ACURA PHARMACEUTICALS, INC
Form 10-Q
October 27, 2008

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20649

Form 10-Q

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

For the quarterly period ended September 30, 2008

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 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 23, 2008 the registrant had 42,723,254 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

UNAUDITED
(in thousands, except par values)

	September 30, 2008	December 31, 2007
ASSETS		
Current Assets		
Cash and cash equivalents	$ 30,894	$ 31,368
Short-term investments	5,039	-
Collaboration revenue receivable	2,616	2,977
Prepaid clinical study costs	-	388
Prepaid insurance	488	202
Prepaid expense and other current assets	148	47
Deferred income taxes	2,866	9,600
Total current assets	42,051	44,582
Non-Current Assets		
Deferred income taxes - non current portion	3,400	-
Property, plant and equipment, net	1,102	1,046
Total assets	$ 46,553	$ 45,628
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accrued expenses	$ 2,084	$ 334
Deferred program fee revenue - current portion	5,053	21,942
Total current liabilities	7,137	22,276
Non-Current Liabilities		
Deferred program fee revenue - non current portion	842	4,632
Total liabilities	7,979	26,908
Commitments and contingencies (Note 9)		
Stockholders’ Equity		
Common stock - $.01 par value; 650,000 shares authorized; 42,723 and 42,706 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	427	427
Additional paid-in capital	342,540	340,153
Accumulated deficit	(304,393)	(321,860)
Total stockholders’ equity	38,574	18,720
Total liabilities and stockholders’ equity	$ 46,553	$ 45,628

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,	
	2008	**2007**	**2008**	**2007**
Revenue				
Program fee revenue	$ 23,678	$ -	$ 1,263	$ -
Milestone revenue	5,000	-	-	-
Collaboration revenue	7,971	-	2,617	-
Total revenue	36,649	-	3,880	-
Operating Expenses				
Research and development expenses	10,859	2,775	3,693	827
Marketing, general and administrative expenses	5,617	1,959	3,373	593
Total operating expenses	16,476	4,734	7,066	1,420
Operating income (loss)	20,173	(4,734)	(3,186)	(1,420)
Other Income (Expense)				
Interest income (expense), net	675	(1,033)	171	(224)
Amortization of debt discount	-	(2,700)	-	(598)
Loss on fair value change of conversion features	-	(3,483)	-	-
Loss on fair value change of common stock warrants	-	(1,904)	-	(236)
Gain on asset disposals	1	22	-	2
Other expense	-	(2)	(17)	-
Total other income (expense)	676	(9,100)	154	(1,056)
Income (loss) before income tax	20,849	(13,834)	(3,032)	(2,476)
Income tax expense (benefit)	3,382	-	(6,180)	-
Net Income (Loss)	$ 17,467	$ (13,834)	$ 3,148	$ (2,476)
Earnings (loss) per share				
Basic	$ 0.38	$ (0.37)	$ 0.07	$ (0.06)
Diluted	$ 0.35	$ (0.37)	$ 0.06	$ (0.06)
Weighted average shares used in computation				
Basic	45,670	36,998	45,680	40,155
Diluted	49,529	36,998	49,409	40,155

See accompanying notes to the consolidated financial statements.

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ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

NINE MONTHS ENDED SEPTEMBER 30, 2008

UNAUDITED
(in thousands, except par values)

	Common Stock $0.01 Par Value - Shares	Common Stock $0.01 Par Value - Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2007	42,706	$ 427	$ 340,153	$ (321,860)	$ 18,720
Net income	-	-	-	17,467	17,467
Stock based compensation	-	-	2,367	-	2,367
Exercise of warrant	17	-	20	-	20
Balance at September 30, 2008	42,723	$ 427	$ 342,540	$ (304,393)	$ 38,574

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, except supplemental disclosures)

	2008	2007
Cash flows from Operating Activities		
Net income (loss)	$ 17,467	$ (13,834)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities		
Depreciation and amortization	108	87
Amortization of debt discount	-	2,700
Deferred income taxes	3,334	-
Loss on fair value change of conversion features	-	3,483
Loss on fair value change of common stock warrants	-	1,904
Common stock issued for interest	-	812
Non-cash stock compensation expense	2,367	874
Gain on asset disposals	(1)	(22)
Impairment reserve against fixed assets	(29)	-
Changes in assets and liabilities		
Collaboration revenue receivable	361	-
Prepaid expenses and other current assets	1	(1,223)
Accounts payable	-	-
Accrued expenses	1,750	231
Deferred program fee revenue	(20,679)	-
Net cash provided by (used in) operating activities	4,679	(4,988)
Cash flows from Investing Activities		
Purchase of investments, net	(5,039)	-
Capital expenditures	(135)	(32)
Proceeds from asset disposals	1	22
Net cash used in investing activities	(5,173)	(10)
Cash flows from Financing Activities		
Proceeds from issuance of senior secured term notes payable	-	2,696
Proceeds from Unit Offering, net	-	14,146
Proceeds from exercise of stock warrant	20	-
Repayments of bridge loans	-	(8)
Payments on capital lease obligations	-	(19)
Net cash provided by financing activities	20	16,815
Decrease in cash and cash equivalents	(474)	11,817
Cash and cash equivalents at beginning of period	31,368	228
Cash and cash equivalents at end of period	$ 30,894	$ 12,045

Cash paid for interest	$	-	$	156
Cash paid for income taxes	$	47	$	-

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES

UNAUDITED
(in thousands, except supplemental disclosures)

Nine Months Ended September 30, 2008

1. Impaired fixed assets with a $52,000 net book value were disposed and a $29,000 reduction in the impairment allowance was favorably recognized.
2. A $5,022,000 valuation allowance against deferred income tax assets was removed which resulted in an equal amount recorded as a benefit against current income tax expense.
3. Deferred income tax assets of $8,356,000 were used to offset an equal amount of current income taxes payable.

Nine Months Ended September 30, 2007

1. The Company issued 47,552 shares of common stock as payment of $460,000 of Senior Secured Convertible Bridge Term Notes Payable accrued interest.
2. The Company issued 36,151 shares of common stock as payment of $352,000 of Secured Term Note Payable accrued interest.
3. Warrants to purchase an aggregate 58,009 shares of common stock were exercised at exercise prices between $1.20 and $6.60 per share in a series of cashless exercise transactions resulting in the issuance of an aggregate 31,362 shares of common stock.
4. The issuance of $896,000 Senior Secured Convertible Bridge Term Notes during the period January 1, 2007 through March 29, 2007 included conversion features measured at $849,000, which resulted in the recording of an equal amount of debt discount and conversion feature liabilities.
5. The change in all separated conversion feature's fair value through March 30, 2007 resulted in a loss of $3,483,000. Due to a debt agreement modification on March 30, 2007, the then current conversion feature fair value of $21,086,000 was reclassified from liabilities to equity.
6. The issuance of $1,800,000 of Senior Secured Bridge Term Notes included conversion features measured at $1,552,000, which resulted in a recording of an equal amount of debt discount to equity.
7. The change in the common stock warrants' fair value through the earlier of their exercise date or March 30, 2007 resulted in a loss of $1,668,000. Due to a debt agreement modification on March 30, 2007, the then current $12,307,000 fair value of all 1,592,100 outstanding common stock warrants was reclassified from liabilities to equity, as was $146,000 of such value related to warrants exercised during the period.
8. Anti-dilution provisions in certain warrant grants were triggered resulting in a loss of $236,000 with an equal amount recorded against equity.
9. Senior Secured Convertible Bridge Term Notes Payable of $10,544,000, less unamortized debt discount of $544,000 was converted into 3,905,184 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, 2008 AND 2007

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements of Acura Pharmaceuticals, Inc. and subsidiary (the "Company") have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accrual adjustments, considered necessary to present fairly the financial position as of September 30, 2008 and results of operations and cash flows for the three months and nine month period ended September 30, 2008 have been made. The results of operations for the three and nine month periods ended September 30, 2008 are not necessarily indicative of results that may be expected for the full year ending December 31, 2008. The unaudited consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2007 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission. The year-end consolidated balance sheet was derived from the audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles. Amounts presented have been rounded to the nearest thousand, where indicated, except per share data and par values. All share and per share data have been adjusted to reflect a one-for-ten reverse stock split on December 5, 2007.

NOTE 2 - RESEARCH AND DEVELOPMENT

Research and Development (“R&D”) expenses include internal R&D activities, external contract research organization (“CRO”) activities, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, depreciation, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and incentive compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include clinical trial studies, regulatory consulting, regulatory counsel, and patent counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. The Company makes payments to CROs based on agreed upon terms including payments in advance of the study starting date. The Company reviews and accrues CRO and clinical trial study expenses based on work performed and relies on estimates of those costs applicable to the stage of completion of a study provided by the CRO. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Advance payments are amortized to expense based on work performed. The Company has entered into several CRO clinical trial agreements pursuant to which $0 and $388,000 was prepaid at September 30, 2008 and December 31, 2007, respectively. Unfunded CRO commitments were $2.8 million and $4.0 million at September 30, 2008 and December 31, 2007, respectively and CRO expenses are expected to be incurred as patients or subjects are enrolled in the clinical studies.

NOTE 3 - REVENUE RECOGNITION AND DEFERRED PROGRAM FEE REVENUE

We recognize revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, “Revenue Recognition in Financial Statements” (“SAB 104”). We have also adopted the provisions of Emerging Issues Task Force, Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables” (“EITF 00-21”). Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured.

