

ACURA PHARMACEUTICALS, INC  
Form 10-Q  
May 01, 2012

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20649**

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**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, 2012**

**or**

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

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

**Commission File Number 1-10113**

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**Acura Pharmaceuticals, Inc.**

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

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New York 11-0853640  
(State or other Jurisdiction of (I.R.S. Employer Identification No.)  
incorporation or organization)

616 N. North Court, Suite 120  
Palatine, Illinois 60067  
(Address of Principal Executive Offices) (Zip Code)

**847 705 7709**

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

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

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

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

Yes  No

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

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

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

As of April 25, 2012 the registrant had 45,861,120 shares of common stock, \$.01 par value, outstanding.



**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY**

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**PART I. FINANCIAL INFORMATION***Item 1. Financial Statements***ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS****(in thousands, except par value)**

	March 31, 2012 (unaudited)	December 31, 2011 (audited)
Assets		
Current assets		
Cash and cash equivalents	\$33,206	\$ 35,685
Income taxes refundable	153	153
Prepaid insurance	126	218
Prepaid expenses and other current assets	71	73
Total current assets	33,556	36,129
Property, plant and equipment, net	1,083	1,044
Total assets	\$34,639	\$ 37,173
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$179	\$ 53
Accrued expenses	758	477
Total current liabilities	\$937	530
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock - \$.01 par value; 100,000 shares authorized; 45,861 and 45,320 shares issued and outstanding at March 31, 2012 and December 31, 2011	458	453
Additional paid-in capital	361,120	361,733
Accumulated deficit	(327,876)	(325,543 )
Total stockholders' equity	33,702	36,643
Total liabilities and stockholders' equity	\$34,639	\$ 37,173

See accompanying notes to the consolidated financial statements.



**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF OPERATIONS****UNAUDITED****(in thousands, except per share data)**

	Three Months Ended March 31,	
	2012	2011
Program fee revenue	\$0	\$233
Operating expenses		
Research and development	903	1,141
Marketing, general and administrative	1,441	1,926
Total operating expenses	2,344	3,067
Loss from operations	(2,344 )	(2,834 )
Other income (expense), net	11	(20 )
Loss before income tax	(2,333 )	(2,854 )
Income tax expense	0	3
Net loss	\$(2,333 )	\$(2,857 )
Loss per share - basic and diluted	\$(0.05 )	\$(0.06 )
Weighted average shares – basic and diluted	47,517	46,987

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

THREE MONTHS ENDED MARCH 31, 2012

## UNAUDITED

(in thousands, except par value)

	Common Stock \$0.01 Par Value - Shares	Common Stock \$0.01 Par Value - Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2011	45,320	\$ 453	\$ 361,733	\$ (325,543 )	\$ 36,643
Net loss	0	0	0	(2,333 )	(2,333 )
Share-based compensation	0	0	424	0	424
Net distribution of common stock pursuant to restricted stock unit award plan	827	8	(7 )	0	1
Common shares withheld for withholding taxes on distribution of restricted stock units	(296 )	(3 )	(1,031 )	0	(1,034 )
Net issuance of common stock pursuant to cashless exercise of stock options	6	0	0	0	0
Common shares withheld for withholding taxes on cashless exercise of stock options	(2 )	0	(7 )	0	(7 )
Issuance of common stock for exercise of stock options	6	0	8	0	8
Balance at March 31, 2012	45,861	\$ 458	\$ 361,120	\$ (327,876 )	\$ 33,702

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)**

	2012	2011
Cash flows used in operating activities:		
Net loss	\$(2,333 )	\$(2,857 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	32	34
Non-cash share-based compensation expense	424	1,299
Loss on disposal of property and equipment	0	2
Changes in operating assets and liabilities:		
Collaboration revenue receivable	0	126
Prepaid expenses and other current assets	94	5
Accounts payable	126	0
Accrued expenses	281	60
Deferred program fee revenue	0	(233 )
Net cash used in operating activities	(1,376 )	(1,564 )
Cash flows used in investing activities – purchase of property and equipment	(71 )	(39 )
Cash flows used in financing activities:		
Exercise of stock options	8	216
Distribution of restricted stock units	1	5
Statutory minimum payroll withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(1,041 )	(1,030 )
Net cash used in finance activities	(1,032 )	(809 )
Net decrease in cash and cash equivalents	(2,479 )	(2,412 )
Cash and cash equivalents at beginning of period	35,685	24,045
Cash and cash equivalents at end of period	\$33,206	\$21,633
Supplemental cash flow information		
Cash paid for:		
Interest	\$0	\$26
Income taxes	\$0	\$0

