ACURA PHARMACEUTICALS, INC
Form 10-Q
October 31, 2011

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20649

Form 10-Q

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

For the quarterly period ended September 30, 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	11-0853640
(State or other Jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
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 þ No o

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 þ No o

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

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

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

As of October 27, 2011 the registrant had 45,318,693 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC.
AND SUBSIDIARY

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC.
AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

UNAUDITED
(in thousands, except par value)

	September 30, 2011	December 31, 2010
Assets		
Current assets		
Cash and cash equivalents	$ 37,660	$ 24,045
Collaboration revenue receivable	-	126
Prepaid expenses and other current assets	426	270
Total current assets	38,086	24,441
Property, plant and equipment, net	1,002	1,052
Total assets	$ 39,088	$ 25,493
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 45	$ -
Accrued expenses	966	686
Income taxes payable	105	-
Deferred program fee revenue	-	466
Total current liabilities	1,116	1,152
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock - $.01 par value; 100,000 shares authorized; 45,316 and 43,894 shares issued and outstanding at September 30, 2011 and December 31, 2010	453	439
Additional paid-in capital	361,416	359,830
Accumulated deficit	(323,897)	(335,928)
Total stockholders' equity	37,972	24,341
Total liabilities and stockholders' equity	$ 39,088	$ 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)

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2011	2010	2011	2010
Revenues				
Program fee revenue	$466	$855	$-	$233
Milestone revenue	20,000	-	-	-
Collaboration revenue	-	2,097	-	59
Total revenues	20,466	2,952	-	292
Operating expenses				
Research and development	3,245	5,714	962	1,142
Marketing, general and administrative	4,840	7,025	1,185	1,716
Total operating expenses	8,085	12,739	2,147	2,858
Income (loss) from operations	12,381	(9,787)	(2,147)	(2,566)
Other (expense) income, net	(9)	17	6	15
Income (loss) before income tax	12,372	(9,770)	(2,141)	(2,551)
Income tax expense	341	10	-	2
Net income (loss)	$12,031	$(9,780)	$(2,141)	$(2,553)
Income (loss) per share				
Basic	$0.25	$(0.21)	$(0.05)	$(0.05)
Diluted	$0.25	$(0.21)	$(0.05)	$(0.05)
Weighted average shares				
Basic	47,392	46,992	47,802	47,100
Diluted	47,627	46,992	47,802	47,100

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

NINE MONTHS ENDED SEPTEMBER 30, 2011

UNAUDITED
(in thousands, except par value)

	Common Stock $0.01 Par Value		Additional Paid - in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2010	43,894	$439	$359,830	$ (335,928)	$24,341
Net income	-	-	-	12,031	12,031
Share-based compensation	-	-	2,133	-	2,133
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	546	6	(667)	-	(661)
Issuance of common stock pursuant to exercise of common stock warrants	336	3	1,073	-	1,076
Balance at September 30, 2011	45,316	$453	$361,416	$ (323,897)	$37,972

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC.
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30,

UNAUDITED
(in thousands)

	2011	2010
Cash flows provided by (used in) operating activities:		
Net income (loss)	$ 12,031	$ (9,780)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	99	101
Non-cash share-based compensation expense	2,133	5,547
Loss on disposal of property and equipment	5	14
Changes in operating assets and liabilities:		
Collaboration revenue receivable	126	302
Prepaid expenses and other current assets	(156)	(161)
Accounts payable	45	-
Accrued expenses	280	170
Income taxes payable	105	-
Deferred program fee revenue	(466)	(855)
Net cash provided by (used in) operating activities	14,202	(4,662)
Cash flows used in investing activities – purchase of property and equipment	(54)	(32)
Cash flows provided by (used in) financing activities:		
Exercise of stock options	217	-
Distribution of restricted stock units	5	-
Net proceeds from warrant exercise	1,076	392
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(1,830)	-
Net cash provided by (used in) finance activities	(532)	392
Net increase (decrease) in cash and cash equivalents	13,615	(4,302)
Cash and cash equivalents at beginning of period	24,045	30,174
Cash and cash equivalents at end of period	$ 37,660	$ 25,872
Supplemental cash flow information		
Cash paid for:		
Interest	$ 26	$ -
Income taxes	$ 218	$ 15

Supplemental Disclosure of Noncash Financing Activities (in thousands):
Nine Months Ended September 30, 2011

1. On the cashless exercises of stock options to acquire 923 shares of common stock, we issued 377 shares and withheld 547 shares both for the exercise costs and for $877 of statutory minimum withholding taxes paid on behalf of the stock option holders.
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 $953 of statutory minimum withholding taxes paid on behalf of the recipients.