In connection with our License, Development and Commercialization Agreement dated October 30, 2007 (the "King Agreement") with King Pharmaceuticals Research and Development, Inc. ("King"), we recognize program fee revenue, collaboration revenue and milestone revenue. Program fee revenue is derived from amortized upfront payments, such as the $30.0 million upfront payment from King received in December 2007, and license fees, such as the $3.0 million option exercise fee paid by King to us in May 2008 upon the exercise of its option to license our third undisclosed opioid analgesic product candidate under the King Agreement. We have assigned a portion of the King upfront payment to each of three product candidates identified in the King Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. Collaboration revenue is derived from reimbursement of development expenses, which are invoiced quarterly in arrears, and are recognized when costs are incurred pursuant to the King Agreement. King is obligated to pay us development milestone payments contingent upon the achievement of certain substantive events in the development of Acurox™ Tablets and other product candidates licensed to King under the King Agreement. Milestone payments from King are recognized as revenue upon achievement of the "at risk" milestone events, which represent the culmination of the earnings process related to that milestone. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones are substantially at risk at the inception of the King Agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment. Each milestone payment is non-refundable and non-creditable when made. The ongoing research and development services being provided to King under the King Agreement are priced at the Company's cost to provide such services. In June 2008, King paid us a $5.0 million milestone payment for successfully achieving the primary endpoints in our pivotal Phase III study, AP-ADF-105 for Acurox™ Tablets.

NOTE 4 - INCOME TAXES

The Company accounts for income taxes under the liability method in accordance with Statement of Financial Accounting Standards No. 109 ("SFAS No. 109"), "Accounting for Income Taxes." Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities and are measured using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, the Company has significant net operating loss carryforwards ("NOLS") that give rise to deferred income tax assets that may be used to offset taxes on future taxable income. However, SFAS 109 requires a valuation allowance against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized because the likelihood of achieving future taxable income is unknown.

At December 31, 2007 and September 30, 2008, based upon the revenues to be derived from the King Agreement, the Company determined it was more likely than not that it would be able to realize some of its deferred income tax assets in the near future and recorded adjustments of $9.60 million and $5.0 million respectively, to its deferred income tax asset valuation allowance account. These adjustments recognized a benefit from income taxes in our income for such periods. 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.

At December 31, 2007 the Company had total NOLs of $135 million. However, it has been determined that certain of these NOLs are limited by Section 382 of the Internal Revenue Code due to the Company's 2004 equity restructuring events. The application of Section 382 has reduced these NOLs by $40 million leaving $95 million of Federal NOLS available to offset current and future taxable income. These NOLs expire between 2009 and 2027.

NOTE 5 - ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	Sept 30, 2008	Dec 31, 2007
Payroll and incentive compensation	$ 1,085	$ 63
Legal fees	102	35
Audit examination and tax preparation fees	110	120
Franchise taxes	60	15
Property taxes	44	34
Clinical, regulatory, trademark, and patent consulting fees	35	50
Clinical studies	430	-
Other accruals	218	17
	$ 2,084	$ 334

NOTE 6 - SHARE-BASED COMPENSATION

The Company has share-based compensation plans including stock options and restricted stock units for its employees and directors. On January 1, 2006, the Company adopted Financial Accounting Standards Board ("FASB") release FASB Statement No. 123 (revised 2004), "Share-Based Payment, ("FASB 123R")". The compensation cost relating to share-based payment transactions is now measured based on the fair value of the equity or liability instruments issued. For purposes of estimating the fair value of each stock option unit on the date of grant, the Company utilized the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of the Company's common stock (as determined by reviewing its historical public market closing prices). Because the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not provide a reliable single measure of the fair value of its employee stock options. Included in the nine month period ended September 30, 2008 and 2007 is $2.4 million and $0.9 million, respectively, and included in the three month period ended September 30, 2008 and 2007 is $1.5 million and $0.2 million, respectively, of share-based compensation expense.

Restricted Stock Unit Award Plan

The Company has a Restricted Stock Unit Award Plan (the "2005 RSU Plan") for its employees and non-employee directors. A Restricted Stock Unit ("RSU") represents the contingent obligation of the Company to deliver a share of its common stock to the holder of the RSU on a distribution date. RSUs for up to 3.5 million shares of common stock are authorized for issuance under the 2005 RSU Plan.

Absent a change of control, one-fourth of vested shares of common stock underlying an RSU award will be distributed (after payment of $0.01 par value per share) on January 1 of each of 2011, 2012, 2013 and 2014. If a change in control occurs (whether prior to or after 2011), the vested shares underlying the RSU award will be distributed at or about the time of the change in control.

In December 2005, an aggregate of 2.75 million RSUs were granted to Company employees. In February 2006, an aggregate of 200,000 RSUs were granted to two of the Company's independent directors. In April 2008, 50,000 RSUs were granted to a Company employee. Of the 3.0 million RSU awards granted, 2.95 million were fully vested as of

December 31, 2007. The balance of 50,000 RSUs are vesting at the rate of 2,500 per month from May 2008 through December 2009.

The weighted average fair value of all RSU grants is $3.49 per share of common stock underlying each RSU. Fair value is defined as the market price per share of the Company's common stock on the date of an RSU grant less the exercise cost of each RSU. The total share-based compensation expense to be incurred by the Company is the fair value of all RSUs granted. The fair value of the February 2006 RSU grant was $0.7 million which was entirely expensed on the grant date as this grant was for performance of past service. The fair value of the December 2005 RSU grant was $9.7 million and was amortized using a graded vesting method which treated the December 2005 RSU grant as a series of awards rather than a single award and attributed a higher percentage of the reported fair value to stock-based compensation expense in the earlier years of the vesting schedule than to the later years. The fair value of the April 2008 RSU grant was $0.4 million. Included in the nine month period ended September 30, 2008 and 2007 is $0.1 million and $0.9 million, respectively and included in the three month period ended September 30, 2008 and 2007 is $0.1 million and $0.2 million, respectively of share-based compensation expense from the RSU awards. As of September 30, 2008, the Company had $0.3 million of unrecognized share-based compensation expense related to the April 2008 RSU grant, which will be recognized over the remaining period of 15 months. As of September 30, 2008 and December 31, 2007, the aggregate intrinsic value of the RSU awards outstanding and vested was $20.8 million and $18.0 million, respectively.

Stock Option Plans

The Company has stock options outstanding under several stock option plans. The Company's 1995 Stock Option Plan expired in May 2005 and its 1998 stock Option Plan expired in April 2008 but options granted under such plans remain outstanding. On April 30, 2008 the Company's shareholders approved a 2008 Stock Option Plan authorizing the granting of options to purchase up to 6.0 million shares of the Company's common stock.

Stock options to purchase 3.1 million and 1.9 million shares with a weighted-average exercise price of $4.94 and $2.54 were outstanding at September 30, 2008 and December 31, 2007, respectively, of which 2.1 million and 1.8 million options were vested at September 30, 2008 and December 31, 2007, respectively. During the three month period ended September 30, 2008, there was no stock option activity. During the nine month period ended September 30, 2008, stock options to purchase an aggregate 1.2 million shares having a weighted average exercise price of $9.58 were granted, options to purchase 49,000 shares expired, and no options were exercised. Included in the nine month and three month periods ending September 30, 2008 are $1.4 million and $2.3 million, respectively of share-based compensation expense from the stock option awards. There was minimal stock compensation expense from stock option awards during the nine month and three month periods ending September 30, 2007.

As of September 30, 2008 the Company had $8.45 million of unrecognized share-based compensation expense, net of estimated forfeitures, related to stock option grants, which will be recognized over the remaining weighted average life of 20 months. Total intrinsic value of stock options outstanding and exercisable at September 30, 2008 and December 31, 2007 was $9.9 million and $8.1 million, respectively.

NOTE 7 - COMMON STOCK WARRANTS

At September 30, 2008, the Company had outstanding common stock purchase warrants, exercisable for an aggregate of approximately 3.9 million shares of common stock, all of which contain cashless exercise features. A warrant for 17,000 shares of common stock was exercised at a cash exercise price of $1.20 per share and warrants to exercise 47,000 shares of common stock at $9.90 expired as unexercised during the nine month period ended September 30, 2008. During the nine month period ended September 30, 2007, warrants to purchase aggregate 58,009 shares of common stock were exercised at exercise prices between $1.20 and $6.60 per share in a series of cashless exercise transactions resulting in the issuance of aggregate 31,362 shares of common stock. At September 30, 2008, outstanding common stock purchase warrants of 409,000, 64,000 and 3,435,000 will expire if unexercised during 2009, 2010 and years thereafter, respectively, and have a weighted average remaining term of 5.1 years. The exercise prices of these warrants range from $1.29 to $3.40 per share, with a weighted average exercise price of $3.17.

NOTE 8- EARNINGS (LOSS) PER SHARE

The computation of basic earnings (loss) per share of common stock is based upon the weighted average number of both common shares and vested RSUs outstanding during the period. A RSU represents the contingent obligation of the Company to deliver a share of its common stock to the holder of a vested RSU on a distribution date. The computation of diluted earnings (loss) per share is based on the same number of both common shares and vested RSUs used in the basic earning (loss) computation, but adjusted for the effect of other potentially dilutive securities. Excluded from the diluted earnings (loss) per share computation at September 30, 2007 are 6.1 million of potentially dilutive securities, as the effect of including them would be antidilutive. Accordingly, the loss per share is the same result for both basic and diluted computations.

