

ACURA PHARMACEUTICALS, INC  
Form 10-Q  
April 21, 2010

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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 March 31, 2010

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

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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 April 20, 2010 the registrant had 43,728,626 shares of common stock, \$.01 par value, outstanding.

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ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETSUNAUDITED  
(in thousands, except par values)

	March 31, 2010	December 31, 2009
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 27,357	\$ 30,174
Collaboration revenue receivable	1,658	357
Prepaid insurance	120	193
Prepaid expenses and other current assets	42	33
<b>Total current assets</b>	<b>29,177</b>	<b>30,757</b>
Property, plant and equipment, net	1,139	1,160
<b>Total assets</b>	<b>\$ 30,316</b>	<b>\$ 31,917</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Deferred program fee revenue	\$ 1,166	\$ 1,555
Accrued expenses	844	452
<b>Total current liabilities</b>	<b>2,010</b>	<b>2,007</b>
Commitments and contingencies		
Stockholders' equity		
Common stock - \$.01 par value; 100,000 shares authorized; 43,728 shares issued and outstanding at March 31, 2010 and December 31, 2009	437	437
Additional paid-in capital	355,125	352,694
Accumulated deficit	(327,256)	(323,221)
<b>Total stockholders' equity</b>	<b>28,306</b>	<b>29,910</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 30,316</b>	<b>\$ 31,917</b>

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF OPERATIONS

## UNAUDITED

(in thousands, except per share data)

	Three Months Ended March 31,	
	2010	2009
<b>Revenues</b>		
Program fee revenue	\$ 389	\$ 1,263
Collaboration revenue	1,651	117
Total revenue	2,040	1,380
<b>Operating expenses</b>		
Research and development expense	3,047	1,129
Marketing, general and administrative expense	3,028	2,448
Total operating expenses	6,075	3,577
Loss from operations	(4,035)	(2,197)
Other income – interest, net	5	69
Loss before income tax	(4,030)	(2,128)
Income tax expense (benefit)	5	(851)
Net loss	\$ (4,035)	\$ (1,277)
<b>Loss per share - basic and diluted</b>	\$ (0.09)	\$ (0.03)
Weighted average shares - basic and diluted	46,855	45,708

See accompanying notes to the consolidated financial statements.

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

THREE MONTHS ENDED MARCH 30, 2010

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, 2009	43,728	\$ 437	\$ 352,694	\$ (323,221)	\$ 29,910
Net loss	-	-	-	(4,035)	(4,035)
Stock based compensation	-	-	2,431	-	2,431
Balance at March 31, 2010	43,728	\$ 437	\$ 355,125	\$ (327,256)	\$ 28,306

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)

	2010	2009
Cash flows from operating activities		
Net loss	\$ (4,035)	\$ (1,277)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	35	32
Deferred income taxes	-	(832)
Non-cash share-based compensation expense	2,431	1,546
Changes in assets and liabilities		
Collaboration revenue receivable	(1,301)	3,413
Prepaid expenses and other current assets	64	198
Accounts payable	-	(382)
Accrued expenses	392	168
Deferred program fee revenue	(389)	(1,263)
Net cash (used in) provided by operating activities	(2,803)	1,603
Cash flows from investing activities		
Investment maturities	-	5,039
Capital expenditures	(14)	(27)
Net cash (used in) provide by investing activities	(14)	5,012
(Decrease) increase in cash and cash equivalents	(2,817)	6,615
Cash and cash equivalents at beginning of period	30,174	30,398
Cash and cash equivalents at end of period	\$ 27,357	\$ 37,013
Cash paid for income taxes	\$ 1	\$ 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.

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2010 AND 2009

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 intended to introduce limits and impediments to abuse by utilizing our proprietary Aversion® Technology, Impede™ Technology and other novel technologies.