Nine Months Ended September 30, 2010

1. Warrants to purchase 64 shares of common stock were exercised at exercise price of $1.29 per share in a series of cashless exercise transactions resulting in the issuance of 14 shares of common stock.

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC.
AND SUBSIDIARY

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 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 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 nine months ended September 30, 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 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 was derived from reimbursement of R&D expenses, which was invoiced quarterly in arrears, and was recognized when costs were incurred pursuant to the Pfizer Agreement. The R&D service that was provided to Pfizer under the Pfizer Agreement was priced at fair value based upon the reimbursement of expenses incurred pursuant to the Pfizer Agreement. We did not incur reimbursable R&D expenses during the nine months ended September 30, 2011 and we do not expect to incur any reimbursable R&D expenses for 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. On June 30, 2011, we received a $20.0 million milestone payment from Pfizer as a result of the FDA approval of Oxecta® (oxycodone HCI, USP) Tablets CII. The trademark Oxecta® is owned by Pfizer or its affiliates.

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 ("NOL") 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. During June 2011, we decreased our valuation allowance on our deferred income tax assets by $5.0 million. We recorded a benefit from income taxes of $5.0 million against our current nine month period income tax provision. At September 30, 2011 we continue to maintain a full valuation on our remaining deferred income tax assets due to uncertainties with respect to future utilization of them. 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:

	Sept 30, 2011	Dec 31, 2010
Compensation and benefits	$ 546	$ 95
Professional services	181	193
Franchise taxes	24	12
Property taxes	21	19
Clinical and regulatory services	85	307
Other fees and services	109	60
Total	$ 966	$ 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 assumptions including the expected volatility of the market price of the Company's common stock, risk-free interest rate and expected dividend yields. The Company uses historical public market closing price volatility and 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:

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2011	2010	2011	2010
Research and development				
Stock options	$ 398	$ 1,151	$ 43	$ 267
RSUs	75	209	-	70
	473	1,360	43	337
General and administrative				
Stock options	1,431	3,674	206	691
RSUs	228	513	-	171
	1,659	4,187	206	862
Total	$ 2,132	$ 5,547	$ 249	$ 1,199

Stock Option Award Plans

At September 30, 2011, the Company has stock options issued and outstanding under three stock option plans. The Company's 1995 Stock Option Plan and 1998 Stock Option Plan have each 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 each of the 1998 Stock Option Plan and the 2008 Stock Option Plan, only one-fourth of vested non-incentive stock options ("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 nine months ended September 30, 2011, 0.23 million NonISOs shares were withheld by the Company upon our employees' election to satisfy $0.9 million of withholding taxes relating to their stock option exercises during such time period.

As of September 30, 2011 the Company had $0.9 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 nine months ended September 30, 2011 and 2010 is as follows:

	Nine Months Ended September 30,			
	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	96	3.43	90	5.47
Exercised	(1,092)	1.33	-	-
Forfeited or expired	(69)	3.38	(49)	15.34
Outstanding, ending	3,178	$ 6.78	3,712	$ 5.77
Options exercisable	2,932	$ 7.17	3,369	$ 5.72

Assumptions used in the Black-Scholes model to determine fair value for the stock option awards granted during the nine months ended September 30, 2011 and 2010 were:

	2011	2010
Dividend yield	0.0 %	0.0 %
Average risk-free interest rate	3.17 %	3.85 %
Average volatility	114 %	122 %
Expected forfeitures	0.0 %	0.0 %
Expected holding period	10 years	10 years
Weighted average grant date fair value	$ 3.23	$ 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.