Net loss used in the Company's earnings (loss) per share computation for the nine month period ended September 30, 2007 include the impact of dividends deemed to have been issued to certain common shareholders as a result of modifications to debt agreements with those shareholders.

(in thousands, except per share data)	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007	Three Months Ended September 30, 2008	Three Months Ended September 30, 2007
Basic earnings (loss) per share				
Numerator:				
Net income (loss)	$ 17,467	$ (13,834)	$ 3,148	$ (2,476)
Deemed dividend from modification of debt	-	(3)	-	-
Net income (loss) allocable to common shareholder	$ 17,467	$ (13,837)	$ 3,148	$ (2,476)
Denominator:				
Common shares (weighted)	42,717	34,620	42,723	37,534
Vested restricted stock units (weighted)	2,953	2,378	2,957	2,621
Weighted average shares used in computing basic earnings (loss) per share allocable to common shareholder	45,670	36,998	45,680	40,155
Basic earnings (loss) per share allocable to common shareholder	$ 0.38	$ (0.37)	$ 0.07	$ (0.06)
Diluted earnings per share				
Denominator:				
Common shares (weighted)	42,717	34,620	42,723	37,534
Vested restricted stock units (weighted)	2,953	2,378	2,957	2,621
Stock options	1,461	-	1,438	-
Common stock warrants	2,398	-	2,291	-
Weighted average shares used in computing diluted earnings per share allocable to common shareholder	49,529	36,998	49,409	40,155
Diluted earnings (loss) per share allocable to common shareholder	$ 0.35	$ (0.37)	$ 0.06	$ (0.06)
Excluded potentially dilutive securities:				
Common stock issuable (see #1 below):				

Stock options (vested and nonvested)	1,173	1,899	1,173	1,899
Nonvested restricted stock units	37	246	37	246
Common stock warrants	-	3,972	-	3,972
Total excluded dilutive common stock equivalents	1,210	6,117	1,210	6,117

(1) Number of common shares issuable is based on maximum number of common shares issuable on exercise or conversion of the related securities as of period end. Such amounts have not been adjusted for the treasury stock method or weighted average outstanding calculations required if the securities were dilutive.

NOTE 9 - COMMITMENTS AND CONTINGENCIES

Employment Agreements

Robert B. Jones commenced employment with us on April 7, 2008 pursuant to an employment agreement dated March 18, 2008 which provides that Mr. Jones will serve as our Senior Vice President and Chief Operating Officer for a term expiring December 31, 2009. The term of the employment agreement provides for automatic one (1) year renewals in the absence of written notice to the contrary from us or Mr. Jones at least ninety (90) days prior to the expiration of the initial term or any subsequent renewal period. Mr. Jones' annual base salary under the employment agreement is $290,000. The employment agreement provides that Mr. Jones is eligible for annual bonuses of up to thirty percent (30%) of his base salary on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. The employment agreement further provides for our grant to Mr. Jones of stock options exercisable for 30,000 shares of common stock at an exercise price of $8.64 which was the closing stock price of the Company's common stock on the NASDAQ at April 4, 2008. The stock option provides for vesting of 1,500 shares on the last day of each month commencing May 31, 2008. The employment agreement also provides for the grant to Mr. Jones of a restricted stock unit award of 50,000 shares of our common stock. The restricted stock unit vests 2,500 shares on the last day of each month commencing May 31, 2008.

The employment agreement of Ron Spivey, Senior Vice President and Chief Scientific Officer was amended to provide that Dr. Spivey will receive a $315,000 bonus payment (in addition to any other payments to which he may be entitled pursuant to the Executive Employment Agreement) if he remains employed by us through December 31, 2008. The bonus payment will also be payable if Dr. Spivey's employment is terminated by us without Cause (as defined in his Executive Employment Agreement) or if he terminates his employment for Good Reason (as defined in his Executive Employment Agreement) prior to December 31, 2008. The bonus payment will be paid on December 31, 2008. In addition, as part of the amendment to Dr. Spivey's Executive Employment Agreement, we entered into an Amended and Restated Employment Agreement to be effective January 1, 2009. The Amended and Restated Employment Agreement provides that commencing January 1, 2009, Dr. Spivey will continue his employment with us through December 31, 2010 on a part-time basis (10 weeks per year) at an annual salary of $120,000 as our Senior Scientific Advisor. Dr. Spivey will report to the Chief Executive Officer and will be eligible for benefits offered to part-time employees.

The employment agreements of Andrew D. Reddick, President and Chief Executive Officer and Peter A. Clemens, Senior Vice President and Chief Executive Officer automatically renewed on October 3, 2008 for a term expiring December 31, 2009.

Financial Advisor Agreement

In connection with the Company's August 2007 Unit Offering, the Company is obligated to pay a fee to the Company's financial advisor upon each exercise of the warrants issued in the Unit Offering, in proportion to the number of warrants exercised. The maximum amount of such fee assuming 100% exercise of such warrants is $255,000. The Company has not reflected this obligation as a liability in its unaudited financial statements as the payment is contingent upon the timing and exercise of the warrants by each of the warrant holders. Such fee, if any, will be paid and charged against earnings as and if the warrants are exercised. No warrants have been exercised under the August 2007 Unit Offering.

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

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

results in future periods.

Forward Looking Statements

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. The most significant of such factors include, but are not limited to, our ability and the ability of King (to whom we have licensed our Aversion® Technology for certain opioid analgesic products in the United States, Canada and Mexico) and the ability other pharmaceutical companies, if any, to whom we may license our Aversion® Technology, to obtain necessary regulatory approvals and commercialize products utilizing Aversion® Technology, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability to fulfill the U.S. Food and Drug Administration's ("FDA") requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date and the results of other laboratory and clinical studies, to support FDA approval of our product candidates, the adequacy of the development program for our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, the risk that the FDA may not agree with our analysis of our clinical studies and may evaluate the results of these studies by different methods or conclude that the results of the studies are not statistically significant, clinically meaningful or that there were human errors in the conduct of the studies or otherwise, the risk that further studies of our product candidates are not positive or otherwise do not support FDA approval or commercially viable product labeling, and the uncertainties inherent in scientific research, drug development, clinical trials and the regulatory approval process. Other important factors that may also affect future results include, but are not limited to: our ability to attract and retain skilled personnel; our ability to secure and protect our patents, trademarks and other proprietary rights; litigation or regulatory action that could require us to pay significant damages or change the way we conduct our business; our ability to compete successfully against current and future competitors; our dependence on third-party suppliers of raw materials; our ability to secure U.S. Drug Enforcement Administration ("DEA") quotas and source the active ingredients for our products in development; difficulties or delays in clinical trials for our product candidate or in the commercial manufacture and supply of our products; and other risks and uncertainties detailed in this Report. When used in this Report, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions identify forward-looking statements.

Company Overview

We are a specialty pharmaceutical company engaged in research, development and manufacture of product candidates providing abuse deterrent features and benefits by utilizing our proprietary Aversion® Technology. Our innovative Aversion® Technology platform has been successfully utilized in multiple opioid analgesic product candidates in development and supported by laboratory studies and statistically significant and clinically meaningful Phase II and Phase III clinical study results for Acurox™ Tablets, our lead product candidate. A strategic alliance with King Pharmaceuticals, Inc. and an issued U.S. patent covering our opioid analgesic product candidates provide substantiation of the potential commercial value of products developed using Aversion® Technology. Our portfolio of product candidates includes opioid analgesics intended to effectively relieve moderate to severe pain while simultaneously discouraging the most common methods of pharmaceutical product misuse and abuse:

- intravenous injection of dissolved tablets or capsules;
- nasal snorting of crushed tablets or capsules; and
- intentional swallowing of excess quantities of tablets or capsules.

Acurox™ is an orally administered immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient and has completed its pivotal Phase III clinical trial successfully meeting the primary pain relief endpoints. In addition to Acurox™, we have four other Aversion® Technology opioid analgesic product candidates in various

stages of development containing the active analgesic ingredients found in the most widely prescribed and frequently abused immediate release opioid containing products. All of our opioid analgesic product candidates utilize Aversion® Technology, which in combination with our anticipated product labeling and drug product listing strategies, are anticipated to provide our opioid products with protection from generic competition through the expiration of our patent in 2025. In addition, we have seven U.S. non-provisional pending patent applications which if issued, are intended to expand our patent estate and cover other drugs susceptible to abuse, including stimulants, tranquilizers and sedatives.

Aversion® Technology Product Candidates [1] (All Immediate Release Tablets)	**Stage of Development/Future Expectations**
Acurox™ (oxycodone HCl/niacin) Tablets	Phase III complete, New Drug Application (NDA) submission projected 12/2008
2nd Undisclosed opioid analgesic	Active Investigational New Drug Application (IND)
3rd Undisclosed opioid analgesic	Proof of concept complete[2]
4th Undisclosed opioid analgesic	Formulation, stability and bioavailability studies are complete. Proof of concept[2] projected Q4 2008
5th Undisclosed opioid analgesic	Formulation, stability and bioavailability studies are complete. Proof of concept[2] projected Q1 2009

(1) King Pharmaceuticals Research and Development Inc., ("King") has either licensed or has an option to licenses all opioid product candidates listed above in the U.S., Canada and Mexico. Refer to description of the King Agreement in this Report.

(2) Proof of concept is attained upon demonstration of certain product stability and bioavailability parameters as defined in the King Agreement.