The accompanying unaudited consolidated financial statements of the Company were prepared in accordance with generally accepted accounting principles for interim financial information and instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments considered necessary to present fairly the Company’s financial position as of March 31, 2010 and results of operations and cash flows for the three months ended March 31, 2010 and 2009 have been made. The results of operations for the three months ended March 31, 2010 are not necessarily indicative of results expected for the full year ending December 31, 2010. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto for the year ended December 31, 2009 included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission. The year-end consolidated balance sheet presented was derived from the audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles. Amounts presented are rounded to the nearest thousand, where indicated, except per share data and par values.

NOTE 2 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. We make payments to the CRO’s based on agreed upon terms and may include payments in advance of the study starting date. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely on 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 studies 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. The Company has entered into several CRO clinical trial agreements pursuant to which these unfunded CRO commitments were \$0.8 million at March 31, 2010 and are expected to be incurred as subjects are enrolled into the clinical studies.

NOTE 3 REVENUE RECOGNITION AND DEFERRED PROGRAM FEE REVENUE

We recognize revenue when there is persuasive evidence that an agreement exists, performance specified in the agreement has occurred, the price is fixed and determinable, and collection is reasonably assured. In connection with



our License, Development, and Commercialization Agreement dated October 30, 2007 (the “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, such as the \$3.0 million option exercise fee paid by King to us in each of May and December 2008 upon the exercise of its option to license a third and fourth opioid analgesic product candidate under the King Agreement. We have assigned an equal portion of King's \$30.0 million 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 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 end in December 2010.

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 R&D services being provided to King under the King Agreement are priced at fair value based upon the reimbursement of expenses incurred pursuant to the King Agreement.

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 R&D efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones were substantially at risk at the inception of the 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.

#### NOTE 4 INCOME TAXES

The Company accounts for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities and are accounted for using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At March 31, 2010 and December 31, 2009 all our remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

#### NOTE 5 ACCRUED EXPENSES

Accrued expenses are summarized as follows:

(in thousands)	Mar 31, 2010	Dec 31, 2009
Payroll, payroll taxes, bonus and benefits	\$ 261	\$ 89
Professional services	128	160
State franchise taxes	25	21
Property taxes	22	19
Clinical and regulatory services	279	75
Marketing studies	32	-

Other fees and services	97	88
	\$ 844	\$ 452

## NOTE 6 SHARE-BASED COMPENSATION

The Company has share-based compensation plans including stock options and restricted stock units (“RSUs”) for its employees and directors. The Company accounts for compensation cost related to share-based payments based on fair value of the stock options and RSUs when awarded to an employee or director. The value of the portion of the award that is ultimately expected to vest is recognized as expense in the relevant accounting periods in the Company’s consolidated financial statement. The Company uses the straight line method for determining the value of share-based compensation. The Company determines the estimated fair value of share-based option awards using the Black-Scholes option pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of the Company’s common stock (as determined by reviewing its historical public market closing prices), risk-free interest rate and expected dividends. 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. 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 using historical exercise activity. Forfeitures are accounted for as they occur. Because the Company’s employee stock options have characteristics significantly different from those of trade options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management’s opinion, the existing model only provides one measure of fair value for its employee stock options.

The Company’s accounting for share-based compensation for RSUs is also based on the fair-value method. The fair value of the RSUs is based on the closing market price of the Company’s common stock on the date of award, less its exercise cost.

### Restricted Stock Unit Award Plan

The Company has RSUs issued and outstanding under a Restricted Stock Unit Award Plan (“2005 RSU Plan”) for its employees and directors. A RSU represents the contingent obligation of the Company to deliver a share of its common stock to the holders of a vested RSU on a specified distribution date. For 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 in our consolidated financial statements.