Supplemental Disclosure of Noncash Financing Activities (in thousands)

For The Three Months Ended March 31, 2012

829 shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan and after withholding 2 shares for \$7 in exercise costs and withholding 296 shares for \$1034 in statutory minimum payroll taxes, a net 531 shares of common stock were issued.

Options to purchase 10 shares of common stock were exercised utilizing various cashless exercise features of our plan and after withholding 4 shares for \$13 in exercise costs and withholding 2 shares for \$7 in statutory minimum payroll taxes, 4 shares of common stock were issued.

For The Three Months Ended March 31, 2011

829 shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan and after withholding 1 share for \$3 in exercise costs and withholding 288 shares for \$948 in statutory minimum payroll taxes, a net 540 shares of common stock were issued.

Options to purchase 100 shares of common stock were exercised utilizing various cashless exercise features of our plan and after withholding 38 shares for \$130 in exercise costs and withholding 22 shares for \$77 in statutory minimum payroll taxes, 40 shares of common stock were issued.

See accompanying notes to the consolidated financial statements.

**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**MARCH 31, 2012 AND 2011**

**NOTE 1 BASIS OF PRESENTATION**

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

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

**NOTE 2 RESEARCH AND DEVELOPMENT**

Research and Development (“R&D”) expenses include internal R&D activities, external Contract Research Organization (“CRO”) services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments, clinical trial studies or other contracted development services. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. We make payments to the CRO's based on agreed upon terms and may include payments in

advance of a study or service starting date. We review and accrue CRO activity expenses based on services performed and rely on estimates of those costs applicable to the stage of completion as provided by the CRO. Accrued CRO activity expenses are subject to revisions as such services progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. At March 31, 2012 and December 31, 2011 we had accrued \$0.2 million and \$28 thousand of CRO activity expenses, respectively.

### **NOTE 3 REVENUE RECOGNITION AND DEFERRED PROGRAM FEE REVENUE**

We recognize revenue when there is persuasive evidence that an agreement exists, performance specified in the agreement has occurred, the price is fixed and determinable, and collection is reasonably assured. In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 (the "Pfizer Agreement") with King Pharmaceuticals Research and Development, Inc. ("King"), a subsidiary of Pfizer, Inc. ("Pfizer"), we recognize program fee revenue, collaboration revenue and milestone revenue.

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

Collaboration revenue is derived from reimbursement of R&D expenses under the Pfizer Agreement. We did not incur reimbursable R&D expenses during the three months ended March 31, 2012 and we do not expect to incur any reimbursable R&D expenses from Pfizer in the future under the Pfizer Agreement.

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

#### **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, 2012 and December 31, 2011 all our remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

#### **NOTE 5 ACCRUED EXPENSES**

Accrued expenses are summarized as follows:

	Mar 31, 2012	Dec 31, 2011
	(in thousands)	
Payroll, payroll taxes, bonus and benefits	\$226	\$104
Professional services	196	191
Franchise taxes	93	60
Property taxes	24	21
Clinical and regulatory services	185	59
Other fees and services	34	42
Total	\$758	\$477

#### **NOTE 6 SHARE-BASED COMPENSATION**

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

	2012	2011
Three Months Ended March 31,	(in thousands)	
Research and development		
Stock options	\$91	\$245
RSUs	0	58
	91	303
General and administrative		
Stock options	333	825
RSUs	0	171
	333	996
Total	\$424	\$1,299