Because the analgesic and other ingredients in all of our opioid product candidates are included in FDA-approved products and the active ingredients have a long history of use and well established safety and efficacy profiles, we intend to utilize the 505(b)(2) NDA regulatory pathway. The FDA has confirmed, in writing to us, that the proposed NDA for Acurox™ would qualify for a Section 505(b)(2) submission. This regulatory strategy has enabled us to pursue a more rapid development of Acurox™, which presently includes only a single Phase III clinical efficacy and safety study, and the ability to reference preclinical and clinical evaluations for currently marketed opioid products. We anticipate this regulatory pathway will be utilized to develop all of our future immediate release opioid product candidates.

Markets for our Opioid Analgesic Product Candidates

It is estimated that 75 million people in the U.S. suffer from pain and, according to U.S. government surveys, 33.1 million people, or more than 10% of the U.S. population, have used prescription opioid analgesics non-medically at some point in their lifetime. Of these abused prescription products, immediate release opioid analgesics ("IR Opioid Products"), which typically require dosing administration every 4 to 6 hours, comprise the vast majority of this abuse compared with extended release opioid products ("ER Opioid Products"), which typically require dosing administration every 12 to 24 hours. In 2007, IMS Health measured 238 million prescriptions dispensed for opioid analgesic tablets and capsules, of which approximately 224 million were for IR Opioid Products and 14 million were for ER Opioid Products. We expect our Aversion® Technology opioid product candidates to compete primarily in the IR Opioid Product segment of the opioid analgesic market.

We have commissioned, through an independent market research firm, numerous market research studies including two which surveyed 401 and 435 opioid analgesic prescribing U.S. based physicians, respectively. These studies revealed that physicians are keenly aware of prescription opioid analgesic abuse and are personally concerned with the potential impact of drug abuse on their respective medical practices. Our survey of 401 physicians indicated that of the prescriptions likely to be written for our product candidates that utilize the analgesic oxycodone, 59% will be switched from immediate release products containing either hydrocodone or oxycodone with the remaining 41% being switched from other currently marketed opioid analgesic products such as codeine, propoxyphene, morphine, and tramadol. 94% of 435 physicians surveyed indicated that they would either prescribe one of the Aversion® Technology products profiled in the market research questionnaire for one of their last five patients receiving an opioid prescription or they are aware of a patient in their practice for whom Aversion® Technology opioid analgesic products would be an appropriate choice.

Acurox™ Tablets Development Program

We have completed or are in process of completing clinical and laboratory studies to assess the efficacy and safety of Acurox™ (oxycodone HCl/niacin) Tablets and to demonstrate its abuse deterrent features and benefits. Acurox™ is our lead product candidate under development in two tablet strengths: 5/30 mg and 7.5/30 mg. In June 2008, we announced positive top-line results from our pivotal Phase III study, AP-ADF-105 ("Study 105"). Study 105 was conducted under a Special Protocol Assessment agreed to by the FDA and demonstrated that Acurox™ Tablets provided statistically significant and clinically meaningful pain relief and were generally well tolerated. We have also completed or have ongoing additional clinical and non-clinical studies intended to demonstrate the abuse deterrent features and benefits of Acurox™ Tablets. Acurox™ Tablets will have an anticipated indication for relieving moderate to severe pain with features and benefits intended to discourage or deter the most common methods of misuse and abuse including:

- intravenous injection of dissolved tablets,
- nasal snorting of crushed tablets, and

· intentional swallowing of excess quantities of tablets.

The FDA has stated that scientifically derived data and information describing the physical characteristics of a product candidate and/or the results of laboratory and clinical studies simulating product abuse may be acceptable to include in the product label. We intend to include in the labels of our product candidates both a physical description of the abuse deterrent characteristics and information from our multiple laboratory and clinical studies designed to simulate the relative difficulty of abusing our product candidates. The extent to which such information will be included in the FDA approved product label will be the subject of our discussions with and agreement by the FDA as part the NDA review process for each of our product candidates. Currently we expect to submit an NDA for Acurox™ Tablets by December 31, 2008. At the time of NDA submission we intend to request a priority review of the application by the FDA, and if accepted, we expect a third quarter, 2009 action date by the FDA. No assurance however can be provided that the FDA will grant a priority review of our 505(b)(2) NDA submission or that our anticipated submission timing will be achieved.

Oxycodone Extraction Study

We, through a CRO, completed a study to assess quantitatively and qualitatively the relative difficulty of extracting oxycodone HCl for purposes of I.V. injection from tablet products containing oxycodone HCl. The CRO was provided with a list of all ingredients (active and inactive) contained in each product, allotted up to 80 hours total time to complete the evaluations, and allowed to use any methodology desired to attempt to extract oxycodone HCl from the tablets in a form suitable for I.V. injection. Products tested were Acurox™ (oxycodone HCl/niacin) Tablets and commercially available OxyContin® (oxycodone HCl) Controlled-Release Tablets, generic oxycodone HCl Tablets, and Percocet® (oxycodone HCl/acetaminophen) Tablets. We intend to utilize the data and results from this laboratory study in our 505(b)(2) NDA submission to the FDA for Acurox™ Tablets. The results of the study are summarized below:

Summary Results of Acurox™ Tablets Laboratory
Oxycodone Extraction Study (described above)

Product Tested, Oxycodone HCl Strength and Product Supplier	**Approximate laboratory time required to produce a form suitable for intravenous injection**	**Extraction Scheme and Yield**	**Extraction Difficulty Rating 1 = Easy to 10 = Difficult**
OxyContin®Tablets 1x 40 mg tablet Purdue Pharma	3 minutes	3 steps ~92% Yield	1
Oxycodone HCl Tablets 8 x 5 mg tablets, Mallinckrodt	6 minutes	3 Steps ~71% Yield	2
Percocet Tablets 8 x 5/325 mg tablets Endo Labs	<10 minutes with vacuum assisted filtration	3 Steps ~75% Yield	3-4
Acurox™ Tablets 8 x 5/30 mg tablets Acura Pharmaceuticals	355 minutes with no success	23 Steps ~0% Yield	10

Niacin Dose Response Clinical Studies in Healthy Subjects

We, through CRO's, completed three clinical studies to determine the optimal amount of niacin to include in our product candidates. The objective of these studies was to determine the amount of niacin that when administered at the expected recommended dose is well tolerated while becoming increasingly difficult to tolerate when administered in excess of the expected recommended dose. We intend to include the data of each of the three clinical studies referenced below in our 505(b)(2) NDA submission to the FDA for Acurox™ Tablets.

Clinical Studies Evaluating Niacin Dose Response in Healthy Subjects		**Study Status**
AP-ADF-101	Phase I: Niacin dose-response (0-75 mg)	Final study report complete
AP-ADF-103	Phase II: Repeat dose safety and tolerability	Final study report complete
AP-ADF-107	Phase II: Niacin dose-response (0-600 mg)	Final study report complete

Study AP-ADF-101 or Study 101: Study 101 was a Phase I clinical trial in 50 healthy subjects with the objective of assessing the safety and tolerability of niacin, determining the appropriate strength of niacin to use in Acurox™ Tablets and evaluating the effect of food on niacin-induced flushing. All subjects received up to five doses of niacin (15, 30, 45, 60 and 75 mg) and one placebo dose taken orally in tablet form on separate days (up to six days) in a random sequence. In the fasted subjects, the 15 and 30 mg doses of niacin were generally similar to placebo in the number of subjects reporting niacin symptoms, the total number of niacin symptoms reported and overall tolerability ratings of "no effect" or "easy to tolerate". In the fasted subjects there was an increase in the number of subjects reporting niacin symptoms and the total number of niacin symptoms reported in the 45 mg, 60 mg and 75 mg doses versus the 30 mg doses. The data suggest that the niacin ingredient in Acurox™ Tablets should be well tolerated by most subjects with minimal, if any, side effects when Acurox™ Tablets are orally administered at expected recommended doses. Niacin related side effects were not observed at any dose in subjects who took niacin with food.

Study AP-ADF-103 or Study 103: Study 103 was a Phase II clinical trial in 66 healthy subjects assessing the safety and tolerability of Acurox™ (oxycodone/niacin) Tablets 5/30 mg at intended dosing in comparison to oxycodone HCl tablets 5 mg without niacin. Subjects were randomly assigned to one of three treatment groups each of which included 5 mg of oxycodone and varying amounts of niacin (0, 30 and 60 mg). A five day run-in phase included at-home dosing four times daily and adverse event and tolerability assessments. A five day treatment phase followed the run-in phase. The treatment phase included dosing with Acurox™ Tablets (with or without niacin) and post-treatment safety and tolerability assessments. Efficacy was measured by the tolerability of Acurox and was evaluated with a Side Effects and Symptoms Questionnaire (SESQ) and an Acurox™ Tolerability Rating Scale.

During the run-in phase, comparable tolerability was demonstrated in subjects who took Acurox™ Tablets with and without niacin. The mean post-dose SESQ total score during the run-in phase was very low in all groups indicating that Acurox™ was generally well-tolerated when taken at expected recommended doses. During the treatment phase, 64% of subjects in Groups 2 and 3 (oxycodone HCl + niacin) reported side effects and symptoms and 50% of subjects in Group 1 (oxycodone alone) reported side effects and symptoms. Most of the side effects and symptoms observed during the treatment phase were mild or moderate in severity. Irrespective of treatment group, approximately three quarters of subjects reported either "no effect" or "easy to tolerate" on the Acurox™ Tolerability Rating Scale. Oxycodone HCl administered four times a day, with or without niacin, was determined to be well tolerated. Adverse events were reported by 77% of subjects throughout both phases of the study. The majority of subjects (55%) reported adverse events during the treatment phase that were considered mild in severity. No severe adverse events were reported in any treatment group and no clinically important trends over time were observed in any treatment group for vital signs measurements.