At March 31, 2010 and December 31, 2009, 3.32 million RSUs were outstanding of which 3.15 million and 3.11 million were fully vested, respectively. During the three months ended March 31, 2009, 24,000 RSUs were awarded having a fair value of \$0.14 million. Share-based compensation from RSU awards in the amount of \$0.1 million is included in R&D expense in the three months ended March 31, 2010 and less than \$12,000 of stock compensation cost is included in R&D expense for the three months ended March 31, 2009. Share-based compensation from RSU awards in the amount of \$0.2 million and \$0.1 million is included in general and administrative (“G&A”) expense in the three months ended March 31, 2010 and 2009, respectively. As of March 31, 2010, the Company had \$1.0 million of unrecognized share-based compensation expense from RSU awards which will be recognized in our consolidated financial statements over their remaining vesting periods.

Distribution of RSU shares to employees may require the Company to make statutory tax withholding payments for such employee on any gain on such shares at the time of distribution. The employee is responsible for providing

sufficient funds to the Company to make such tax payments. However, under the 2005 RSU Plan, the employee may elect to take a partial distribution of shares and have the Company retain the balance of the share distribution. In such an event, the Company becomes obligated to directly pay the withholding taxes of such employee and will retain a sufficient number of shares such that the fair market value of the retained shares will cover the tax withholding. The Company has not reflected this obligation as a liability in its consolidated financial statements as the tax payment is contingent upon both the timing and the distribution of the RSU shares to the employee and the closing market price of our common stock at the time of distribution. Such taxes will be paid and charged against additional paid in capital as the RSU shares are distributed

## Stock Option Award Plans

At March 31, 2010, the Company has stock options issued and outstanding under three stock option plans. The Company's 1995 and 1998 Stock Option Plans have expired but stock options awarded under such plans remain outstanding under the terms of those plans. The Company's 2008 Stock Option plan remains in effect. Under the 1998 and 2008 stock option plans, only one-fourth of vested non-incentive stock options ("NonISO") may be exercised during each of calendar years 2011, 2012, 2013 and 2014.

At March 31, 2010, stock options to purchase 3.7 million common shares were outstanding of which 3.0 million and 2.7 million options were vested at March 31, 2010 and December 31, 2009, respectively. During the three months ended March 31, 2010 and 2009, options to purchase 0.1 million shares and 0.2 million shares of common stock were awarded and options to purchase 27,000 shares and 17,000 shares expired, respectively. No stock options were exercised during either period. Share-based compensation from option awards in the amount of \$0.5 million and \$0.3 million is included in R&D expense in each of the three months ended March 31, 2010 and March 31, 2009, respectively. Share-based compensation from option awards in the amount of \$1.7 million and \$1.2 million is included in G&A expense in the three month ended March 31, 2010 and March 31, 2009, respectively. Assumptions used in the Black-Scholes model to determine fair value for the 2010 and 2009 stock option awards were:

	2010	2009
Dividend yield	0.0%	0.0%
Average risk-free interest rate	3.85%	2.77%
Average volatility	122%	124%
Expected forfeitures	0.0%	0.0%
Expected holding period	10 years	10 years
Weighted average grant date fair value	\$ 5.23	\$ 6.28

As of March 31, 2010 the Company had \$4.6 million of unrecognized stock option compensation expense, net of estimated forfeitures, which will be recognized in our consolidated financial statements over their remaining vesting periods. Under the stock option plans, if a change in control occurs, an acceleration of unvested shares will occur and any unrecognized share-based compensation expense will be recognized in our consolidated financial statements.

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

## NOTE 7 COMMON STOCK WARRANTS

At March 31, 2010, the Company has common stock warrants outstanding exercisable for 2.4 million shares of common stock. Common stock warrants having cashless exercise features and exercisable for 0.1 million shares at an exercise price of \$1.29 per share will expire in May 2010 if not exercised. Common stock warrants having cashless exercise features and exercisable for 2.3 million shares at an exercise price of \$3.40 per share will expire in August 2014 if not exercised.