A summary of the RSU Plan as of September 30, 2011 and 2010 and for the nine months then ended consisted of the following:

	Nine Months Ended September 30,			
	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	-	-	-	-
Distributed	(829)	(829)	-	-
Vested	-	49	-	116
Forfeited or expired	-	-	-	-
Outstanding, ending	2,487	2,487	3,316	3,228

NOTE 7 COMMON STOCK WARRANTS

At September 30, 2011, the Company had common stock warrants outstanding exercisable for 1.9 million shares of common stock at an exercise price of $3.40 per share with an expiration date of August 2014. Warrants exercisable for 0.34 million shares of common stock were exercised during the nine months ended September 30, 2011.

NOTE 8 EARNINGS (LOSS) PER SHARE

The 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.

	Nine Months Ended September 30,		Three Months Ended September 30,	
(in thousands, except per share data)	2011	2010	2011	2010
Basic income (loss) per share computation				
Numerator:				
Net income (loss)	$12,031	$(9,780)	$(2,141)	$(2,553)
Denominator:				
Common shares (weighted)	44,914	43,825	45,315	43,895
Vested RSUs (weighted)	2,478	3,167	2,487	3,205
Weighted average number of shares outstanding	47,392	46,992	47,802	47,100
Basic income (loss) per common share	$0.25	$(0.21)	$(0.05)	$(0.05)
Diluted income per share computation				
Numerator:				
Net income (loss)	$12,031	$(9,780)	$(2,141)	$(2,553)
Denominator:				
Common shares (weighted)	44,914	43,825	45,315	43,895
Vested RSUs (weighted)	2,478	3,167	2,487	3,205
Stock options	142	-	-	-
Common stock warrants	93	-	-	-
Weighted average number of shares outstanding	47,627	46,992	47,802	47,100
Diluted income (loss) per common share	$0.25	$(0.21)	$(0.05)	$(0.05)
Excluded potentially dilutive securities:				
Common shares issuable (1):				
Nonvested RSUs	-	88	-	88
Common stock options (vested and nonvested)	2,507	3,713	3,179	3,713
Common stock warrants	-	2,193	1,856	2,193
Total excluded dilutive common stock equivalents	2,507	5,994	5,035	5,994

(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.

9

NOTE 9 COMMITMENTS AND CONTINGENCIES

Securities Class Action and Derivative 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 filed a motion to dismiss this case on May 13, 2011. 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 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®/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 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. Earlier this year, over 70 plaintiffs filed Reglan litigation in the Circuit Court of St. Clair County, Illinois entitled Agresta v. Walgreens et al., in which we, together with numerous generic and brand drug companies, are a named defendant. However, none of these Illinois state court complaints have been served on us.

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. In Philadelphia and New Jersey, Generic Defendants, including Acura, have filed dispositive motions based on the Mensing decision, which we expect will be ruled upon by the respective Courts in the 4th quarter of 2011. A similar motion will be filed in the near future in the California proceedings. We believe these claims are without merit and intend to 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 obligations. In addition, during the nine months ended September 30, 2011, employees exercising stock options elected to have 0.22 million common shares withheld by the Company in satisfaction of their combined $0.8 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. 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 ability of us or our licensee's to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of any 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 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," "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 2010 Annual Report on Form 10-K and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, each as 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® (oxycodone HCI, USP) Tablets CII, or Oxecta (formerly Acurox®), was approved for marketing by the United States Food and Drug Administration, or FDA, on June 17, 2011. Oxecta is an immediate-release oxycodone hydrochloride, or HCl, tablet utilizing our proprietary Aversion® Technology. 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. Oxecta will be manufactured and is being commercialized by Pfizer under our October 2007 license agreement with a subsidiary of Pfizer. We are eligible to receive tiered royalties ranging from 5% to 25% on net sales of Oxecta. The royalties commence on the first anniversary of the first commercial sale of Oxecta which we do not expect to occur during 2011. The trademark Oxecta® is owned by Pfizer or its affiliate.

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.