Study AP-ADF-107 or Study 107: Study 107 was a Phase II clinical trial in 50 healthy volunteers evaluating the dose-response for niacin-induced flushing, safety, and tolerability of the Acurox™ Tablet matrix (excluding oxycodone HCl) at various dose levels in both fasted and fed subjects. Each subject randomly received eight oral doses of niacin (30, 60, 90, 120, 240, 360, 480, and 600 mg) and three doses of placebo on eleven separate days. Half of the subjects took each dose of study drug following a FDA standardized high-fat breakfast and half remained fasted for at least 2 hours after study drug administration. With fasted subjects, there was minimal or no effect of niacin at doses of 30 to 60 mg, with ³96% of subjects reporting either "no effect" or "easy to tolerate". Niacin was also well tolerated at doses of 90 mg, with 86% of fasted subjects reporting either "no effect" or "easy to tolerate" and 14% reporting "mildly unpleasant, but tolerable". As niacin doses escalated from 120 to 360 mg, a transition occurred resulting in a larger proportion of fasted subjects (22% to 73%) reporting mildly unpleasant, unpleasant, or intolerable effects. At doses of 480 and 600 mg, most fasted subjects (³86%) reported mildly unpleasant, unpleasant, or intolerable effects. At least 40% of subjects dosed at 480 and 600 mg reported either "unpleasant and difficult to tolerate" or "intolerable and would never take [niacin] again". All fed subjects receiving 30 to 240 mg niacin reported "no effect" or "easy to tolerate". In fed subjects, niacin was also generally well tolerated at doses of 360 to 600 mg with most fed subjects (³68%) reporting "no effect" or "easy to tolerate". The majority of fasted subjects (54% to 88%) reported flushing at doses of 240 to 600 mg;

while the majority of fed subjects (64%) did not report flushing until doses of 600 mg.

Clinical Studies to Evaluate Tolerability of Nasal Snorting and Excess Oral Doses in Subjects with a History of Opioid Abuse		**Study Status**
AP-ADF-106	Phase I: Evaluate relative safety, tolerability, pharmacokinetics, subjective effects and potential abuse liability of intra-nasally administered crushed Acurox™ Tablets, crushed generic oxycodone HCl tablets and pure oxycodone HCl powder	Subject enrollment complete. Final clinical study report expected Q4 2008
AP-ADF-102	Phase II: Evaluate relative dislike of oxycodone HCl/niacin versus oxycodone HCl alone	Final study report complete
AP-ADF-111	Phase II: Evaluate potential abuse liability of Acurox™ Tablets versus oxycodone HCl alone	Subject enrollment complete and principal investigator's report complete. Final clinical study report expected Q4 2008

Study AP-ADF-106 or Study 106: This will be a two part Phase I, single blind, randomized, clinical study, in 10 subjects with a history of recreational nasal opioid abuse to assess the potential abuse liability of crushed Acurox™ Tablets, crushed generic oxycodone HCl tablets and pure oxycodone HCl powder. The primary objective of Part 1 will be to determine the maximum number of crushed Acurox™ Tablets that can reasonably be nasally snorted in a single administration by providing the subjects with escalating amounts of crushed Acurox™ Tablets starting at one half of a 7.5/30 mg tablet and increasing in half tablet increments on successive days. Part 1 will also assess over the 8 hours following administration vital signs, subjective ratings of liking and somatic discomfort and objective assessments of the nasal cavity. Part 2 will assess the relative abuse liability of intra-nasally administered crushed Acurox™ Tablets, pure oxycodone powder and crushed generic oxycodone HCl immediate release tablets, all with a quantity of oxycodone HCl equivalent to the group median highest tolerated dose of Acurox™ Tablets determined in Part 1. Part 2 measurements will be made over 12 hours and include vital signs, subjective measures of liking and somatic (bodily) discomfort, objective assessments of the nasal cavity and the pharmacokinetics of oxycodone absorbed through the mucosal membrane. Subject enrollment in Study 106 is complete and we expect study results in the forth quarter of 2008.

Study AP-ADF-102 or Study 102: Study 102 was a Phase II, single center, randomized, double blind crossover design clinical trial in 24 subjects with a history of opioid abuse with a primary endpoint to assess, whether the subjects disliked the drug effect they were feeling when varying levels of niacin were administered in combination with 40 mg of oxycodone HCl compared to 40 mg oxycodone (alone) and a placebo. Each subject was randomized to a dosing sequence that included doses of niacin (0, 240, 480 , and 600 mg) administered in combination with 40 mg oxycodone, while the subjects were fasted and 600 mg niacin in combination with 40 mg oxycodone administered following a standardized high-fat meal. Each dosing day, vital sign measures and subjective and behavioral effects were assessed before dosing (baseline) and at 0.5, 1, 1.5, 2, 3, 4, 5, 6, and 12 hours after dosing. After completion of the study, subjects responded to a Treatment Enjoyment Assessment Questionnaire to select which of the treatments they would take again. The maximum scale response to the question “Do you dislike the drug effect you are feeling now?” (i.e., the “Disliking Score”), was designated as the primary efficacy variable. Study results were as follows:

(1) In the fasting state, all three doses of niacin in combination with oxycodone 40mg produced significant (p less than or equal to .05) Disliking Scores compared to oxycodone 40mg alone. No other subjective measure was significantly affected by the niacin addition to oxycodone.

(2) The high fat meal eliminated the niacin effect and also delayed the time to oxycodone peak blood levels.

(3) The addition of niacin to oxycodone alters the subjective response to oxycodone as indicated by the significant responses on the Disliking Score. This observation in conjunction with the results from the Treatment Enjoyment Questionnaire indicates that the addition of niacin reduces the attractiveness of oxycodone to opiate abusers.

(4) There were no serious adverse events. Niacin produced a dose related attenuation of pupillary constriction, diastolic blood pressure increase and probably systolic blood pressure increase produced by oxycodone. The alterations by niacin on the vital sign responses to oxycodone 40 mg were minimal, were seen primarily with the 600 mg niacin dose and were not clinically significant.

The principal study investigator's overall conclusion was that the results of Study 102 supported the hypothesis that the addition of niacin to oxycodone in a minimal ratio of 30 mg niacin to 5 mg oxycodone is aversive when compared to oxycodone alone. The addition of niacin did not alter the safety profile of oxycodone alone. We intend to include the data and results from Study 102 in our 505(b)(2) NDA submission for Acurox™ Tablets to the FDA.

Study AP-ADF-111 or Study 111: Study 111 is entitled "A Phase II, Single-Center, Randomized, Double-Blind, Assessment of the Abuse Liability of Acurox™ (oxycodone HCl and niacin) Tablets in Subjects with a History of Opioid Abuse". In Study 111, 30 fasted subjects with a history of opioid abuse received a single dose of study drugs every 48 hours for 9 days and were enrolled in two dosing sequences. The first dosing sequence (Sequence 1) included randomized doses of (i) niacin 240mg alone; (ii) a combination of oxycodone HCl 40mg with niacin 240mg (4 times the expected recommended dose of Acurox™ Tablets 5/30mg); and (iii) placebo tablets. The objective of Sequence 1 was to assess the effects of oxycodone HCl on the effects of niacin. The second dosing sequence (Sequence 2) included randomized doses of (i) a combination of oxycodone HCl 40mg with niacin 240mg (4 times the expected recommended dose of Acurox™ Tablets 5/30mg) and (ii) oxycodone HCl 40mg alone. Sequence 2 was designed to assess the abuse liability and abuse deterrence potential of Acurox™ Tablets versus oxycodone HCl alone. On each dosing day, vital sign measures and subjective and behavioral effects were assessed before dosing (baseline) and at 0.5, 1, 1.5, 2, 3, 4, 5, 6, and 12 hours after dosing. Vital signs included measurement of pupil size, blood pressure, heart rate, oral temperature and respiratory rate. For both Sequence 1 and Sequence 2, subjective changes were measured with a two item Drug Rating Questionnaire-Subject (DRQS) and a 40 item short form of the Addiction Research Center Inventory (ARCI). The ARCI was comprised of three scale scores including the Morphine Benzedrine Group scale (MBG) measuring euphoria, the LSD/dysphoria scale measuring somatic/bodily discomfort and dysphoria and the Pentobarbital Chlorpromazine Alcohol Group scale (PCAG) measuring apathetic sedation. For Sequence 2 only, in addition to the DRQS and ARCI, subjects also completed a Street Value Assessment Questionnaire and a Treatment Enjoyment Assessment Questionnaire.

Sequence 1 results demonstrated that response to niacin 240 mg alone compared to placebo causes significant dislike scores ($p = .03$), and significant LSD/dysphoria scores ($p < .001$) with these negative niacin induced effects manifesting rapidly, reaching peak at 0.5-1.5 hours and thereafter diminishing. At 0.5 hours after drug administration, oxycodone HCl 40 mg has limited effect on niacin-induced disliking and dysphoric effects. At the one hour observation and afterward, oxycodone may attenuate niacin-induced disliking and dysphoric effects.