NOTE 8 EARNINGS (LOSS) PER SHARE

Computation of basic earnings (loss) per share of common stock is based on the sum of the weighted average number of outstanding common shares and vested RSUs during the period. Computation of diluted earnings (loss) per share is based on the sum of the common shares and vested RSUs used in the basic earnings (loss) computation, adjusted for the effect of other potentially dilutive securities. Excluded from the diluted earnings (loss) per share computation at March 31, 2010 and 2009 are 6.3 million and 7.1 million of potentially dilutive securities, as the effect of including these securities would be antidilutive. Accordingly for the three months ending March 31, 2010 and 2009 the loss per share is the same for both basic and diluted computations.

(in thousands, except per share data)	Three months ended	
	2010	March 31, 2009
<b>Basic and diluted loss per share</b>		
Numerator:		
Net loss	\$ (4,035)	\$ (1,277)
Denominator:		
Common shares (weighted)	43,729	42,736
Vested restricted stock units (weighted)	3,126	2,972
Weighted average number of shares		
outstanding	46,855	45,708
Basic and diluted loss per common share	\$ (0.09)	\$ (0.03)
Excluded potentially dilutive securities:		
Common stock issuable (1):		
Stock options	3,734	3,138
Common stock warrants	2,380	3,870
Nonvested restricted stock units	165	46
<b>Total excluded dilutive shares</b>	<b>6,279</b>	<b>7,054</b>

(1) 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.

## 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 of other pharmaceutical companies, if any, to whom we may license our Aversion® Technology or Impede™ Technology, to obtain necessary regulatory approvals and commercialize products utilizing such technologies, 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 laboratory and clinical studies we may complete in the future, to support FDA approval of our product candidates, the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, 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, whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications or for abuse deterrent features, whether our product candidates will ultimately deter abuse in commercial settings, and the uncertainties inherent in scientific research, drug development, laboratory and 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 conducting 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 2009 Annual Report on Form 10-K filed with the Securities and Exchange Commission. When used on this website, 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 introduce limits or impediments to abuse utilizing our proprietary Aversion® and Impede™ Technologies. Our Aversion® Technology opioid analgesic product candidates are intended to effectively relieve pain while simultaneously discouraging common methods of opioid product misuse and abuse, including the:

- 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® Tablets, 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 and on June 30, 2009 we received from the FDA a Complete Response Letter ("CRL"). The CRL raised issues regarding the potential abuse deterrent benefits of Acurox® Tablets. On September 2, 2009 we and King met with the FDA and agreed that the data and studies supporting the Acurox® Tablets NDA would be presented to an FDA Advisory Committee. The FDA scheduled an April 22, 2010 joint Advisory Committee meeting to discuss the NDA for Acurox® Tablets and the results of studies evaluating the addition of niacin for the purpose of reducing the misuse of oxycodone. The scheduled meeting will be a joint meeting of the Anesthetic and Life Support Drugs and the Drug Safety and Risk Management Advisory Committees.

Although the FDA stated at the September 2nd meeting that no new clinical trials were required, Acura and King conducted Study AP-ADF-114 ("Study 114") to provide additional evidence supporting the abuse deterrent potential of Acurox® Tablets. On March 8, 2010, Acura and King announced Study 114 top-line results demonstrated that two different potentially abused excess oral doses of Acurox® Tablets are significantly disliked compared to equivalent excess oral doses of oxycodone HCl tablets alone (without niacin). All five co-primary endpoints comparing the like/dislike of excess doses of Acurox® Tablets with the like/dislike of equivalent excess doses of oxycodone HCl tablets alone (without niacin) each achieved statistical significance ( $p < 0.0001$ ). Study 114 primary endpoint results are supplemented by multiple independently measured secondary endpoints, all of which achieved statistically significant results ( $p < 0.05$ ). The Study 114 design may be reviewed at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (from the [clinicaltrials.gov](http://www.clinicaltrials.gov) home page click on "Search for Clinical Trials" and then enter "Acurox" in the search box).

In addition to Acurox®, we (and/or our licensee, King) are developing other immediate release opioid product candidates utilizing our Aversion® Technology including Vycavert® (hydrocodone bitartrate/niacin/APAP), Acuracet® (oxycodone HCl/niacin/APAP) and additional undisclosed opioid product candidates. Four of these opioid product candidates are licensed to King under our License, Development and Commercialization Agreement dated

October 30, 2007. We have also initiated development of an extended release opioid product candidate which is not licensed to King.

All of our opioid product candidates utilizing Aversion® Technology and are encompassed by two issued U.S. 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 through the expiration of our patents in 2025.

We are also developing a benzodiazepine tablet product candidate utilizing Aversion® Technology. On March 15, 2010 we announced clinical evaluation is now allowed under an Investigational New Drug application (“IND”) filed with the FDA for this product candidate. The primary active ingredient in this product candidate is intended for the treatment of anxiety disorders. Benzodiazepine products are classified as Schedule IV controlled substances by the U.S. Drug Enforcement Administration (“DEA”). We have completed a 2-way pilot crossover pharmacokinetic study in 9 healthy adult subjects of a single oral dose of the Aversion® Technology benzodiazepine product candidate compared to the reference listed drug. While this product candidate did not achieve bioequivalence to the reference listed drug in this small pilot study, we believe such product candidate may demonstrate bioequivalence to the reference listed drug in a larger pivotal scale study.

In addition to our Aversion® Technology, as part of our continuing research efforts we are investigating and developing novel mechanisms to incorporate abuse deterrent characteristics into abused and misused pharmaceutical products. In this regard we are engaged in laboratory evaluation of a new product candidate developed with our novel Impede™ Technology. Impede™ Technology is primarily intended to inhibit the conversion of pseudoephedrine HCl (a legally available nasal decongestant) into methamphetamine (an illicit and frequently abused drug).

#### King 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® Tablets, Acuracet® Tablets, Vycavert® Tablets and a fourth undisclosed opioid analgesic product candidate utilizing our proprietary Aversion® Technology. King has an option to license in the King Territory certain future opioid analgesic products developed utilizing our Aversion® Technology.

We are responsible, using commercially reasonable efforts, for all Acurox® 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® 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 March 31, 2010 we have received aggregate payments of \$56.6 million from King, consisting of a \$30.0 million non-refundable upfront cash payment, \$15.6 million in reimbursed R&D expenses relating to Acurox® Tablets, \$6.0 million in fees relating to King’s exercise of its option to license each of 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, 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.

Under the terms of the King Agreement, King may terminate the Agreement in its entirety by providing notice to Acura or King may terminate the Agreement with respect to an individual product by providing 12 month advance notice to Acura.

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 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.

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 April 20, 2010, we had cash and cash equivalents of \$26.9 million. We estimate that our current cash reserves will be sufficient to fund operations and the development of Aversion® Technology and Impede™ Technology and related product candidates through at least the next 12 months.

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 Months Ended March 31, 2010 and 2009

(\$ in thousands):	March 31, 2010	2009	Dollars	Change %
<b>Revenues</b>				
Program fee revenue	\$ 389	\$ 1,263	\$ (874)	(69)%
Collaboration revenue	1,651	117	1,534	1311
Total revenue	2,040	1,380	660	48
<b>Operating expenses</b>				
Research and development expense	3,047	1,129	1,918	170
Marketing, general and administrative expense	3,028	2,448	580	24
Total operating expenses	6,075	3,577	2,498	70
Loss from operations	(4,035)	(2,197)	1,838	84
Other income – interest, net	5	69	(64)	(93)

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Loss before income tax	(4,030)	(2,128)	1,902	89
Income tax expense (benefit)	5	(851)	(856)	(101)
Net loss	\$ (4,035)	\$ (1,277)	\$ 2,758	216%

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#### Revenues

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 ended March 31, 2010 and 2009 from amortization of this upfront fee was \$0.4 million and \$1.3 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 will extend through December, 2010.

Collaboration revenue recognized in the three months ended March 31, 2010 and 2009 was \$1.7 million and \$0.1 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 R&D expenses.

#### Operating Expenses

R&D expense during the three months ended March 31, 2010 and 2009 were for product candidates utilizing our Aversion® and Impede™ Technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2010 and 2009 results are non-cash share-based compensation charges of \$0.6 million and \$0.3 million. Excluding the share-based compensation expense, there is a \$1.6 million increase in development expenses primarily attributable to conducting Study 114 for Acurox® Tablets, our ongoing development activities for the benzodiazepine tablet product candidate, the initiation of development of an extended release opioid product candidate and our continuing research efforts with a product candidate using our novel Impede™ Technology.

Marketing expenses during the three months ended March 31, 2010 and 2009 primarily consisted of various market data research studies on both of our Aversion® and Impede™ Technologies. Our G&A expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll. Included in the 2010 and 2009 results are non-cash share-based compensation charges of \$1.9 million and \$1.3 million, respectively. Excluding the share-based compensation expense, our marketing, general and administrative expenses remained relatively unchanged.

#### Other Income

During the three months ended March 31, 2010 and 2009, the cash was invested in accordance with the investment policy approved by our Board of Directors resulting in nominal interest income earned in 2010 and \$0.1 million in 2009.

#### Net Loss

The Company records its tax provision using a 40% effective tax rate. The net loss for the three months ended March 31, 2010 includes no federal income tax benefit provision due to uncertainty of its future utilization and a state tax provision. The Company's net loss for the three months ended March 31, 2009 includes an income tax benefit provision of \$0.9 million.

#### Liquidity and Capital Resources

At March 31, 2010, the Company had unrestricted cash and cash equivalents of \$27.4 million compared to \$30.2 million at December 31, 2009. The Company had working capital of \$27.2 million at March 31, 2010 compared to \$28.8 million at December 31, 2009. The decrease in our cash position of \$2.8 million is primarily due to our period's net loss adjusted for certain non-cash items such as deferred program fee revenue, and charges for stock compensation offset by the collection of our collaboration revenue receivable. Cash flows generated in operating activities were \$1.6 million for the three months 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.

At April 20, 2010, the Company had cash and cash equivalents of approximately \$26.9 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.

## Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company's 2009 Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company's critical accounting policies described in the 2009 Annual Report are also applicable to 2010.

## 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 2010 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, 2009, 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 2009 Form 10-K).

We may become involved in patent litigation or other intellectual property proceedings relating to our Aversion® or Impede™ Technologies or product candidates which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include:

- litigation or other proceedings we may initiate against third parties to enforce our patent rights or other intellectual property rights;
- litigation or other proceedings we may initiate against third parties seeking to invalidate the patents held by such third parties or to obtain a judgment that our products do not infringe such third parties' patents;
- litigation or other proceedings third parties may initiate against us to seek to invalidate our patents or to obtain a judgment that third party products do not infringe our patents;
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if our competitors file patent applications that claim technology also claimed by us, we may be forced to participate in interference or opposition proceedings to determine the priority of invention and whether we are entitled to patent rights on such invention; and

- if third parties initiate litigation claiming that our products infringe their patent or other intellectual property rights, we will need to defend against such proceedings.

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

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

We are aware of a competitor who has suggested to the USPTO that the USPTO should declare an interference between that competitor's pending patent application and one of our U.S. patents for the Aversion® Technology. We believe that there is no valid basis for declaring such an interference and that even if such an interference were declared, that we would prevail. There can be no assurance, however, that such an interference will not be declared or if declared, that we will ultimately succeed such that this competitor would not obtain patent claims which could encompass our lead product candidate and other product candidates in development.

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

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

#### 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

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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.

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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 21, 2010

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