	35
Audit and tax professional services	59	89
Franchise taxes	232	144
Property taxes	40	39
State income taxes	-	94
Clinical, regulatory, trademarks, and patent services	107	217
Other fees and services	245	188
	$ 1,052	$ 883

NOTE 7 – SHARE-BASED COMPENSATION

The Company has share-based compensation plans including stock options and restricted stock units for its employees and directors. On January 1, 2006, the Company adopted Financial Accounting Standards Board ("FASB") release FASB Statement No. 123 (revised 2004), "Share-Based Payment, ("FASB 123R")". FASB 123R requires companies to estimate the fair value of stock-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 stock-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 as determined 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. Included in the three month periods ended March 31, 2009 and 2008 is $1.5 million and $0.1 million, respectively of share-based compensation expense.

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 Restricted Stock Unit ("RSU") represents the contingent obligation of the Company to deliver a share of its common stock to the holder of the RSU on a distribution date. RSUs for up to 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.

At March 31, 2009 and December 31, 2008, 3.02 million and 3.00 million RSU awards were outstanding, respectively and 2.98 million and 2.95 million were fully vested, respectively. During the three months ended March 31, 2009, an award of 24,000 RSUs was granted with 1,000 common shares vesting per month from March 2009 through February 2011. The Black-Scholes value of the award was $0.14 million which will be recognized as share-based compensation expense over the vesting period of the award under a straight-line amortization method. Included in the three month period ended March 31, 2009 is $0.1 million of share-based compensation expense from all RSU awards. There was no share-based compensation expense from RSU awards during the three months ended March 31, 2008. As of March 31, 2009, the Company had $0.3 million of unrecognized share-based compensation expense from RSU awards which will be recognized over the remaining period of twenty-two months. The assumptions used in the Black-Scholes model to determine fair value for the 2009 RSU grant was:

	2009
Dividend yield	0.00%
Risk-free interest rate	1.50%
Volatility	107%
Forfeitures	0.00%
Expected life of option	3.4 years
Grant date fair value	$ 5.69

The weighted average fair value of all RSU grants is $3.51 per share of common stock underlying each RSU. As of March 31, 2009 and December 31, 2008, the aggregate intrinsic value of the RSU awards outstanding and vested was $19.1 million and $21.8 million, respectively.

Stock Option Plans

The Company has stock options outstanding under three stock option plans. The Company’s 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 the Company's 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 3.1 million and 3.0 million shares with a weighted-average exercise price of $4.89 and $6.95 were outstanding at March 31, 2009 and December 31, 2008, respectively, of which 2.4 million and 2.2 million options were vested at March 31, 2009 and December 31, 2008, respectively. During the three month periods ended March 31, 2009 and 2008, options to purchase 0.2 million and 0.1 million shares of common stock having a weighted average exercise price of $6.49 and $6.50, respectively, were granted. During the three month periods ended March 31, 2009 and 2008, stock options to purchase 17,000 shares and 44,000 shares expired. No stock options were exercised during either period. Included in the three month periods ending March 31, 2009 and 2008 are $1.4 million and $0.1 million, respectively of share-based compensation expense from stock option awards. The assumptions used in the Black-Scholes model to determine fair value for the 2009 stock option grants were:

	2009
Dividend yield	0.0%
Average risk-free interest rate used	2.77%
Average volatility used	124%
Forfeitures	0.0%
Expected life of option	10 years
Weighted average grant date fair value	$ 6.28

As of March 31, 2009 the Company had $6.7 million of unrecognized share-based compensation expense, net of estimated forfeitures, related to stock option grants, which will be recognized over the remaining vesting period of twenty-two months. Total intrinsic value of stock options outstanding and exercisable at March 31, 2009 and December 31, 2008 was $8.8 million and $10.5 million, respectively.

NOTE 8 – COMMON STOCK WARRANTS

At March 31, 2009, the Company had outstanding common stock purchase warrants, exercisable for an aggregate of approximately 3.9 million shares of common stock, all of which contain cashless exercise features. During the three month period ended March 31, 2009, warrants to purchase 38,000 shares of common stock were exercised at $3.40 per share in a series of cashless exercise transactions resulting in the issuance of 17,000 shares of common stock. At March 31, 2009, outstanding stock purchase warrants to acquire 0.4 million, 0.1 million, and 3.4 million common shares will expire if unexercised during 2009, 2010 and years thereafter, 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 $3.17.