Sequence 2 demonstrated that the combination of oxycodone HCl 40mg and niacin 240mg (4 times the expected recommended dose of Acurox™ Tablets 5/30mg) had the potential to be aversive when compared to oxycodone HCl 40mg alone as shown by statistically significant and clinically meaningful results in the dislike/like scores ($p = .033$), the Treatment Enjoyment Assessment scores ($p = .005$) and the LSD/dysphoria scores ($p<.001$). The dislike/like score at 0.5 hours was designated the primary measure of abuse liability and abuse deterrence potential for Acurox™ Tablets 5/30mg and the Treatment Enjoyment Assessment scores and LSD/dysphoria scores at 0.5 hours were additional measures of the abuse deterrence potential of Acurox™ Tablets. Subjective measures not achieving statistical significance included the MBG scores measuring euphoria, the PCAG score measuring apathetic sedation and the Street Value Assessment Questionnaire score, in which subjects indicated they would pay more for oxycodone HCl alone compared to Acurox™ Tablets ($p=.097$).

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In this study of 30 subjects with a history of opioid abuse there were no serious adverse events reported. Alterations by niacin compared to placebo on vital signs were minimal and not clinically meaningful. The differences in vital signs between oxycodone HCl/niacin and niacin alone at 4 times the expected recommended dose of Acurox™ Tablets were minimal and not clinically meaningful.

	Clinical Study to Evaluate Efficacy and Safety in Patients with Moderate to Severe Pain	Study Status
AP-ADF-105	Phase III: Pivotal efficacy and safety	Final study report complete

Study AP-ADF-105 or Study 105: Study 105 is entitled "A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter, Repeat-dose Study of the Safety and Efficacy of Acurox™ (oxycodone HCl and niacin) Tablets versus Placebo for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Patients." A total of 405 patients were randomized to one of three treatment arms of approximately 135 patients per arm. One treatment arm received a dose of two Acurox™ Tablets 5/30 mg, a second treatment arm received a dose of two Acurox™ Tablets 7.5/30 mg, and the third treatment arm received a dose of two placebo tablets. Study drugs were administered every 6 hours for 48 hours. The primary endpoint was the sum of the difference in pain intensity, measured on a 100mm visual analog scale (VAS), compared to baseline over a 48 hour period ("$SPID_{48}$"). Prior to initiating Study 105, the study design, endpoints and statistical analysis plan were submitted to and agreed by the FDA under a Special Protocol Assessment and the study was conducted accordingly. Results of Study 105 demonstrate that compared to placebo, Acurox™ Tablets 5/30 mg and 7.5/30 mg both met the primary pain relief endpoint with p=.0001 and p<.0001, respectively. Acurox™ Tablets were generally well tolerated with the most prevalent reported adverse events in patients receiving Acurox™ Tablets being nausea, vomiting, dizziness, pruritus and flushing; side effects known to be consistent with opioid and niacin therapies. Most adverse events were mild or moderate and there were no serious adverse events. Six patients (2.2%) receiving Acurox™ Tablets withdrew from the study due to treatment-emergent adverse events compared with no withdrawals due to treatment-emergent adverse events for the placebo group. We intend to include the data and results from Study 105 in our 505(b)(2) NDA submission for Acurox™ Tablets.

Expectations for Acurox™ Tablets Product Labeling

The FDA has publicly stated that explicit claims of abuse deterrence will not be permitted in product labeling unless such claims are supported by double blind controlled clinical studies demonstrating an actual reduction in product abuse by patients or drug abusers. We believe the cost, time and practicality of designing and implementing clinical studies adequate to support explicit labeling claims of abuse deterrence are prohibitive. The FDA has stated that scientifically derived data and information describing the physical characteristics of a product candidate and/or the results of laboratory and clinical studies simulating product abuse may be acceptable to include in the product label. We intend to include in the labels of our Aversion® Technology product candidates both a physical description of the abuse deterrent characteristics and information from our multiple laboratory and clinical studies designed to simulate the relative difficulty of abusing our product candidates. The extent to which such information will be included in the FDA approved product label will be the subject of our discussions with and agreement by the FDA as part of the NDA review process for each of our product candidates. Further, because FDA closely regulates promotional materials, even if FDA initially approves labeling that includes a description of the abuse deterrent characteristics of the product, the FDA will continue to review the acceptability of promotional labeling claims and product advertising campaigns for our product candidates.

King Agreement

In October, 2007, we entered into a License, Development and Commercialization Agreement with King Research and Development, Inc. (the "King Agreement") to develop and commercialize certain opioid analgesic products utilizing our proprietary Aversion® Technology in the United States, Canada and Mexico (the "King Territory"). Development and commercialization of all product candidates are directed by a joint steering committee. We are responsible for developing at least four opioid analgesic product candidates to pre-specified development and regulatory milestones. We are responsible for compiling, submitting and obtaining U.S. regulatory approval with the FDA for an NDA for Acurox™ Tablets and assisting King in obtaining FDA approval and other approvals in the King Territory for all other product candidates licensed to King. King will be responsible for commercial manufacturing, marketing, selling and distributing licensed products in the King Territory.

In December 2007, upon closing the King Agreement, we received from King a non-refundable upfront cash payment of $30.0 million in consideration for a license to Acurox™ Tablets and a second undisclosed opioid product candidate, and an option to license in the King Territory all future opioid analgesic products developed by us utilizing Aversion® Technology. Pursuant to the King Agreement, King will reimburse us for all research and development expenses incurred by us for Acurox™ Tablets beginning from September 19, 2007 and all research and development expenses incurred by us related to future products after King's exercise of its option to exclusively license each future product. From September 19, 2007 through September 30, 2008, we have been paid and/or accrued $10.0 million in research and development expense reimbursement from King.

In May 2008, King exercised its option to a 3rd undisclosed opioid product candidate and paid us a $3.0 million option exercise fee. In June 2008, King paid us a $5.0 million milestone fee upon the successful achievement of the primary endpoints for our pivotal Phase III clinical study for Acurox™ Tablets. We may receive up to $23 million in additional non-refundable payments for each product candidate licensed to King, including Acurox™, by achieving certain regulatory milestones in specific countries in the King Territory. We can also receive option fees for additional opioid product candidates licensed to King as well as a one-time $50 million sales milestone upon the first attainment of $750 million in net sales of all our licensed products across all King Territories. In addition, following the first anniversary of the first commercial sale of a licensed product in the U.S., King will pay us royalties ranging from 5% to 25% depending on the combined annual net sales of all products licensed by us to King across all King Territories, with the highest applicable royalty rate applied to such combined annual sales.

The foregoing description of the King Agreement contains forward-looking statements about Acurox™ Tablets, and other products being developed pursuant to the King Agreement. As with any pharmaceutical products under development or proposed to be developed, substantial risks and uncertainties exist in development, regulatory review and commercialization process. There can be no assurance that any product developed, in whole or in part, pursuant to the King Agreement will receive regulatory approval or prove to be commercially successful. Accordingly, investors in the Company should recognize that there is no assurance that the Company will receive the milestone payments or royalty revenues described in the King Agreement or even if such milestones are achieved, that the related products will be successfully commercialized and that any royalty revenues payable to us by King will materialize. For further discussion of other risks and uncertainties associated with the Company, see Item 1A in Part II in this Report and our Annual Report on Form 10-K for the year ended December 31, 2007, under the heading “Risks Factors”.

Patents and Patent Applications

In April 2007, the United States Patent and Trademark Office (“USPTO”), issued to us a patent titled “Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms”. The 54 allowed claims in this patent encompass certain pharmaceutical compositions intended to deter the most common methods of prescription opioid analgesic product misuse and abuse. These patented pharmaceutical compositions include specific opioid analgesics such as oxycodone, hydrocodone, hydromorphone, morphine, codeine, tramadol, and propoxyphene, among others. We believe this patent covers all of our opioid product candidates currently in development.

In June 2008, the USPTO issued to us a Notice of Allowance for 21 claims for a non-provisional patent application titled “Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms” (the “122 Application”). Upon consideration of a potential interference proceeding between the 122 Application and a third party patent application containing a claim similar to a claim in our 122 Application, we filed with the USPTO a petition to withdraw the 122 Application and a Request for Continued Examination of the 122 Application. We also simultaneously cancelled from the 122 Application the claim similar to the claim included in the third party patent application. In September 2008 the USPTO issued to the Company a second Notice of Allowance for the remaining 20 claims in the 122 Application. Although we do not believe there is a basis for the USPTO to declare an interference, at this stage we can make no assurances that the USPTO will not declare an interference relating to any of the 20 claims contained in the second Notice of Allowance for our 122 Application.

In September 2008, the USPTO also issued to us a Notice of Allowance for 18 claims for a non-provisional patent application encompassing certain combinations of *kappa* and *mu* opioid receptor agonists intended to deter opioid analgesic product misuse and abuse.

In addition to our issued U.S. Patent and the two Notice of Allowances issued in September 2008, we also have five U.S. non-provisional pending patent applications, three WO/PCT pending patent applications, and multiple

international patent applications filed relating to compositions containing abuseable active pharmaceutical ingredients. Except for those rights conferred in the King Agreement, we have retained all intellectual property rights to our Aversion® Technology and related product candidates.

Reference is made to Part II, “Item 1A. Risk Factors Relating to the Company” for a discussion, among other things, of pending patent applications owned by third parties including claims that may encompass our Acurox® Tablets and other product candidates. If such third party patent applications result in valid and enforceable issued patents containing claims in their current form, we or our licensees could be required to obtain a license to such patents, should one be available, or alternatively, to alter our product candidates to avoid infringing such third-party patents.

Company’s Present Financial Condition

At October 24, 2008, we had cash, cash equivalents and short term investments of approximately $35.0 million. We estimate that our current cash reserves will be sufficient to fund operations and the development of Aversion® Technology and related product candidates through at least the next 12 months.

As described in Note 10 - Recent Events, in December, 2007, we and King Research and Development Inc., ("King") closed a License, Development and Commercialization Agreement (the “King Agreement”) to develop and commercialize certain opioid analgesic products utilizing our proprietary Aversion® Technology in the United States, Canada and Mexico. During the nine months ended September 30, 2008, we recognized revenues of $20.7 million of the $30.0 million upfront cash payment received from King in December 2007, recognized a $3.0 million option exercise fee paid to us by King upon the exercise of its option to license a third opioid analgesic product candidate, recognized a $5.0 million Acurox™ Tablet development milestone received from King, and recognized revenues for reimbursement by King of our Acurox™ Tablet development expenses. We have yet to generate any royalty revenues from product sales. We expect to rely on our current cash resources and additional payments that may be made under the King Agreement and under similar license agreements with other pharmaceutical company partners, of which there can be no assurance, in funding our continued operations. Our cash requirements for operating activities may increase in the future as we continue to conduct pre-clinical studies and clinical trials for our product candidates, maintain, defend, if necessary and expand the scope of our intellectual property, hire additional personnel, or invest in other areas.

Results of Operations for the Nine Month Period Ended September 30, 2008 and 2007

	September 30,		Change	
($ in thousands):	**2008**	**2007**	**Dollars**	**%**
Revenue				
Program fee revenue	$ 23,678	$ -	$ 23,678	*%
Milestone revenue	5,000	-	5,000	*
Collaboration fee revenue	7,971	-	7,971	*
Revenue	36,649	-	36,649	*
Operating Expenses				
Research and development expenses	10,859	2,775	8,084	291
Marketing, general and administrative expenses	5,617	1,959	3,658	187
Total operating expenses	16,476	4,734	11,472	242
Operating income (loss)	20,173	(4,734)	24,907	526
Other Income (Expense)				
Interest income (expense), net	675	(1,033)	1,708	165
Amortization of debt discount	-	(2,700)	(2,700)	(100)
Loss on fair value change of conversion features	-	(3,483)	(3,483)	(100)
	-	(1,904)	(1,904)	(100)

Loss on fair value change of common stock warrants							
Gain on asset disposals		1		22		(21)	(95)
Other expense		-		(2)		(2)	(100)
Total other income (expense)		676		(9,100)		9,776	107
Income (loss) before income tax expense		20,849		(13,834)		34,683	251
Income tax expense (benefit)		3,382		-		(3,382)	*
Net income (loss)	$	17,467	$	(13,834)	$	31,301	226%

Revenue

In December 2007, King paid us a $30.0 million upfront fee in connection with the closing of the King Agreement. Program fee revenue recognized for the nine month period ended September 30, 2008 from amortization of this upfront fee was $20.7 million. We have assigned a portion of the program fee revenue to each of three product candidates identified under the King Agreement and expect to recognize the remainder of the program fee revenue ratably over our estimate of the development period for each of these product candidates identified in the King Agreement. We currently estimate the development period to extend through November, 2009. Also, included in program fee revenue is a $3.0 million option exercise fee paid by King to us in May 2008 upon the exercise of its option to license a third opioid analgesic product candidate under the King Agreement. The Company had no program fee revenue for the nine month period ended September 30, 2007.

In June 2008, King paid us a $5.0 million milestone payment for successfully achieving the primary end points in our pivotal Phase III study, AP-ADF-105 for Acurox™ Tablets. The Company had no milestone revenue for the nine month period ended September 30, 2007.

Collaboration revenue recognized for the nine month period ended September 30, 2008 was $8.0 million for billed reimbursement of our Acurox™ Tablets development expenses incurred pursuant to the King Agreement from January 1, 2008 to September 30, 2008. We invoice King in arrears on a calendar quarter basis for our reimbursable development expenses under the King Agreement. We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying research and development expenses. The Company had no collaboration revenue for the nine month period ended September 30, 2007.

Operating Expenses

Research and development expense during the nine month periods ended September 30, 2008 and 2007 were for product candidates utilizing our Aversion® Technology, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2008 and 2007 results are non-cash stock-based compensation charges of $0.6 million and $0.4 million, respectively. Excluding the stock-based compensation expense, there is an $8.0 million increase in development expenses primarily attributable to increasing clinical study costs, including our pivotal Phase III clinical trial for Acurox™.

Marketing expenses during the nine month periods ended September 30, 2008 and 2007 consisted of Aversion® Technology primary market data research studies. Our general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll costs. Included in the 2008 and 2007 results are non-cash stock-based compensation charges of $1.8 million and $0.5 million, respectively. Excluding the stock-based compensation expense, there is an increase of $2.4 million in general and administrative expenses including $240 legal services, $106 audit and tax services, $369 state franchise taxes, $168 tax reserves, $65 market data research, $28 corporate insurance premium, $141 shareholder services and $1.1 million payroll and incentive compensation accruals.

Other Income (Expense)

Through August 19, 2007 we incurred interest expense on our $5.0 million Secured Term Note at a variable interest rate of prime plus 4.5% per annum and thereafter at a fixed interest rate of 10.0% per annum. Interest expense on this note was paid in common stock through August 19, 2007 and thereafter in cash which deferred until we fully repaid the note on December 7, 2007. In 2007, we also incurred interest expense on our $10.544 million Senior Secured Convertible Bridge Notes (collectively, the “Bridge Loans”) at the fixed rate of 10.0%. Interest on such Bridge Loans was paid in our common stock. On August 20, 2007, the entire $10.544 million principal amount of the Bridge Loans was converted into Units consisting of our common stock and warrants in accordance with our Unit Offering. During the nine month period ended September 20, 2008, the cash proceeds received pursuant to the King Agreement were primarily invested in bank commercial paper with maturity dates less than 12 months and in overnight sweep

investments, resulting in interest income of $676.

Net Income (Loss)

The Company's net income for the nine month period ended September 30, 2008 includes a provision for an income tax expense of $8.4 million which has been offset by $5.0 million of income tax benefits recorded from the anticipated utilization of the Company's deferred tax assets. The Company anticipates the utilization of its deferred tax assets to offset income taxes payable and has reflected such expectation in our September 30, 2008 Balance Sheet.

The Company's net loss for the nine month period ended September 30, 2007 includes a) debt discount amortization expense of $2.7 million arising from values assigned to conversion features on issuances of bridge loans, b) $3.5 million loss on fair value changes to amended conversion features on bridge loans being accounted for as mark-to-market liabilities c) $1.9 million loss on fair value changes to common stock warrants being accounted for as mark-to-market liabilities and (d) $4.7 million is operating and other losses.

Results of Operations for the Three Month Period Ended September 30, 2008 and 2007

	September 30,		Change	
($ in thousands):	**2008**	**2007**	**Dollars**	**%**
Revenue				
Program fee revenue	$ 1,263	$ -	$ 1,263	*%
Collaboration fee revenue	2,617	-	2,617	*
Revenue	3,880	-	3,880	*
Operating Expenses				
Research and development expenses	3,693	827	2,866	347
Marketing, general and administrative expenses	3,373	593	2,780	469
Total operating expenses	7,066	1,420	5,646	398
Operating loss	(3,186)	(1,420)	1,766	124
Other Income (Expense)				
Interest income (expense), net	171	(224)	395	177
Amortization of debt discount	-	(598)	(598)	(100)
Loss on fair value change of common stock warrants	-	(236)	(236)	(100)
Gain on asset disposals	-	2	(2)	(100)
Other expense	(17)	-	17	*
Total other income (expense)	154	(1,056)	1,210	115
Loss before income tax benefit	(3,032)	(2,476)	556	23
Income tax benefit	(6,180)	-	6,180	*
Net income (loss)	$ 3,148	$ (2,476)	$ 5,624	227%

Revenue

King paid us a $30.0 million upfront fee in connection with the closing of the King Agreement in December 2007. Revenue recognized in the three month period ended September 30, 2008 from amortization of this upfront fee was $1.3 million. We have assigned a portion of the program fee revenue to each of three product candidates identified under the King Agreement and expect to recognize the remainder of the program fee revenue ratably over our estimate of the development period for each of these product candidates identified in the King Agreement. We currently estimate the development period to extend through November, 2009. The Company had no program fee revenue for the three month period ended September 30, 2007.

Collaboration revenue recognized in the three month period ended September 30, 2008 was $2.6 million for billed reimbursement of our Acurox™ tablet development expenses incurred pursuant to the King Agreement from July 1, 2008 to September 30, 2008. We invoice King in arrears on a calendar quarter basis for our reimbursable development expenses under the King Agreement. We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying research and development expenses. The Company had no collaboration revenue for the three month period ended September 30, 2007.

Operating Expenses

Research and development expense during the three month periods ended September 30, 2008 and 2007 were for product candidates utilizing our Aversion® Technology, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2008 and 2007 results are non-cash stock-based compensation charges of $0.4 million and $0.1 million, respectively. Excluding the stock-based compensation expense, there is a $2.6 million increase in development expenses primarily attributable to clinical study costs for Acurox™.

Marketing expenses during the three month period ended September 30, 2008 and 2007 consisted of Aversion® Technology primary market data research studies. Our general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll. Included in the 2008 and 2007 results are non-cash stock-based compensation charges of $1.1 million and $0.1 million, respectively. Excluding the stock-based compensation expense, there is a $1.8 million increase in general and administrative expenses including $87 legal services, $55 audit and tax services, $369 state franchise taxes, $168 tax reserves, $95 market data research and $1.0 million payroll and incentive compensation accruals.

Other Income (Expense)

Through August 19, 2007 we incurred interest expense on our $5.0 million Secured Term Note at a variable an interest rate of prime plus 4.5% per annum and thereafter at a fixed interest rate of 10.0% per annum. Interest expense on this note was paid in common stock through August 19, 2007 and thereafter in cash which was deferred until we fully repaid the note on December 7, 2007. In 2007, we also incurred interest expense on our $10.544 million Senior Secured Convertible Bridge Notes (collectively, the "Bridge Loans") at the fixed rate of 10.0%. Interest on such Bridge Loans was paid in our common stock. On August 20, 2007, the entire $10.544 million principal amount of the Bridge Loans was converted into Units consisting of our common stock and warrants in accordance with our Unit Offering. During the three month period ended September 30, 2008, the cash proceeds received pursuant to the King Agreement were primarily invested in bank commercial paper with maturity dates less than 12 months and in overnight sweep investments resulting in interest income of $171.

Net Income (Loss)

The Company's net income for the three month period ended September 30, 2008 includes a provision for an income tax benefit of $1.16 million from the periods operating results and by $5.0 million of income tax benefits recorded from the anticipated utilization of the Company's deferred tax assets. The Company anticipates the utilization of its deferred tax assets to offset income taxes payable and has reflected such expectation in our September 30, 2008 Balance Sheet.

The Company's net loss for the three month period ended September 30, 2007 includes debt discount amortization expense of $0.6 million arising from values assigned to conversion features on issuances of Bridge Loans, $0.2 million loss on fair value changes to common stock warrants being accounted for as mark-to-market liabilities, and $1.4 million in operating and other losses.

Liquidity and Capital Resources

At September 30, 2008, the Company had unrestricted cash, cash equivalents and short-term investments of $35.9 million compared to $31.4 million in aggregate cash and cash equivalents at December 31, 2007. The Company had working capital of $34.9 million at September 30, 2008 compared to $22.3 million at December 31, 2007. The increase in our cash position of $4.5 million is primarily due to our receipt from King of a $3.0 million option exercise fee and a $5.0 million milestone payment. The increase in working capital of $12.6 million is primarily due to the recognition of a portion of the deferred program fee revenue offset by the utilization of our deferred tax assets against our recorded income tax provision and our receipt of the option exercise fee and milestone payment described above. Cash flows generated in operating activities were $4.7 million for the nine month period ended September 30, 2008

primarily representing net income for the period recognizing certain non cash items such as deferred program fee revenue, net deferred tax assets, and charges for stock compensation. Cash flow used in operating activities for the nine month period ended September 30, 2007 primarily represented our net losses for the period less non-cash charges related to amortization of debt discount, fair value changes of conversion features and common stock warrants, stock compensation and common stock issued for interest. Capital expenditures of $0.1 million and our purchase of short-term investments of $5.0 million were our financing activities for the 2008 period. Capital expenditures offset by proceeds from asset disposal include cash flows used in investing activities for the 2007 period was $10,000. The cash exercise of a warrant for $20,000 constituted our financing activities for the 2008 period. Our financing activities of $16.8 million for the 2007 nine month period related primarily to additional bridge loan borrowings and proceeds under the Company’s Unit Offering.

At October 24, 2008, the Company had cash, cash equivalents, and short-term investments of approximately $35.0 million. The Company estimates that such cash reserves will be sufficient to fund the development of Aversion® Technology product candidates and related operating expenses at least through the next 12 months.

The following table presents the Company's expected cash requirements for contractual obligations outstanding as of September 30, 2008 (in thousands):

Expected cash payments under contractual obligations outstanding at September 30, 2008	**Total**	**Due in 2008**	**Due in 2009**	**Due in 2010**	**Due Thereafter**
Clinical trials and services	$ 2,779	$ 2,779	$ -	$ -	$ -
Operating leases	14	7	7	-	-
Employment agreements	1,134	604	410	120	-
Marketing research studies	40	40	-	-	-
Total contractual cash obligations	$ 3,967	$ 3,430	$ 417	$ 120	$ -

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company's 2007 Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company does not believe there is a consequential likelihood that materially different amounts would be reported under different conditions or using different assumptions. The Company's critical accounting policies described in the 2007 Annual Report are also applicable to 2008.

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 2008 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II

Item 1A. ***Risk Factors Relating To The Company***

In addition to the Risk Factors set forth in Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2007, shareholders and prospective investors in the Company's common stock should carefully consider

the following risk factors. Each of the below risk factors updates the risk factor having the same or similar caption description in our 2007 Form 10-K.

Even if the FDA Approves Acurox™ for commercial distribution, if Acurox™ is not approved with labeling describing its abuse deterrent features, we will be unable to refer to the abuse deterrent characteristics of Acurox™ to promote the product.

Our strategy for Acurox™ depends upon our ability to distinguish Acurox™ from other immediate release oxycodone containing products based on its abuse deterrent features. As with all of our product candidates utilizing Aversion® Technology, even if Acurox™ is approved by the FDA, our failure to achieve approval of labeling that sufficiently differentiates Acurox™ from other immediate release oxycodone containing products may adversely affect our business and results of operations. The FDA has publicly stated that explicit product label claims of abuse deterrence will not be permitted unless such claims are supported by double blind controlled clinical studies demonstrating an actual reduction in product abuse by patients or drug abusers. Because the cost, time and practicality of designing and implementing clinical studies adequate to support explicit claims of abuse deterrence are prohibitive, we are not pursuing and have not conducted the clinical trials necessary to include an explicit product label claim of abuse deterrence.

Instead, we intend to rely on certain clinical and laboratory studies to support the inclusion of information about the physical, abuse deterrent characteristics of Acurox™ to support promotion that refers to the abuse deterrent characteristics of the product. We intend to include in the labels of our product candidates both a physical description of the abuse deterrent characteristics and information from our multiple laboratory and clinical studies designed to simulate the relative difficulty of abusing our product candidates. However, the extent to which such information will be included in the FDA approved product label will be the subject of our discussions with, and agreement by, the FDA as part of the NDA review process for each of our product candidates. The outcome of those discussions with the FDA will determined whether we will be able to market our product candidates with labeling that sufficiently differentiates them from competitive products with comparable therapeutic profiles but without abuse deterrent features. If the FDA does not approve the Acurox™ labeling with such information, we will not be able to promote Acurox™ based on its abuse deterrent features and may not be able to differentiate Acurox™ from other oxycodone products or be able to charge a premium price above the price of such competitive products which could adversely affect our business and results of operations.

Because FDA closely regulates promotional materials and other promotional activities, even if FDA initially approves labeling that includes a description of the abuse deterrent characteristics of the product, FDA may object to our marketing claims and product advertising campaigns.

We or our licensees may not obtain required FDA approval; the FDA approval process is time-consuming and expensive.

The development, testing, manufacturing, marketing and sale of pharmaceutical products are subject to extensive federal, state and local regulation in the United States and other countries. Satisfaction of all regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product candidate, and requires the expenditure of substantial resources for research, development and testing. Substantially all of our operations are subject to compliance with FDA regulations. Failure to adhere to applicable FDA regulations by us or our licensees would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive.

We or our licensees may encounter delays or rejections during any stage of the regulatory approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the product candidates to meet, the FDA’s requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of an NDA,

or a 505(b)(2) NDA, the FDA may refuse to file the application, deny approval of the application, require additional testing or data and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. The FDA commonly takes one to two years to grant final approval for an NDA, or 505(b)(2) NDA. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we or our licensees desire and could affect the marketability of products utilizing our Aversion® Technology.

Even if we comply with all the FDA regulatory requirements, we or our licensees may never obtain regulatory approval for any of our product candidates. If we or our licensees fail to obtain regulatory approval for any of our product candidates, we will have fewer commercialized products and correspondingly lower revenues. Even if regulatory approval of our products is received, such approval may involve limitations on the indicated uses or promotional claims we or our licensees may make for our products, or otherwise not permit a labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles but without abuse deterrence features. Such events would have a material adverse effect on our operations and financial condition.

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

The market may not be receptive to products incorporating our Aversion® Technology.

The commercial success of products utilizing our Aversion® Technology approved for marketing by the FDA and other regulatory authorities will depend on acceptance by health care providers and others that such products are clinically useful, cost-effective and safe. There can be no assurance given, even if we or our licensees succeed in the development of products utilizing our Aversion® Technology and receive FDA approval for such products, that products utilizing the Aversion® Technology would be accepted by health care providers and others. Factors that may materially affect market acceptance of products utilizing our Aversion® Technology include but are not limited to: (i) the relative advantages and disadvantages of products utilizing our Aversion® Technology compared to competitive products; (ii) the relative timing to commercial launch of products utilizing our Aversion® Technology compared to competitive products; (iii) the relative safety and efficacy of products utilizing our Aversion® Technology compared to competitive products; (iv) the labeling approved by the FDA for products utilizing our Aversion® Technology; and (v) the willingness of third party payors to reimburse for or otherwise pay for products utilizing our Aversion® Technology. