

ACURA PHARMACEUTICALS, INC
Form 10-Q
April 28, 2011

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, 2011

or

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

For the transition period from _____ to _____

Commission File Number 1-10113

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

New York
(State or other Jurisdiction of
incorporation or organization)

11-0853640
(I.R.S. Employer Identification No.)

616 N. North Court, Suite 120
Palatine, Illinois
(Address of Principal Executive Offices)

60067
(Zip Code)

847 705 7709
(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 S-T (§232.405 of this

Edgar Filing: ACURA PHARMACEUTICALS, INC - Form 10-Q

charter) during the preceding 12 months (or to such shorter period that the registrant was required to submit and post such files).

Yes " No "

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

Large accelerated filer "

Accelerated filer "

Non-accelerated filer

Smaller reporting company "

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

As of April 27, 2011 the registrant had 44,832,617 shares of common stock, \$.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

INDEX

	Page No.	
PART 1. FINANCIAL INFORMATION		
Item 1.	Financial Statements (Unaudited)	
	Consolidated Balance Sheets March 31, 2011 and December 31, 2010	1
	Consolidated Statements of Operations Three months ended March 31, 2011 and March 31, 2010	2
	Consolidated Statement of Stockholders' Equity Three months ended March 31, 2011	3
	Consolidated Statements of Cash Flows Three months ended March 31, 2011 and March 31, 2010	4
	Notes to Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	11
Item 4.	Controls and Procedures	17
PART II. OTHER INFORMATION		
Item 1.	Legal Proceedings	17
Item 1A.	Risk Factors	17
Item 6.	Exhibits	18
Signatures		18

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

UNAUDITED

(in thousands, except par value)

	March 31, 2011	December 31, 2010
Assets		
Current assets		
Cash and cash equivalents	\$21,633	\$ 24,045
Collaboration revenue receivable	-	126
Prepaid expenses and other current assets	262	270
Total current assets	21,895	24,441
Property, plant and equipment, net	1,055	1,052
Total assets	\$22,950	\$ 25,493
Liabilities and Stockholders' Equity		
Current liabilities		
Accrued expenses	\$743	\$ 686
Deferred program fee revenue	233	466
Total current liabilities	976	1,152
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock - \$.01 par value; 100,000 shares authorized; 44,640 and 43,894 shares issued and outstanding at March 31, 2011 and December 31, 2010	446	439
Additional paid-in capital	360,313	359,830
Accumulated deficit	(338,785)	(335,928)
Total stockholders' equity	21,974	24,341
Total liabilities and stockholders' equity	\$22,950	\$ 25,493

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,	
	2011	2010
Revenues		
Program fee revenue	\$233	\$389
Collaboration revenue	-	1,651
Total revenues	233	2,040
Operating expenses		
Research and development	1,141	3,047
Marketing, general and administrative	1,926	3,028
Total operating expenses	3,067	6,075
Loss from operations	(2,834)	(4,035)
Other (expense) income, net	(20)	5
Loss before income tax	(2,854)	(4,030)
Income tax expense	3	5
Net loss	\$(2,857)	\$(4,035)
Loss per share - basic and diluted	\$(0.06)	\$(0.09)
Weighted average shares – basic and diluted	46,987	46,855

See accompanying notes to the consolidated financial statements.

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

THREE MONTHS ENDED MARCH 31, 2011

UNAUDITED
(in thousands, except par value)

	Common Stock \$0.01 Par Value - Shares	Common Stock \$0.01 Par Value - Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2010	43,894	\$439	\$359,830	\$ (335,928)	\$24,341
Net loss	-	-	-	(2,857)	(2,857)
Share-based compensation	-	-	1,299	-	1,299
Distribution of common stock pursuant to restricted stock unit award plan	540	5	(953)	-	(948)
Issuance of common stock pursuant to exercise of stock options	206	2	137	-	139
Balance at March 31, 2011	44,640	\$446	\$360,313	\$ (338,785)	\$21,974

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)

	2011	2010
Cash flows used in operating activities:		
Net loss	\$(2,857)	\$(4,035)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	34	35
Non-cash share-based compensation expense	1,299	2,431
Loss on disposal of property and equipment	2	-
Changes in operating assets and liabilities:		
Collaboration revenue receivable	126	(1,301)
Prepaid expenses and other current assets	5	64
Accrued expenses	60	392
Deferred program fee revenue	(233)	(389)
Net cash used in operating activities	(1,564)	(2,803)
Cash flows used in investing activities – purchase of property and equipment	(39)	(14)
Cash flows used in financing activities:		
Exercise of stock options	216	-
Distribution of restricted stock units	5	-
Statutory minimum payroll withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(1,030)	-
Net cash used in finance activities	(809)	-
Net decrease in cash and cash equivalents	(2,412)	(2,817)
Cash and cash equivalents at beginning of period	24,045	30,174
Cash and cash equivalents at end of period	\$21,633	\$27,357
Supplemental cash flow information		
Cash paid for:		
Interest	\$26	\$-
Income taxes	\$-	\$1

Supplemental Disclosure of Noncash Financing Activities:

Three Months Ended March 31, 2011

1. On the cashless exercise of a stock option to acquire 100 shares of common stock, we issued 40 shares and withheld 60 shares both for the exercise cost and for the election on \$77 of statutory minimum withholding taxes paid on behalf of the optionee.
2. On the distribution of 735 restricted stock units, we issued 446 shares of common stock and withheld 289 shares both for the common stock par values and for the elections on \$953 of statutory minimum withholding taxes paid on behalf of the recipients.

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2011 AND 2010

NOTE 1 BASIS OF PRESENTATION

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the “Company”, “We”, or “Our”) is a specialty pharmaceutical company engaged in research, development and manufacture of product candidates intended to provide abuse deterrent features and benefits utilizing our proprietary Aversion® and Impede™ Technologies.

The accompanying unaudited consolidated financial statements of the Company were prepared in accordance with generally accepted accounting principles for interim financial information and instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments considered necessary to present fairly the Company’s financial position, results of operations and cash flows have been made. The results of operations for the three months ended March 31, 2011 are not necessarily indicative of results expected for the full year ending December 31, 2011. 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, 2010 included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission. The 2010 year-end consolidated balance sheet presented in this Report was derived from the Company’s 2010 year-end audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles. Amounts presented in the financial statements and footnotes are rounded to the nearest thousands, 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”) services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. We make payments to the CRO’s based on agreed upon terms and may include payments in advance of a study starting date. We review and accrue CRO expenses and clinical trial study expenses based on services 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.

NOTE 3 REVENUE RECOGNITION AND DEFERRED PROGRAM FEE REVENUE

We recognize revenue when there is persuasive evidence that an agreement exists, performance specified in the agreement has occurred, the price is fixed and determinable, and collection is reasonably assured. In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 (the “Pfizer Agreement”) with King Pharmaceuticals Research and Development, Inc. (“King”), a subsidiary of Pfizer, Inc. (“Pfizer”), we recognize program fee revenue, 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 Pfizer Agreement. We have assigned an equal portion of the \$30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. The recognition of the program fee revenue for two of the three product candidates was completed by June 2008. At March 31, 2011 there was \$0.2 million unrecognized program fee revenue assigned to the last remaining product candidate and we currently estimate the development period on this product candidate to extend through June 2011.

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

Milestone revenue is contingent upon the achievement of certain pre-defined events in the Pfizer Agreement. Milestone payments received under the Pfizer Agreement are recognized as revenue upon achievement of the “at risk” milestone events. Milestone payments are triggered either by the results of our R&D efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones were substantially at risk at the inception of the Pfizer Agreement and the amounts of the revenue correspond to the milestone payments set forth in the Pfizer Agreement. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone. Milestone revenue is non-refundable and non-creditable upon payment.

NOTE 4 INCOME TAXES

The Company accounts for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities and are accounted for using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At both March 31, 2011 and December 31, 2010 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:

	Mar 31,	Dec 31,
	2011	2010
Payroll, payroll taxes, bonus and benefits	\$ 204	\$ 95
Professional services	213	193
Franchise taxes	23	12
Property taxes	20	19
Clinical and regulatory services	196	307
Other fees and services	87	60
Total	\$ 743	\$ 686

NOTE 6 SHARE-BASED COMPENSATION

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

Our non-cash share-based compensation expense comprises the following:

Three Months Ended March 31,	2011	2010
Research and development		
Stock options	\$ 245	\$ 498
RSUs	58	70
	303	568
General and administrative		
Stock options	825	1,692
RSUs	171	171
	996	1,863
Total	\$ 1,299	\$ 2,431

Stock Option Award Plans

At March 31, 2011, 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 option (“NonISO”) may be exercised during each of calendar years 2011, 2012, 2013 and 2014.

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

employees and the closing market price of our common stock at the time of exercise. Such withholding tax will be paid and charged against additional paid in capital as the NonISOs are exercised. During the three months ended March 31, 2011, 0.02 million NonISOs shares were withheld by the Company upon employee's election to satisfy \$0.08 million of withholding tax payments relating to a stock option exercise during such period.

As of March 31, 2011 the Company had \$1.9 million of unrecognized share-based compensation expense from stock option grants, which will be recognized in our consolidated financial statements over their remaining vesting periods. Under the stock option plans, if a change in control occurs, an acceleration of unvested shares will occur and any remaining unrecognized share-based compensation expense will be recognized in our consolidated financial statements.

Our stock option award activity during the three months ended March 31, 2011 and 2010 is as follows:

	Three Months Ended March 31,			
	2011		2010	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, beginning	4,243	\$ 5.40	3,671	\$ 5.90
Granted	90	3.46	90	5.47
Exercised	(266)	1.30	-	-
Forfeited or expired	(3)	11.40	(27)	18.75
Outstanding, ending	4,064	\$ 5.62	3,734	\$ 5.80
Options exercisable	3,544	\$ 6.02	2,978	\$ 5.60

Assumptions used in the Black-Scholes model to determine fair value for the stock option awards granted during the three months ended March 31, 2011 and 2010 were:

	2011		2010	
Dividend yield	0.0	%	0.0	%
Average risk-free interest rate	3.36	%	3.85	%
Average volatility	115	%	122	%
Expected forfeitures	0.0	%	0.0	%
Expected holding period	10 years		10 years	
Weighted average grant date fair value	\$ 3.26		\$ 5.23	

Restricted Stock Unit Award Plan

The Company has RSUs issued and outstanding under a Restricted Stock Unit Award Plan ("2005 RSU Plan") for its employees and directors. A RSU represents the contingent obligation of the Company to deliver a share of its common stock to the holders of a vested RSU on a specified distribution date. 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 on January 1 of each of 2011, 2012, 2013 and 2014. Distribution of RSU shares to employees may require the Company to make minimum statutory withholding tax ("withholding tax") payments for such employee on any gain on such shares at the time of distribution. The employee is responsible for providing sufficient funds to the Company to make such withholding tax payments. However, under the 2005 RSU Plan, the employee may elect to take a partial distribution of shares and have the Company retain the balance of the share distribution in satisfaction of the withholding tax payments. In such event, the Company becomes obligated to directly pay the withholding taxes of such employee and will retain a sufficient number of shares such that the fair market value of the retained shares will offset the employee's withholding taxes. The Company has not reflected this obligation as a liability in its consolidated financial statements as the withholding tax payments are contingent upon the timing and number of RSU shares distributed to employees and the closing market price of our common stock at the time of distribution. Such withholding taxes will be paid and charged against additional paid-in capital as the RSU shares are distributed. On January 1, 2011, 0.54 million vested shares were distributed to our employees and 0.29 million shares were withheld by the Company upon our employees' election to exchange RSUs in satisfaction of \$1.0 million withholding tax obligations relating to RSU distributions on such date.

As of March 31, 2011, the Company had \$0.1 million of unrecognized share-based compensation expense from RSU activity which will be recognized in our consolidated financial statements over their remaining vesting periods unless

a change in control occurs. If a change in control occurs, 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.

A summary of the RSU Plan as of March 31, 2011 and 2010 and for the three months then ended consisted of the following:

	Three Months Ended March 31, 2011		2010	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	3,316	3,267	3,316	3,112
Granted	-	-	-	-
Exercised	(829)	(829)	-	-
Vested	-	39	-	39
Forfeited or expired	-	-	-	-
Outstanding, ending	2,487	2,477	3,316	3,151

NOTE 7 COMMON STOCK WARRANTS

At March 31, 2011, the Company had common stock warrants outstanding exercisable for 2.2 million shares of common stock at an exercise price of \$3.40 per share with an expiration date of August 2014.

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, 2011 and 2010 are 6.3 million of potentially dilutive securities, as the effect of including these securities would be antidilutive.

	Three Months Ended March 31, 2011	2010
Basic and diluted loss per share computation		
Numerator:		
Net loss	\$ (2,857)	\$ (4,035)
Denominator:		
Common shares (weighted)	44,524	43,729
Vested RSUs (weighted)	2,463	3,126
Weighted average number of shares outstanding	46,987	46,855
Basic and diluted loss per common share	\$ (0.06)	\$ (0.09)
Excluded potentially dilutive securities:		
Common shares issuable (1):		
Nonvested RSUs	11	46
Stock options (vested and nonvested)	4,064	3,734
Common stock warrants	2,193	2,380
Total	6,268	6,279

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

NOTE 9 COMMITMENTS AND CONTINGENCIES

Securities and Class Action Litigation

A lawsuit captioned *Bang v. Acura Pharmaceuticals, et al*, was filed on September 10, 2010 in the United States District Court for the Northern District of Illinois, Eastern Division (Case 1:10-cv-05757) against us and certain of our current and former officers seeking unspecified damages on behalf of a putative class of persons who purchased our common stock between February 21, 2006 and April 22, 2010. The complaint alleged that certain Company officers made false or misleading statements, or failed to disclose material facts in order to make statements not misleading, relating to our Acurox® with Niacin Tablet product candidate, resulting in violations of Section 10(b) of the Securities Exchange Act of 1934 (the “Exchange Act”), Rule 10b-5 under the Exchange Act and Section 20(a) of the Exchange Act. The complaint further alleges that such false or misleading statements or omissions had the effect of artificially inflating the price of our common stock. On March 14, 2011, an amended complaint was filed in this lawsuit. The amended complaint asserts the same claims as the initial complaint based upon the same alleged false or misleading statements, and has added three of our current directors as defendants. The Court has changed the caption of this case to *In re Acura Pharmaceuticals, Inc. Securities Litigation*. We believe that the allegations in the complaint are without merit and intend to vigorously defend the litigation

On October 25, 2010, Kiley Hill, a purported stockholder of the Company filed a shareholder derivative action in the Circuit Court of Cook County, Illinois, Chancery Division captioned *Hill v. Acura Pharmaceuticals et al.* (Case No. 2010-CH-46380), against our directors and certain of our executive officers, generally relating to the same events that are the subject of the class action litigation described above. The complaint purports to be brought on our behalf and names us as a nominal defendant. The complaint seeks unspecified damages from the individual defendants for breaches of fiduciary duty, abuse of control, gross mismanagement, contribution and indemnification, waste of corporate assets and unjust enrichment for actions occurring from at least February 21, 2006 through April 22, 2010. Substantively similar complaints captioned *Hagan v. Acura Pharmaceuticals et al.* (Case No. 2010-CH-46621) and *Newell v. Reddick et al* (Case No. 2010-CH-46873) were filed in the Circuit Court of Cook County, Illinois, Chancery Division, by other purported stockholders of the Company on October 27, 2010 and October 28, 2010, respectively. We have agreed to a temporary stay of these derivative actions

Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to the Company, has been named along with numerous other companies as a defendant in cases filed in three separate state coordinated litigations pending in Pennsylvania, New Jersey and California, respectively captioned *In re: Reglan® /Metoclopramide Mass Tort Litigation*, Philadelphia County Court of Common Pleas, January Term, 2010, No. 01997; *In re: Reglan® Litigation*, Superior Court of New Jersey, Law Division, Atlantic County, Case No. 289, Master Docket No. ATL-L-3865-10; and *Reglan®/Metoclopramide Cases*, Superior Court of California, San Francisco County, Judicial Council Coordination Proceeding No. 4631, Superior Court No.: CJC-10-004631. In this product liability litigation against numerous pharmaceutical product manufacturers and distributors, including the Company, plaintiffs claim injuries from their use of the Reglan® brand of metoclopramide and generic metoclopramide. In the Pennsylvania state court mass tort proceeding, more than 200 lawsuits have been filed against the Company and Halsey Drug Company alleging that Plaintiffs developed neurological disorders as a result of their use of the Reglan® brand and/or generic metoclopramide. Recently, Plaintiffs also brought over 30 individual lawsuits against the Company in the New Jersey litigation. Plaintiffs have

not yet served any individual lawsuits upon the Company in the California actions or in other jurisdictions. In the lawsuits filed to date, Plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by the Company. The Company discontinued manufacture and distribution of generic metoclopramide more than 15 years ago. The Company believes these claims are without merit and will vigorously defend these actions.

Statutory Minimum Withholding Tax Obligations

Under our stock option plans and our 2005 RSU plan, our employees may elect to have shares withheld upon exercise of options and upon the exchange of RSUs in satisfaction of the statutory minimum withholding tax obligations of such employees relating to such option exercises or RSU exchanges. On January 1, 2011, certain of our employees elected to have 0.29 million common shares withheld by the Company upon the exchange of their RSUs in satisfaction of their combined \$1.0 million withholding tax obligation. In addition, during the three months ended March 31, 2011, employees exercising stock options elected to have 0.22 million common shares withheld by the Company in satisfaction of their combined \$0.08 million withholding tax obligations.

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

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

Forward-Looking Statements

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. 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"), a wholly-owned subsidiary of Pfizer, (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 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, the ability for consumers to purchase our Impede™ products without a prescription, 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. When used in this Report, the words "estimate,"

"project," "anticipate," "expect," "intend," "believe," and similar expressions identify forward-looking statements.

Company Overview

We are a specialty pharmaceutical company engaged in research, development and manufacture of product candidates intended to provide abuse deterrent features and benefits utilizing our proprietary Aversion® 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:

- intravenous injection of dissolved tablets or capsules;
- nasal snorting of crushed tablets or capsules; and
- intentional swallowing of excess quantities of tablets or capsules (when product candidates are formulated with niacin).

In addition to our opioid product candidates utilizing Aversion® Technology, we are investigating and developing novel mechanisms to incorporate abuse deterrent features into additional abused and misused pharmaceutical products. In this regard we have developed Impede™ PSE, a pseudoephedrine hydrochloride (“PSE”) tablet product utilizing our Impede™ Technology. Impede™ Technology utilizes a proprietary mixture of functional inactive ingredients intended to limit or impede extraction of PSE from the tablet for use as a starting material in producing the illicit drug methamphetamine. We are also developing an undisclosed benzodiazepine product candidate utilizing Aversion® Technology intended for the treatment of anxiety disorders.

Pfizer Agreement

In 2007, we entered into a license agreement (the “Pfizer Agreement”) with King Pharmaceuticals Research and Development, Inc., a subsidiary of Pfizer, to develop and commercialize in the United States, Canada and Mexico (the “Pfizer Territory”) Acurox® Tablets, Acuracet® Tablets, Vycavert® Tablets and a fourth undisclosed opioid analgesic product candidate utilizing our proprietary Aversion® Technology. Pfizer has an option to license in the Pfizer Territory certain future opioid analgesic products developed utilizing our Aversion® Technology. In March 2011, Pfizer completed its acquisition and subsequent merger of King’s parent company into Pfizer.

We are responsible, using commercially reasonable efforts, for all Acurox® with Niacin Tablet development activities through FDA approval of a 505(b)(2) NDA, for which certain expenses are reimbursed to us by Pfizer. After NDA approval, for which no assurances can be given, Pfizer will be responsible for manufacturing and commercializing Acurox® with Niacin Tablets in the U.S. With respect to all other products licensed by Pfizer pursuant to the Pfizer Agreement in all Pfizer Territories, including Acurox® Tablets, Pfizer will be responsible, at its own expense, for development, regulatory, manufacturing and commercialization activities.

As of March 31, 2011 we have received aggregate payments of \$58.5 million from Pfizer, consisting of a \$30.0 million non-refundable upfront cash payment, \$17.5 million in reimbursed R&D expenses relating to both Acurox® with Niacin Tablets and Acurox® Tablets, \$6.0 million in fees relating to Pfizer’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® with Niacin Tablets. The Pfizer Agreement provides for Pfizer to pay us: (a) a \$3.0 million option exercise fee for each future opioid product candidate Pfizer licenses, (b) up to \$23 million in regulatory milestone payments for each Pfizer licensed product candidate, including Acurox® Tablets, in specific countries in the Pfizer 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 Pfizer Territories. In addition, for sales occurring following the one year anniversary of the first commercial sale of the first licensed product sold, Pfizer will pay us a royalty at one of six rates ranging from 5% to 25% based on the level of combined annual net sales for all products licensed by us to Pfizer in all Pfizer Territories, with the highest applicable royalty rate applied to such combined annual sales. No minimum

annual fees are payable by either party under the Pfizer Agreement.

Under the terms of the Pfizer Agreement, Pfizer may terminate the Agreement (i) in its entirety at any time by written notice to Acura and (ii) with respect to an individual product by providing 12 month advance notice to Acura.

The foregoing description of the Pfizer Agreement contains forward-looking statements about Acurox® Tablets, Acurox® with Niacin Tablets, and other product candidates pursuant to the Pfizer 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 Pfizer 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 Pfizer 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 Pfizer will materialize.

Acurox® Tablets

We and Pfizer are jointly developing opioid analgesic product candidates without niacin utilizing our patented Aversion® Technology. On December 17, 2010, Pfizer submitted a NDA for Acurox® (oxycodone HCl) Tablets to the FDA. On February 10, 2011, the FDA notified Pfizer of the FDA's acceptance for filing of the Acurox® Tablets NDA and the grant of a priority review classification. The Prescription Drug User Fee Act non-binding target date for completion of FDA's review is June 17, 2011.

In addition to filing acceptance and assignment of a priority review classification, the FDA's filing communication letter to Pfizer also includes preliminary comments about potential review issues relating to the intranasal abuse liability study included in the Acurox® Tablets NDA. The preliminary notice of potential review issues is not indicative of deficiencies that may be identified during the FDA's review of the NDA. No assurance can be given that any issues raised as part of the FDA's review of the Acurox® Tablets NDA (including the potential review issues in the FDA's filing communication letter) will be addressed to the FDA's satisfaction or that the Acurox® Tablets NDA will be approved by the FDA.

Acurox® with Niacin Tablets

We submitted a NDA for Acurox® with Niacin Tablets (oxycodone HCl/niacin) on December 30, 2008 and received a Complete Response Letter (CRL) from the FDA on June 30, 2009. An FDA Advisory Committee meeting was held on April 22, 2010 to discuss Acurox® with Niacin Tablets and the result of the studies evaluating the addition of niacin for the purpose of reducing misuse of oxycodone by excess oral consumption. The FDA Advisory Committee voted at such meeting that they did not have sufficient evidence to support the approval of the NDA for Acurox® with Niacin Tablets for the treatment of moderate to severe pain, considering the deterrent effects of niacin and the potential abuse deterrent features specific to Acurox® with Niacin Tablets. The FDA questioned: (a) the perceived increased incidence of flushing when Acurox® with Niacin Tablets are taken by pain patients at recommended doses, (b) a lack of evidence supporting the effectiveness of niacin to reduce peak drug liking (Emax) when taken at abused (high) doses in the fasted state, and (c) the potential to mitigate the effectiveness of niacin with food or NSAIDS.

To provide additional support for the abuse deterrent benefits of niacin in Acurox® with Niacin Tablets, we and Pfizer conducted an additional oral abuse liability study (AP-ADF-114 (Study 114)). Study 114 was not included in the original NDA filing for Acurox® with Niacin Tablets. We and Pfizer are continuing to evaluate the results of Study 114 and intend to submit a response to the FDA's June 2009 Complete Response Letter for Acurox® with Niacin Tablets.

All of our opioid product candidates utilizing Aversion® Technology (with or without niacin) 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 licensed to Pfizer with protection from generic competition through the expiration of our patents in 2025.

Expectations for Product Labeling

The FDA has publicly stated that abuse-deterrent label claims or indications require robust, long-term epidemiological data supporting a change in levels of abuse in the community over a reasonably long period of time. We believe the cost, time and practicality of designing and implementing clinical studies, as opposed to epidemiology studies, adequate to support explicit labeling claims of abuse deterrence are prohibitive. The FDA has stated that scientifically derived data and information describing the physical characteristics of a product candidate and/or the results of laboratory and clinical studies simulating product abuse may be acceptable to include in the product label. We intend to include in the labels of our Aversion® Technology product candidates (whether with or without niacin) both a physical description of the abuse deterrent characteristics and information from our laboratory and clinical studies designed to simulate the relative difficulty of abusing our product candidates. The extent to which such information will be included in the FDA approved product label will be subject of our discussions with an agreement by the FDA as part of the NDA review process for each of our product candidates. Further, because FDA closely regulates promotional materials, even if FDA initially approves labeling that includes a description of the abuse deterrent characteristics of the product, the FDA's Division Drug Marketing, Advertising, and Communication (i.e. DDMAC) will continue to review the acceptability of promotional labeling claims and product advertising campaigns for our marketed products.

Impede™ Technology Product Candidates in Development

We have developed Impede™ PSE, a pseudoephedrine hydrochloride ("PSE") tablet product candidate utilizing our Impede™ Technology. Impede™ Technology utilizes a proprietary mixture of functional inactive ingredients intended to limit or impede extraction of PSE from the tablets for use as a starting material in producing the illicit drug methamphetamine. The unique mixture of inactive ingredients in the Impede™ PSE product candidate are generally recognized as safe.

We are initially developing Impede™ PSE 30 mg Tablets and have demonstrated our product: (a) is bioequivalent to Sudafed® 30 mg Tablets and a 30 mg store brand (generic) and (b) in independent laboratory tests, effectively impedes the extraction of PSE for conversion into methamphetamine using the three most common extraction methods. Although tablet products containing 60 mg or less of PSE are considered by the FDA to be safe and effective for use by the general public without a prescription, the federal 2006 Combat Methamphetamine Epidemic Act requires PSE containing products to be kept behind the pharmacy counter and sold in limited quantities. Oregon, Mississippi and local jurisdictions in Missouri have enacted regulations requiring a doctor's prescription to obtain PSE containing products from the pharmacy and several other states, as well as the federal government, are considering or have considered similar regulations.

We believe our 30 mg PSE tablet product developed utilizing Impede™ Technology meets or will meet the FDA's requirements for "Over-the-Counter Human Drugs Which are Generally Recognized as Safe and Effective and Not Misbranded" as set forth in the Code of Federal Regulations at 21 CFR 330.1 which will allow us to commercialize our Impede™ PSE Tablets without submitting a NDA to the FDA.

We have commenced scale-up of our Impede™ PSE manufacturing process to quantities required for commercial distribution. It is our expectation to commercially manufacture Impede™ PSE Tablets at a third party supplier and to market, sell and distribute the product directly to national and regional drug store chains.

Aversion® Technology Non-Opioid Product Candidates in Development

We are developing a benzodiazepine tranquilizer product candidate utilizing our Aversion® Technology intended for the treatment of anxiety disorders. We have had a face-to-face meeting with the FDA's Division of Psychiatry

Products (DPP) regarding our proposed strategy for developing a benzodiazepine containing product candidate with abuse deterrent features and benefits. At that meeting, DPP recommended our benzodiazepine containing product candidate and proposed investigational new drug application strategy be reviewed by the Division of Anesthesia and Analgesia Products (DAAP). DPP's view was that although our proposed product contains a benzodiazepine indicated for a psychiatric condition, that it would be more appropriate for DAAP to review our proposed development strategy due to their broader experience with products intended to reduce abuse. We requested a meeting with DAAP. Following a discussion internal to the FDA, DAAP referred the meeting request back to the DPP. We and the DPP could not agree on a development strategy for our proposed product candidate. We are currently assessing alternate benzodiazepine product candidates and development strategies.

Our benzodiazepine product candidate is intended to be encompassed by numerous pending U.S. patent applications. There can be no assurances that such pending patent applications will result in issued patent claims encompassing our benzodiazepine product candidate.

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 the mixture of functional inactive ingredients and 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.

Neither of the 920 Patent, 402 Patent or 726 Patent requires niacin to be a constituent of a product for the product to be within the scope of the patent claims.

In addition to our issued U.S. patents, we have filed multiple U.S. patent applications and international patent applications relating to compositions containing abusable active pharmaceutical ingredients. Except for those rights conferred in the Pfizer 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 27, 2011, we had cash and cash equivalents of approximately \$20.7 million. We estimate that our current cash reserves will be sufficient to fund operations and the development of Aversion® and Impede™ Technologies and related product candidates through at least the next 12 months.

We have yet to generate any revenues or royalty revenues from product sales. We expect to rely on our current cash resources and additional payments that may be made under the Pfizer 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, incur litigation costs, hire additional personnel, or invest in other areas.

Results of Operations for the Three Months Ended March 31, 2011 and 2010

	March 31,		Increase (Decrease)	
	2011	2010	Dollars	%
Revenues				
Program fee revenue	\$ 233	\$ 389	\$ (156)	(40)%
Collaboration revenue	-	1,651	(1,651)	(100)
Total revenue	233	2,040	(1,807)	(89)

Edgar Filing: ACURA PHARMACEUTICALS, INC - Form 10-Q

Operating expenses				
Research and development	1,141	3,047	(1,906)	(63)
Marketing, general and administrative	1,926	3,028	(1,102)	(36)
Total operating expenses	3,067	6,075	(3,008)	(50)
Loss from operations	(2,834)	(4,035)	(1,201)	(30)
Other (expense) income, net	(20)	5	(25)	(500)
Loss before income tax	(2,854)	(4,030)	(1,176)	(29)
Income tax expense	3	5	(2)	(40)
Net loss	\$ (2,857)	\$ (4,035)	\$ (1,178)	(29)%

Revenue

Pfizer paid us a \$30.0 million upfront fee in connection with the closing of the Pfizer Agreement in December 2007. We have assigned an equal portion of Pfizer's \$30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. Program fee revenue recognized in the three months ended March 31, 2011 and 2010 from amortization of this upfront fee was \$0.2 million and \$0.4 million, respectively. At March 31, 2011 there was \$0.2 million unrecognized program fee revenue assigned to the last remaining product candidate and we currently estimate the development period on this product candidate to extend through June 2011.

Collaboration revenue recognized in the three months ended March 31, 2010 was \$1.7 million for invoiced reimbursement of our Acurox® Tablet and Acurox® with Niacin Tablet development expenses incurred pursuant to the Pfizer Agreement. We invoice Pfizer in arrears on a calendar quarter basis for our reimbursable development expenses under the Pfizer Agreement. We did not incur development expenses on the Acurox® products during the first quarter 2011 and we estimate such expenses in the future for which we will receive reimbursement from Pfizer to be minimal.

Operating Expense

R&D expense during the three months ended March 31, 2011 and 2010 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 2011 and 2010 results are non-cash share-based compensation expenses of \$0.3 million and \$0.6 million, respectively. Excluding the share-based compensation expense, there is a \$1.6 million decrease in development expenses primarily attributable to a reduction of our clinical study costs on the Acurox® products. Our ongoing development activities include our benzodiazepine tablet product candidate, an extended release opioid product candidate, and the commencement of scale-up for our Impede™ PSE manufacturing process to quantities required for commercial distribution.

Marketing expenses during the three months ended March 31, 2011 and 2010 primarily consisted of market research studies on 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 2011 and 2010 results are non-cash share-based compensation expenses of \$1.0 million and \$1.9 million, respectively. Excluding the share-based compensation expense, our marketing, general and administrative expenses decreased \$0.2 million.

Other Income

During the three months ended March 31, 2011 and 2010, our cash was invested in accordance with the investment policy approved by our Board of Directors resulting in minimal interest income earned in 2011 and 2010 due to the prevailing low interest rates.

Net Loss

The Company records its tax provision using a 40% effective tax rate. The net loss for the three months ended March 31, 2011 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization. A state tax provision was recorded for the Company's subsidiary operations apportioned to one state jurisdiction.

Liquidity and Capital Resources

At March 31, 2011, the Company had unrestricted cash and cash equivalents of \$21.6 million compared to \$24.0 million at December 31, 2010. The Company had working capital of \$20.9 million at March 31, 2011 compared to \$23.3 million at December 31, 2010. The decrease in our cash position is primarily due to the period's net loss and the payment of employee withholding taxes approximating \$1.0 million associated with the exercise of stock options and RSU distributions during such period, adjusted for certain non-cash items such as deferred program fee revenue and share-based compensation expenses offset by the collection of our collaboration revenue receivable.

At April 27, 2011, the Company had cash and cash equivalents of approximately \$20.7 million. We estimate that our current cash reserves will be sufficient to fund operations and the development of Aversion® and Impede™ Technologies and related product candidates through at least the next 12 months.

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company's 2010 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 2010 Annual Report are also applicable to 2011.

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 2011 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors 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, 2010, shareholders and prospective investors in the Company's common stock should carefully consider the following risk factor (which update the risk factor having a similar caption description in our 2010 Form 10-K).

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

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

- the relative advantages and disadvantages of our products compared to competitive products;
- the relative timing to commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
 - the product labeling approved by the FDA for our products;
 - the willingness of third party payers to reimburse for our prescription products;
 - the willingness of consumers and/or retailers to pay for our products;
 - the willingness of retailers to stock our products; and
- the willingness of consumers to obtain a physicians' prescription for our Impede™ product candidates, if required.

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

Item 6. Exhibits

The exhibits required by this Item are listed below.

31.1 Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.

31.2 Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.

32.1 Certification of Periodic Report by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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 28, 2011

ACURA PHARMACEUTICALS, INC.

/s/ Robert B. Jones
Robert B. Jones
Senior VP & Chief Operating Officer

/s/ Peter A. Clemens

Peter A. Clemens
Senior VP & Chief Financial Officer