NOTE 9– EARNINGS (LOSS) PER SHARE

The computation of basic earnings (loss) per share of common stock is based upon the weighted average number of both common shares and vested RSUs outstanding during the period. A RSU represents the contingent obligation of the Company to deliver a share of its common stock to the holder of a vested RSU on a distribution date. The computation of diluted earnings (loss) per share is based on the same number of both common shares and vested RSUs used in the basic earning (loss) computation, but adjusted for the effect of other potentially dilutive securities. Excluded from the diluted earnings (loss) per share computation at March 31, 2009 are 7.1 million of potentially dilutive securities, as the effect of including them would be antidilutive. Accordingly, the loss per share is the same result for both basic and diluted computations.

(in thousands, except per share data)	Three Months Ended March 31, 2009	2008
Basic (loss) earnings per share		
Numerator:		
Net (loss) income allocable to common shareholder	$ (1,277)	$ 7,449
Denominator:		
Common shares (weighted)	42,736	42,707
Vested restricted stock units (weighted)	2,972	2,950
Weighted average shares used in computing basic (loss) earnings per share allocable to common shareholder	45,708	45,657
Basic (loss) earnings per share allocable to common shareholder	$ (0.03)	$ 0.16
Diluted (loss) earnings per share		
Denominator:		
Common shares (weighted)	42,736	42,707
Vested restricted stock units (weighted)	2,972	2,950
Stock options	-	1,448
Common stock warrants	-	2,334
Weighted average shares used in computing diluted (loss) earnings per share allocable to common shareholder	45,708	49,439
Diluted (loss) earnings per share allocable to common shareholder	$ (0.03)	$ 0.15
Excluded potentially dilutive securities:		

Common stock issuable (see #1 below):		
Stock options (vested and nonvested)	3,138	86
Nonvested restricted stock units	46	-
Common stock warrants	3,870	47
Total excluded dilutive common stock equivalents	7,054	133

(1) Number of shares issuable represents those securities which were either i) nonvested at quarter end or ii) were vested but antidilutive. The number of shares is based on maximum number of shares issuable on exercise or conversion of the related securities as of year 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 10 – COMMITMENTS AND CONTINGENCIES

Employment Agreement

On March 23, 2009 we entered into an agreement with Garth Boehm, Ph.D., to be employed as our Vice President of Modified Release Dosage Form Development. Dr. Boehm is expected to commence employment with us in May 2009.

Financial Advisor Agreement

In connection with the Company's August 2007 Unit Offering, the Company is obligated to pay a fee to the Company's financial advisor upon each exercise of the warrants issued in the Unit Offering, in proportion to the number of warrants exercised. The maximum amount of such fee assuming 100% exercise of such warrants is $0.3 million. The Company has not reflected this obligation as a liability in its unaudited financial statements as the payment is contingent upon the timing and exercise of the warrants by each of the warrant holders. Such fee, if any, will be paid and charged against earnings as and if the warrants are exercised. No warrants have been exercised under the August 2007 Unit Offering.

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. 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® Technology for certain opioid analgesic products in the United States, Canada and Mexico) and the ability other pharmaceutical companies, if any, to whom we may license our Aversion® Technology, to obtain necessary regulatory approvals and commercialize products utilizing Aversion® 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 completed to date and the results of other laboratory and clinical studies, 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 skilled 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 candidate

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 on Form 10-K 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 providing abuse deterrent features and benefits utilizing our proprietary Aversion® Technology. Our innovative Aversion® Technology platform has been successfully utilized in developing multiple opioid analgesic products candidates. Development of Acurox® (oxycodone HCl/niacin) Tablets, our lead product candidate, is supported by numerous laboratory studies and statistically significant and clinically meaningful Phase II and Phase III study results. Additional product candidates in development are supported by laboratory and bioequivalence studies. Our portfolio of product candidates includes opioid analgesics intended to effectively relieve pain 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.

Acurox®, our lead product candidate, 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) New Drug Application ("NDA") for Acurox® Tablets to the FDA including a request for Priority review. On March 3, 2009 we announced such NDA was accepted for filing by the FDA with a Priority review classification. The user fee goal date for the Acurox® Tablets NDA under the Prescription Drug User Fee Act (PDUFA) is June 30, 2009. The FDA's timelines described in the PDUFA guidance are flexible and subject to change based on workload and other potential review issues. In addition to Acurox®, we have numerous Aversion® Technology opioid analgesic product candidates in various stages of development containing the active analgesic ingredients found in widely prescribed and frequently abused products. All of our product candidates utilize Aversion® Technology and are covered by issued US patents, which in combination with our anticipated product labeling and drug product listing strategies are anticipated to provide our opioid products with protection from generic competition in the U.S. through the expiration of our patents in 2025.

King Agreement

We have entered into a license agreement (the "King Agreement") dated October 30, 2007 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®, Acuracet® (oxycodone HCI/niacin/APAP) Tablets, Vycavert™ (hydrocodone bitartrate/niacin/APAP) Tablets and a fourth undisclosed opioid analgesic product candidate utilizing our proprietary Aversion® Technology. King has an option to license in the King Territory all future opioid analgesic products developed utilizing Aversion® Technology. The King Agreement provides that we or King may develop additional opioid analgesic product candidates utilizing our Aversion® Technology and, if King exercises its option to license such additional product candidates, they will be subject to the milestone and royalty payments and other terms of the King Agreement.

We are responsible, using commercially reasonable efforts, for all Acurox® Tablet development activities through FDA approval of a 505(b)(2) NDA, the expenses for which are reimbursed by King. After NDA approval King will be responsible for manufacturing and commercializing Acurox® 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. Subject to the King Agreement, King will have final decision making authority with respect to all development and commercialization activities for all licensed products.

As of March 31, 2009, we had received aggregate payments of $55.4 million from King, consisting of a $30.0 million non-refundable upfront cash payment, $14.4 million in reimbursed research and development expenses relating to Acurox® Tablets, $6.0 million in fees relating to King's exercise of its option to license an undisclosed opioid analgesic tablet product and Vycavert™ Tablets, and a $5.0 million milestone fee for successful achievement of the primary endpoints for our pivotal Phase III clinical study for Acurox® 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® Tablets, across 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® 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 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 deterrence compositions than our 920 Patent. The USPTO previously issued to us a Notice of Allowance for a 21st claim in our 726 Patent application. Upon consideration of a potential interference proceeding between the 726 Patent application and a third party patent application, we filed with the USPTO a Request for Continued Examination of the 726 Patent application and cancelled from such application the claim similar to the claim included in the third party patent application.

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 addition to our three issued U.S. patents, we also have five U.S. non-provisional pending patent applications and multiple international patent applications filed 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 and related product candidates.

Company's Present Financial Condition

At April 29, 2009, we had cash, cash equivalents and short term investments of approximately $36.5 million. We estimate that our current cash reserves will be sufficient to fund operations and the 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 three months ended March 31, 2009, we recognized revenues of $1.3 million of the $30.0 million upfront cash payment received from King in December 2007 and recognized $0.1 million of revenues for reimbursement by King of our Acurox® Tablet development 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.

Results of Operations for the Three Month Period Ended March 31, 2009 and 2008

($ in thousands):	March 31, 2009	2008	Change Dollars	%
Revenue				
Program fee revenue	$ 1,263	$ 13,707	$ (12,444)	(91) %
Collaboration revenue	117	3,377	(3,260)	(97)
Total revenue	1,380	17,084	(15,704)	(92)
Operating expenses				
Research and development expenses	1,129	4,082	(2,953)	(72)
Marketing, general and administrative expenses	2,448	870	1,578	181
Total operating expenses	3,577	4,952	(1,375)	-
Operating (loss) income	(2,197)	12,132	(14,329)	(118)
Other income - interest, net	69	297	(228)	(77)
(Loss) income before income tax	(2,128)	12,429	(14,557)	(117)
Income tax (benefit) expense	(851)	4,980	5,831	(117)
Net (loss) income	$ (1,277)	$ 7,449	$ (8,726)	(117) %

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 month periods ended March 31, 2009 and 2008 from amortization of this upfront fee was $1.3 million and $13.7 million, respectively. We have assigned a portion of the program fee revenue to each of three product candidates identified under the King Agreement and expect to recognize the remainder of the program fee revenue ratably over our estimate of the development period for each of these product candidates identified in the King Agreement. We currently estimate the development period to extend through November, 2009.

Collaboration revenue recognized in the three month periods ended March 31, 2009 and 2008 was $0.1 million and $3.4 million for billed reimbursement of our Acurox® Tablet development expenses incurred pursuant to the King Agreement. We invoice King in arrears on a calendar quarter basis for our reimbursable development 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 development expenses.

Operating Expenses

Research and development expense during the three month periods ended March 31, 2009 and 2008 were for product candidates utilizing our Aversion® Technology, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2009 result are non-cash stock-based compensation charges of $0.3 million. There was a nominal amount of stock-based compensation charges in the 2008 result. Excluding the stock-based compensation expense, there is a $3.3 million decrease in development expenses primarily attributable to clinical study costs for Acurox® Tablets.

Marketing expenses during the three month periods ended March 31, 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. Included in the 2009 and 2008 results are non-cash stock-based compensation charges of $1.3 million and $0.1 million, respectively. Excluding the stock-based compensation expense, there is a $0.4 million increase in general, administrative and marketing expenses primarily in areas such as $0.1 million for patent legal services, $0.1 million for state franchise taxes and $0.2 million for incentive compensation accruals.

Other Income (Expense)

During the three month periods ended March 31, 2009 and 2008, the cash was invested in accordance with the investment policy approved by our Board of Directors resulting in interest income of $0.1 million and $0.3 million, respectively.

Net Income (Loss)

The Company records its tax provision using a 40% effective tax rate. The net loss for the three months ended March 31, 2009 includes a provision for an income tax benefit of $0.9 million. The Company's net income for the three month period ended March 31, 2008 includes a tax provision of $5.0 million.

Liquidity and Capital Resources

At March 31, 2009, the Company had unrestricted cash and cash equivalents of $37.0 million compared to $35.4 million in cash, cash equivalents and short-term investments at December 31, 2008. The Company had working capital of $36.3 million at March 31, 2009 compared to $36.0 million at December 31, 2008. The increase in our cash position of $1.6 million is primarily due to the collection of our collaboration revenue receivable during the three month period ending March 31, 2009. Cash flows generated in operating activities were $1.6 million for the three month period ended March 31, 2009 primarily representing the collection of the collaboration revenue receivable offset by the period's net loss adjusted for certain non cash items such as deferred program fee revenue, deferred income taxes, and charges for stock compensation. Cash flow used in operating activities for the three month period ended March 31, 2008 primarily represented our recognition of deferred program fee revenue offset by the period's net income and change in deferred income taxes. The cash flow from investing activities resulted from the maturity of our short term investments during the 2009 period and the purchase of short term investments for the 2008 period.

At April 29, 2009, the Company had cash, cash equivalents, and short-term investments of approximately $36.5 million. The Company estimates that such cash reserves will be sufficient to fund the development of Aversion® Technology product candidates and related operating expenses at least through the next 12 months.

The following table presents our expected cash payments on contractual obligations outstanding as of March 31, 2009:

	Payments due by period				
(in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	$ 31	$ 23	$ 8	—	—
Clinical studies	37	37	—	—	—
Employment agreements	855	735	120	—	—
Total	$ 923	$ 795	$ 128	—	—

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

(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 first fiscal quarter of 2009 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II

Item 1A. Risk Factors Relating To The Company

In addition to the Risk Factors set forth in Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2008, shareholders and prospective investors in the Company's common stock should carefully consider the following risk factors (which update the risk factors having similar caption descriptions in our 2008 Form 10-K).

If King is not successful in commercializing Acurox® Tablets and other licensed product candidates incorporating the Aversion® Technology our revenues and our business will suffer.

Pursuant to our License, Development and Commercialization Agreement for certain of our opioid analgesic product candidates, King is responsible for manufacturing, marketing, pricing, promoting, selling, and distributing such product candidates in the US., Canada and Mexico. 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 the products 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. In this event our revenues and/or royalties for these products could be adversely impacted.

King's manufacturing facility is currently the sole commercial source of supply for Acurox® and our other product candidates licensed to King. If King's manufacturing facility fails to obtain sufficient DEA quotas for the opioid active ingredients contained in such product candidates, fails to source adequate quantities of active and inactive ingredients, fails to comply with regulatory requirements, or otherwise experiences disruptions in commercial supply of our product candidates, product revenue and our royalties could be adversely impacted.

King has a diversified product line for which Acurox® and our other product candidates licensed to King will vie for King's promotional, marketing, and selling resources. If King fails to commit sufficient promotional, marketing and selling resources to our products, product revenue and our royalties could be adversely impacted.

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 King prices our product candidates inappropriately, fails to position our products properly, targets inappropriate physician specialties, or otherwise does not provide sufficient promotional support, product revenue and our royalties could be adversely impacted.

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, or a 505(b)(2) 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. The FDA commonly takes more than a year to grant final approval for an NDA, or 505(b)(2) NDA. The Prescription Drug User Fee Act ("PDUFA") sets time standards for 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 products utilizing our Aversion® Technology.

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. If we or our licensees fail to obtain regulatory approval for any of our product candidates, we will have fewer commercialized products and correspondingly lower revenues. Even if regulatory approval of our products 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. Such events would have a material adverse effect on our operations and financial condition.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the drug-approval process, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions to close manufacturing plants allegedly not operating in conformity with current Good Manufacturing Practices ("cGMP") and to stop shipments of allegedly violative products. In the event the FDA takes any such action relating to our products (if any are approved by FDA), such actions would have a material adverse effect on our operations and financial condition.

Item 6. Exhibits

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

10.1 Employment Agreement dated as of March 23, 2009 between Acura Pharmaceuticals, Inc. and Garth Boehm.

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.

April 29, 2009

ACURA PHARMACEUTICALS, INC.

/s/ Andrew D. Reddick
Andrew D. Reddick
President & Chief Executive Officer

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