### *Stock Option Award Plans*

At March 31, 2012, the Company has stock options issued and outstanding under three stock option plans. The Company's 1995 and 1998 Stock Option Plans have expired but stock options awarded under such plans remain outstanding under the terms of those plans. The Company's 2008 Stock Option Plan remains in effect. Under the 1998 and 2008 stock option plans, only one-fourth of vested non-incentive stock option ("NonISO") having an exercise price less than fair market value at the date of grant 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, 2012, 16 thousand NonISOs were exercised by our employees. Our employees' elections to withhold 6 thousand shares in satisfaction of \$20 thousand for both exercise costs and withholding tax obligations resulted in the net issuance of 10 thousand shares. During the three months ended March 31, 2011, 0.27 million NonISOs were exercised by our employees. Our employees' elections to withhold 61 thousand

shares in satisfaction of \$0.2 million for both exercise costs and withholding tax obligations resulted in the net issuance of 0.2 million shares.

As of March 31, 2012 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, 2012 and 2011 is as follows:

	Three Months Ended March 31,			
	2012	2011	2012	2011
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, beginning	3,556	\$ 6.41	4,243	\$ 5.40
Granted	105	3.48	90	3.46
Exercised	(16 )	1.30	(266 )	1.30
Forfeited or expired	(204 )	9.33	(3 )	11.40
Outstanding, ending	3,441	\$ 6.17	4,064	\$ 5.62
Options exercisable	2,878	\$ 6.70	3,544	\$ 6.02

Assumptions used in the Black-Scholes model to determine fair value for the stock option awards granted during the three months ended March 31, 2012 and 2011 were:

	2012	2011		
Dividend yield	0.0	% 0.0	%	
Average risk-free interest rate	1.97	% 3.36	%	
Average volatility	114	% 115	%	
Expected forfeitures	0.0	% 0.0	%	
Expected holding period	10 years	10 years		
Weighted average grant date fair value	\$3.25	\$3.26		

### ***Restricted Stock Unit Award Plan***

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

financial statements as the withholding tax payments are contingent upon the timing and number of RSU shares distributed to employees and the closing market price of our common stock at the time of distribution. Such withholding taxes will be paid and charged against additional paid-in capital as the RSU shares are distributed.

On each of January 1, 2012 and 2011, 0.83 million RSUs were distributed to our employees and directors. Our employees' elections to withhold 0.3 million shares in satisfaction of \$1.0 million withholding tax obligations resulted in the net issuance of 0.53 million shares in January 2012. Our employees' elections to withhold 0.29 million shares in satisfaction of \$1.0 million withholding tax obligations resulted in the net issuance of 0.54 million shares in January 2011.

A summary of the RSU Plan as of March 31, 2012 and 2011 and for the three months then ended consisted of the following:

	Three Months Ended March 31,			
	2012		2011	
	(in thousands)			
	Number		Number	
	Number of Vested		Number of Vested	
	of RSUs	RSUs	of RSUs	RSUs
Outstanding, beginning	2,487	2,487	3,316	3,267
Granted	0	0	0	0
Distributed	(829 )	(829 )	(829 )	(829 )
Vested	0	0	0	39
Forfeited or expired	0	0	0	0
Outstanding, ending	1,658	1,658	2,487	2,477

#### NOTE 7 COMMON STOCK WARRANTS

The Company has outstanding common stock purchase warrants at March 31, 2012 exercisable for 1.9 million shares of common stock having an exercise price of \$3.40 per share and expiration date of August 2014. These warrants contain a cashless exercise feature.

#### NOTE 8 EARNINGS (LOSS) PER SHARE

Computation of basic earnings (loss) per share of common stock is based on the sum of the weighted average number of outstanding common shares and vested RSUs during the period. Computation of diluted earnings (loss) per share is based on the sum of the common shares and vested RSUs used in the basic earnings (loss) computation, adjusted for the effect of other potentially dilutive securities. Excluded from the diluted earnings (loss) per share computation at March 31, 2012 and 2011 are 5.3 million and 6.3 million, respectively, of potentially dilutive securities, as the effect of including these securities would be antidilutive.