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 candidates are a benzodiazepine product for the treatment of anxiety disorders and a stimulant product for the treatment of attention deficit disorder.

We are also developing an over-the-counter, or OTC, immediate-release pseudoephedrine HCl tablet, utilizing our proprietary Impede™ Technology (“Nexafed” formerly referred to as Impede PSE). 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®. Our Impede Technology is a proprietary mixture of inactive ingredients designed to limit or impede extraction of pseudoephedrine from tablets for use as a starting material in producing 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 5mg and 7.5mg 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. 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 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.

Consistent with FDA guidance on requiring 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 reported in this study has not yet been established. There is no evidence that Oxecta has a reduced abuse liability compared to immediate-release oxycodone.

Further, the 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. Pfizer has agreed to a post-approval commitment with the FDA to perform an epidemiology study to assess the actual impact on abuse with Oxecta® tablets.

The misuse and abuse of pharmaceutical products in general, and opioid analgesics in particular, is a significant societal problem. Opioid analgesics, which are used to treat both acute and chronic pain, are the most widely-prescribed and most often abused pharmaceutical products in the United States. It is estimated that 75 million people in the United States suffer from pain, and, according to U.S. government surveys, 35 million people, or more than 10% of the U.S. population, have used prescription opioid analgesics for non-medical purposes at some point in their lifetime. We expect our Aversion Technology opioid products to compete primarily in the market for immediate-release opioid products, or IR Opioid Products. In 2010, IMS Health reported 260 million prescriptions dispensed for opioid analgesic tablets and capsules, of which approximately 244 million were for IR Opioid Products and 16 million were for extended-release opioid tablet and capsule products, or ER Opioid Products. Immediate-release oxycodone HCI products represent approximately 5% of the immediate-release opioid prescriptions in the United States.

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 September 30, 2011, 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 commence one year after the first commercial sale of Oxecta.

Nexafed™

Our Nexafed product (formerly referred to as Impede™ PSE) is an immediate-release pseudoephedrine HCl tablet which utilizes our patent pending Impede Technology. Our Impede Technology, a proprietary mixture of inactive ingredients, is designed to limit or impede extraction of PSE from tablets for use as a starting material in producing methamphetamine. We are developing Nexafed 30mg tablets and have demonstrated that our product is bioequivalent

to Johnson & Johnson's Sudafed® 30mg Tablets and a 30mg generic store brand. We sponsored independent laboratory tests that demonstrated our Impede™ Technology effectively prevents the extraction of PSE for conversion into methamphetamine using the three most common extraction methods. We provided Nexafed tablet samples to scientists associated with a law enforcement agency for their testing. The law enforcement testing demonstrated that the Impede™ Technology blocked the extraction of pseudoephedrine in several tests that were conducted under various conditions. In one test method, however, an unknown amount of methamphetamine, with unknown purity, was reportedly produced. We are assessing the results of these studies and intend to perform our own tests to better understand this finding. As a result, we have delayed commercialization activities on Nexafed pending these tests.

Methamphetamine is a highly addictive illicit drug used non-medically by an estimated 13 million people at some point in their lifetime. In 2006 regulations relating to over-the counter sale of PSE products were amended with the enactment of the Federal Combat Methamphetamine Epidemic Act, or CMEA. The CMEA was enacted in response to an alarming increase in and widespread conversion of PSE containing products into methamphetamine. Among other things, the CMEA requires retail stores to maintain their inventory of PSE containing products in a secured location and restricts the amount of PSE products a store can sell to an individual customer. Implementation of the CMEA initially reduced the number of illegal methamphetamine laboratory seizures reported by the Drug Enforcement Administration, or DEA, as the then most commonly used process for conversion of PSE to methamphetamine required substantial quantities of PSE. However, a newer process for converting PSE to methamphetamine requires less PSE. Possibly as a result of this new conversion process, the DEA reported 2009 clandestine methamphetamine laboratory seizures increased 62% over the low reported in 2007. Some states have enacted laws that are stricter than federal requirements by requiring PSE products to be sold only upon a doctor's prescription. Impede Technology is designed to deter the conversion of PSE to methamphetamine, including by use of both the older and newer conversion processes. In response to the ongoing methamphetamine problem, several local jurisdictions (state, counties and/or local municipalities) have enacted or propose to enact legislation to require a physician's prescription to obtain a PSE-containing product.

PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products. 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. Our 2010 market research study showed that 93% of the 204 pharmacists surveyed believe that PSE has superior efficacy as a nasal decongestant compared to phenylephrine, although we are unaware that this perceived superiority has been established by any scientific studies. Due to the CMEA restrictions on PSE products, many cold, sinus and allergy products replaced PSE with phenylephrine to avoid the security and consumer sales volume restrictions imposed by the CMEA on PSE 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 decongestants, analgesics, cough suppressants and antihistamines and have strong consumer brand recognition. The CMEA requires that all non-prescription PSE products be held securely behind the pharmacy counter. The CMEA also sets monthly consumer purchase volume limits and has necessitated consumer interaction with pharmacy personnel to purchase PSE-containing products. We expect that Nexafed will be subject to all of the PSE restrictions of the CMEA and specific state PSE laws. We intend to capitalize on this consumer-pharmacist interaction at the point of sale by soliciting distribution to the pharmacies of national and regional drug store chains and educating and encouraging pharmacists to recommend Nexafed to their customers. In our 2010 survey of 204 pharmacists, pharmacists indicated they would recommend Nexafed, if available in the pharmacy, more than competing products. 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 a New Drug Application, or NDA, or an Abbreviated New Drug Application, or ANDA, by the FDA for commercial distribution and marketing. We believe 30mg Nexafed developed utilizing Impede Technology meets or will meet the requirements of the FDA's "Over-the-Counter Human Drugs Which are Generally Recognized as Safe and Effective and Not Misbranded" and "Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-The-Counter Use" (the OTC Monograph). Under these regulations, PSE tablet products are deemed to be safe and effective for OTC use as a decongestant at a dose of 60 mg

every 4-6 hours for adults, and 30 mg every 4-6 hours for children 6-12 years old, and so long as all other conditions of the Monograph are met, such products may be marketed without an approved NDA or ANDA. As such, we intend to commercialize Nexafed in accordance with the monograph without submitting a NDA or ANDA to the FDA.

Product Labeling for Impede Technology Products

We believe we can advertise the extraction characteristics and benefits of our OTC Nexafed product which are supported by our research studies. We expect that our other Impede Technology products in development for marketing pursuant to an NDA or ANDA will be subject to a label approved by the FDA. We expect that such a label will require submission of our scientifically derived laboratory data and we intend to seek descriptions of our abuse liability studies in the FDA approved product label, although there can be no assurance that this will be the case.

Aversion Technology with Niacin

Our Aversion Technology had optionally included niacin, which can cause dose-related flushing side effects which may be disliked when the product is abused by over ingestion.

We submitted, with Pfizer, a NDA with the FDA in December 2008 for immediate release oxycodone with Aversion technology with niacin (Acurox with niacin). In June 2009, the FDA issued a "complete response" letter and, in April 2010, an FDA advisory committee determined that it did not have sufficient evidence to support approval of immediate release oxycodone with Aversion technology with niacin. Pfizer notified us on October 4, 2011 that it will not pursue further development of immediate release oxycodone with Aversion technology with niacin.

Patents and Patent Applications

In April 2007, the United States Patent and Trademark Office, or USPTO, issued to us U.S. Patent No. 7,201,920 titled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms," or 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 U.S. Patent No. 7,476,402, or 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 U.S. Patent No. 7,510,726, or 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 July 2011, the USPTO issued to us U.S. Patent No. 7,981,439, or the 439 Patent, with 7 allowed claims. The 439 Patent encompasses certain compositions including any water soluble drug of abuse intended to deter the most common methods of prescription opioid analgesic product misuse and abuse. We believe our stimulant and benzodiazepine product candidates currently in development are encompassed by the 439 Patent.

In addition to our issued U.S. patents, we have filed multiple U.S. patent applications and international patent applications relating to compositions containing abusable active pharmaceutical ingredients as well as applications covering our Impede Technology. 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.

Reference is made to the Risk Factors contained in Item 1A of Part II of our Report on Form 10-Q for the quarter ended June 30, 2011 for a discussion, among other things, of patent applications and patents owned by third parties including claims that may encompass our Aversion Technology and Oxecta tablets.

Company's Present Financial Condition

At September 30, 2011, we had cash and cash equivalents of $37.7 million, which includes the $20.0 million milestone payment from Pfizer triggered by FDA approval of the Oxecta NDA, and working capital of $37.0 million compared to cash and cash equivalents of $24.0 million and working capital of $23.3 million at December 31, 2010.

We had income from operations of $12.0 million for the nine months ended September 30, 2011 compared to a loss from operations of $9.8 million for the nine months ended September 30, 2010. We had accumulated deficits of approximately $323.8 million and $335.9 million at September 30, 2011 and December 31, 2010, respectively. We estimate that our current cash reserves will be sufficient to fund our operations and the development and commercialization of our 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 the Pfizer Agreement, including our receipt of royalties from Pfizer, which royalty obligations only apply to sales occurring after the one year anniversary of the first commercial sale of Oxecta, and any potential payments related to the achievement of specified milestones for Oxecta and other product candidates under the Pfizer Agreement, and under any future license agreements with other pharmaceutical company partners, of which there can be no assurance of us entering into, and revenues, if any, from our commercialization of our Nexafed Tablets, for which there can be no assurance. Our cash requirements for operating activities may increase in the future as we conduct pre-clinical studies and clinical trials for our product candidates, maintain, defend, if necessary, 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 Nine Months Ended September 30, 2011 and 2010

	September 30,		Increase (Decrease)	
	2011	2010	Dollars	%
Revenues				
Program fee revenue	$ 466	$ 855	$ (389)	(46)%
Milestone revenue	20,000	-	20,000	*
Collaboration revenue	-	2,097	(2,097)	(100)
Total revenue	20,466	2,952	17,514	593
Operating expenses				
Research and development	3,245	5,714	(2,469)	(43)
Marketing, general and administrative	4,840	7,025	(2,185)	(31)
Total operating expenses	8,085	12,739	(4,654)	(37)
Income (loss) from operations	12,381	(9,787)	22,168	227
Other (expense) income, net	(9)	17	26	153
Income (loss) before income tax	12,372	(9,770)	22,142	227
Income tax expense	341	10	331	3,310
Net income (loss)	$ 12,031	$ (9,780)	$ 21,811	223%

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 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 nine months ended September 30, 2011 and 2010 from amortization of this upfront fee was $0.5 million and $0.9 million, respectively. On June 17, 2011 the Oxecta NDA was approved and we recognized $20.0 million milestone revenue while fully recognizing the remaining program fee revenue.

Collaboration revenue recognized in the nine months ended September 30, 2010 was $2.1 million for invoiced reimbursement of our R&D expenses incurred pursuant to the Pfizer Agreement. We invoice Pfizer in arrears on a calendar quarter basis. We did not incur reimbursable R&D expenses during the nine months 2011 and we do not expect to incur any future reimbursable R&D expenses from Pfizer.

Operating Expense

R&D expense during the nine months ended September 30, 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, compensation, benefits and other personnel related expenses, and facility costs. Included in the 2011 and 2010 results are non-cash share-based compensation expenses of $0.5 million and $1.4 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 Oxecta. Our ongoing development activities include our benzodiazepine tablet product candidate, an extended release opioid product candidate, and the scale-up for our Nexafed manufacturing process to batch sizes that would be required if we commercially distribute.

Marketing expenses during the nine months ended September 30, 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 $1.7 million and $4.2 million, respectively. Excluding the share-based compensation expense, our marketing, general and administrative expenses increased $0.3 million.

Other Income

During the nine months ended September 30, 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 Income (Loss)

During June 2011, we decreased our valuation allowance on our deferred income tax assets by $5.0 million. We recorded a benefit from income taxes of $5.0 million against our current period's income tax provision. The net income for the nine months ended September 30, 2011 includes a income tax provision only for federal alternative minimum income taxes as we expect to utilize our federal net operating loss income tax carryforwards to offset our expected federal regular income taxes. A state income tax provision was recorded for the Company's operations apportioned to various state jurisdictions.

Results of Operations for the Three Months Ended September 30, 2011 and 2010

	September 30,		Increase (Decrease)	
	2011	2010	Dollars	%
Revenues				
Program fee revenue	$ -	$ 233	$ (233)	(100) %
Milestone revenue	-	-	-	-
Collaboration revenue	-	59	(59)	(100)
Total revenue	-	292	(292)	(100)
Operating expenses				
Research and development	962	1,142	(180)	(16)
Marketing, general and administrative	1,185	1,716	(531)	(31)
Total operating expenses	2,147	2,858	(711)	(25)
Income (loss) from operations	(2,147)	(2,566)	(419)	(16)
Other income (expense), net	6	15	(9)	(60)
Income (loss) before income tax	(2,141)	(2,551)	(410)	(16)
Income tax expense	-	2	(2)	(100)
Net income (loss)	$ (2,141)	$ (2,553)	$ (412)	(16) %

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 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 September 30, 2010 from amortization of this upfront fee was $0.2 million. On June 17, 2011 the Oxecta NDA was approved and we fully recognized the remaining program fee revenue at that time.

17

Collaboration revenue recognized in the three months ended September 30, 2010 was $0.1 million for invoiced reimbursement of our R&D expenses incurred pursuant to the Pfizer Agreement. We invoice Pfizer in arrears on a calendar quarter basis. We did not incur reimbursable R&D expenses during the third quarter 2011 and we do not expect to incur any future reimbursable R&D expenses from Pfizer.

Operating Expense

R&D expense during the three months ended September 30, 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, compensation, benefits and other personnel related expenses, and facility costs. Included in the 2011 and 2010 results are non-cash share-based compensation expenses of $0.1 million and $0.3 million, respectively. Excluding the share-based compensation expense, there is a $0.1 million increase in development expenses. Our ongoing development activities include our benzodiazepine tablet product candidate, an extended release opioid product candidate, and the scale-up for our Nexafed manufacturing process to batch sizes which will be required if we commercially distribute.

Marketing expenses during the three months ended September 30, 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 $0.2 million and $0.9 million, respectively. Excluding the share-based compensation expense, our marketing, general and administrative expenses increased $0.1 million.

Other Income

During the three months ended September 30, 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 Income (Loss)

During June 2011, we decreased our valuation allowance on our deferred income tax assets by $5.0 million. We recorded a benefit from income taxes of $5.0 million against our current period's income tax provision. The net income for the three months ended September 30, 2011 does not includes a tax provision. We expect to utilize our federal net operating loss income tax carryforwards to offset our expected federal regular income taxes. A state income tax provision was recorded for the Company's operations apportioned to various state jurisdictions.

Liquidity and Capital Resources

At September 30, 2011, the Company had cash and cash equivalents of $37.7 million, including the $20.0 million milestone payment by Pfizer triggered by FDA approval of the Oxecta NDA, compared to $24.0 million at December 31, 2010. The Company had working capital of $37.0 million at September 30, 2011 compared to $23.3 million at December 31, 2010. The increase in our cash provided by operations is due to the period's net income resulting from the milestone revenue relating to FDA approval of the Oxecta NDA, offset by the payment of employee withholding taxes approximating $1.8 million associated with the exercise of stock options and RSU distributions during the nine month period, adjusted for certain non-cash items such as deferred program fee revenue and share-based compensation expenses.

At October 27, 2011, the Company had cash and cash equivalents of approximately $37.1 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 third 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 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.CAL XBRL Taxonomy Extension Calculation Linkbase

101.LAB XBRL Taxonomy Extension Label Linkbase

101.PRE XBRL Taxonomy Extension Presentation Linkbase

101.DEF XBRL Taxonomy Extension Definition Linkbase

19

SIGNATURES

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

October 27, 2011

ACURA PHARMACEUTICALS, INC.

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

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