	2012	2011
	(in thousands except per share data)	
Three Months Ended March 31,		
Basic and diluted loss per share computation		
Numerator:		
Net loss	\$ (2,333 )	\$ (2,857 )
Denominator:		

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Common shares (weighted)	45,859	44,524
Vested RSUs (weighted)	1,658	2,463
Weighted average number of shares outstanding	47,517	46,987
Basic and diluted loss per common share	\$ (0.05 )	\$ (0.06 )
Excluded potentially dilutive securities:		
Common shares issuable (1):		
Nonvested RSUs	0	11
Stock options (vested and nonvested)	3,441	4,064
Common stock warrants	1,856	2,193
Total	5,297	6,268

(1) The number of shares is based on maximum number of shares issuable on exercise or conversion of the related securities 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

### **Shareholder Derivative Action**

In October 2010 certain purported stockholders of the Company filed shareholder derivative actions in the Circuit Court of Cook County, Illinois, Chancery Division against our directors and certain of our executive officers, alleging 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<sup>®</sup> 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. On March 30, 2012, the Court granted our motion to dismiss these shareholder derivative actions.

### **Reglan<sup>®</sup>/Metoclopramide Litigation**

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

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

In Philadelphia, New Jersey and California, Generic Defendants, including Acura, have filed dispositive motions based on the *Mensing* decision. The New Jersey and California courts are expected to issue their rulings later this year. On November 18, 2011, the Philadelphia trial court denied Generic Defendants' dispositive motion. In December 2011, the Generic Defendants appealed this ruling, which the trial court refused to modify on reconsideration. Nonetheless, the trial court has approved certification of the federal preemption issues based on the *Mensing* decision for immediate appeal to the Pennsylvania Superior Court. A decision on this appeal should be issued later this year which could result in dismissal of all of the Philadelphia cases against Generic Defendants, although there can be no assurance in this regard. As any potential loss is neither probable or estimable, we have not accrued for any potential loss related to this matter as of March 31, 2012. Legal fees related to this matter are currently covered by our insurance carrier.

### **Statutory Minimum Withholding Tax Obligations**

Under the terms of our stock option plans and our 2005 RSU plan, our employees may elect to have shares withheld upon their option exercises and their RSU exchanges whereby requiring the Company to satisfy their statutory minimum withholding tax obligations from these transactions. During each of the three months ended March 31, 2012 and 2011, 0.3 million shares were withheld from these transactions in satisfaction of \$1.0 million of withholding tax obligations.

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

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

### ***Forward-Looking Statements***

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements.

Forward-looking statements may include, but are not limited to, our and our licensee's ability to successfully launch and commercialize our products and technologies including Oxecta® Tablets and Nexafed™ Tablets, the price discounting that may be offered by Pfizer for Oxecta®, the ability of us or our licensee's to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, expectations regarding potential market share for our products and the timing of first sales, our ability to enter into additional license agreements for our other product candidates, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability of our patents to protect our products from generic competition, and the ability to fulfill the U.S. Food and Drug Administration's, or FDA, requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development to meet over-the-counter, or OTC, Monograph standards as applicable, the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, whether the FDA will agree with our analysis of our clinical and laboratory studies and how it may evaluate the results of these studies or whether further studies of our product candidates will be required to support FDA approval, whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and will be able to promote the features of our abuse discouraging technologies, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede technology will disrupt the processing of pseudoephedrine into methamphetamine. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our 2011 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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

## **Company Overview**

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

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



In addition to Oxecta, we have licensed to Pfizer the rights to develop, manufacture and commercialize three other immediate-release opioid products utilizing our Aversion Technology in the United States, Canada and Mexico, including:

- hydrocodone bitartrate / acetaminophen tablets;
- oxycodone HCl / acetaminophen tablets; and
- an undisclosed opioid analgesic tablet product.

Pfizer is solely responsible for developing and commercializing these products using commercially reasonable efforts.

We believe our Aversion Technology can also be used to develop and commercialize unique formulations of non-opioid pharmaceutical products associated with abuse and intentional misuse. Our initial non-opioid product candidate is a stimulant product for the treatment of attention deficit disorder.

We are also developing Nexafed™, an over-the-counter, or OTC, immediate-release pseudoephedrine HCl tablet, utilizing our proprietary Impede™ Technology. Pseudoephedrine HCl, or PSE, is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products, including Johnson & Johnson's Sudafed® product. Our Impede Technology is a proprietary mixture of inactive ingredients designed to impede the extraction of pseudoephedrine from tablets for producing methamphetamine or disrupt the direct conversion of PSE in tablets into methamphetamine.

## **Oxecta®**

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

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

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

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

We expect Oxecta to compete primarily in the market for immediate-release opioid products or IR Opioid Products. IMS Health reports that, in 2011, IR oxycodone products held just 6% (14.8 million dispensed prescriptions) of the 244 million prescription market for IR Opioid Products. Comparatively, hydrocodone bitartrate/acetaminophen IR products accounted for 55% of the IR Opioid prescription market while oxycodone hydrochloride/acetaminophen accounted for 16%. These latter two combination drugs are under development by Pfizer using our Aversion technology.

IMS Health reports that the 14.8 million prescriptions for IR oxycodone products contained 1.6 billion tablets. Comparatively, IMS Health reports that 1.8 billion IR oxycodone tablets, or 13% more, were shipped from drug distribution centers to all healthcare providers during the 12 months ending November 2011. A majority of this difference can be attributed to distribution channels such as hospitals and federal facilities that consume product without a corresponding prescription. This difference increases to 25% for the 5 mg IR oxycodone products.

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

In October 2007, we entered into a License, Development and Commercialization Agreement, or the Pfizer Agreement, with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer, covering the United States, Canada and Mexico. Under the Pfizer Agreement, Pfizer will manufacture and commercialize Oxecta in the United States and develop and commercialize three additional opioid analgesic products utilizing our proprietary Aversion Technology, including hydrocodone / acetaminophen, oxycodone / acetaminophen and an undisclosed opioid analgesic tablet product. As of March 31, 2012, we had received an aggregate of \$78.5 million in payments from Pfizer in the form of a \$30.0 million upfront cash payment, milestone payments, option fees and reimbursement for research and development expenses, including a \$20.0 million milestone fee relating to the receipt of FDA approval of the New Drug Application, or NDA, for Oxecta. In addition, we are eligible to receive milestone payments based on future regulatory events and product sales achievements, reimbursement for certain research and development expenses and tiered royalties of 5%-25% on combined annual net sales of all products commercialized under the Pfizer Agreement. Royalty payments under the Pfizer Agreement commence one year after the first commercial sale of Oxecta.

**Aversion Hydrocodone Bitartrate / Acetaminophen Tablets**

Enrollment in a pharmacokinetic and bioequivalence study of Aversion hydrocodone bitartrate / acetaminophen tablets has been completed. This Pfizer study was an open label, single dose, randomized, two-period, two-way crossover study comparing the Aversion product to Norco® Tablets in 47 healthy adult subjects.

## Nexafed™

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

PSE is sold in products as the only active ingredient in both immediate and extended-release products. In addition, PSE is combined with other cold, sinus and allergy ingredients such as pain relievers, cough suppressants and antihistamines. PSE also competes against phenylephrine, an alternate nasal decongestant available in non-prescription products.

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

create Nexafed product awareness through television, radio, and print advertising.

Most PSE-containing products are classified by the FDA for OTC sale, or without a doctor's prescription, and many product formulations do not require the approval of an NDA or an Abbreviated New Drug Application, or ANDA, by the FDA for commercial distribution and marketing. 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. We believe 30 mg Nexafed 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 FDA's regulations applicable to OTC Monograph products. As such, we intend to commercialize Nexafed without submitting a NDA or ANDA to the FDA. We have contracted with a third party manufacturer for the scale up and commercial manufacture of Nexafed.

Recently, several states have considered or are considering legislation to move all PSE products to require a physician's prescription prior to selling by the pharmacy. These legislations have included an exemption for products that meet certain "extraction" or other methamphetamine reduction standards, which we do not believe our product meets. One such legislation in Missouri was ultimately deferred as a competitive product being considered for exemption did not clinically demonstrate efficacy and questions arose concerning the suitability of the extraction and methamphetamine conversion testing.

### **Company's Present Financial Condition**

At April 25, 2012, we had cash and cash equivalents of approximately \$32.5 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 product sales or royalty revenues from product sales. To fund our continued operations, we expect to rely on our current cash resources, additional payments that may be made under Pfizer Agreement and under future license agreements with other pharmaceutical company partners, of which there can be no assurance of obtaining, and revenues, if any, from our commercialization of our Nexafed Tablets. 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, scale up commercial supply of Nexafed, commercialize Nexafed, or invest in other areas.

**Results of Operations for the Three Months Ended March 31, 2012 and 2011**

	March 31,		Increase (Decrease)	
	2012	2011	Dollars	%
Program fee revenue	\$0	\$233	\$(233)	(100)%
Operating expenses				
Research and development	903	1,141	(238)	(21 )
Marketing, general and administrative	1,441	1,926	(485)	(25 )
Total operating expenses	2,344	3,067	(723)	(24 )
Loss from operations	(2,344)	(2,834)	(490)	(17 )
Other income (expense), net	11	(20 )	31	155
Loss before income tax	(2,333)	(2,854)	(521)	(18 )
Income tax expense	0	3	(3 )	(100)
Net loss	\$(2,333)	\$(2,857)	\$(524)	(18 )%

***Revenue***

Pfizer paid us a \$30.0 million upfront fee in connection with the closing of the Pfizer Agreement in December 2007. We assigned an equal portion of Pfizer's \$30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognized the upfront payment as program fee revenue ratably over the development period for each identified product candidate, all which was completed in June 2011. Program fee revenue recognized in the three months ended March 31, 2011 from amortization of this upfront fee was \$0.2 million.

***Operating Expense***

R&D expense during the three months ended March 31, 2012 and 2011 were for product candidates utilizing our Aversion® and Impede™ Technologies, including costs of preclinical, clinical trials, clinical supplies and related

formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2012 and 2011 results are non-cash share-based compensation expenses of \$0.1 million and \$0.3 million, respectively. Excluding the share-based compensation expense, our aggregate development expenses remained relatively unchanged between reporting periods.

Marketing expenses during the three months ended March 31, 2012 and 2011 primarily consisted of market research studies on our Aversion<sup>®</sup> and Impede<sup>™</sup> Technologies. Our G&A expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll. Included in the 2012 and 2011 results are non-cash share-based compensation expenses of \$0.3 million and \$1.0 million, respectively. Excluding the share-based compensation expense and the \$0.2 million in U.S. government research grants under the Qualifying Therapeutic Discovery Project Program received by us during 2011, our marketing, general and administrative expenses remained relatively unchanged between reporting periods.



***Other Income (Expense)***

During the three months ended March 31, 2012 and 2011, our cash was invested in accordance with the investment policy approved by our Board of Directors resulting in minimal interest income earned in 2012 and 2011 due to the prevailing low interest rates. We have no financial debt obligations.

***Net Loss***

The net loss for the three months ended March 31, 2012 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

***Liquidity and Capital Resources***

At March 31, 2012, the Company had unrestricted cash and cash equivalents of \$33.2 million compared to \$35.7 million at December 31, 2011. The Company had working capital of \$32.6 million at March 31, 2012 compared to \$35.6 million at December 31, 2011. The decrease in our cash position is primarily due to the period's net loss and the payment of employees' withholding taxes approximating \$1.0 million associated with their option exercises and RSU exchanges during such period, adjusted for the non-cash share-based compensation expenses.

At April 25, 2012, the Company had cash and cash equivalents of approximately \$32.5 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 2011 Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company's critical accounting policies described in the 2011 Annual Report are also applicable to 2012.

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

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

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

## PART II. OTHER INFORMATION

### *Item 1. Legal Proceedings*

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

### *Item 6. Exhibits*

The exhibits required by this Item are listed below.

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

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

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

101.INS

XBRL Instance Document

101.SCH

XBRL Taxonomy Extension Schema Document

101.CALXBRL Taxonomy Extension Calculation Linkbase

101.LAB

XBRL Taxonomy Extension Label Linkbase

101.PRE

XBRL Taxonomy Extension Presentation Linkbase

*Signatures*

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

April 26, 2012 ACURA PHARMACEUTICALS, INC.

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

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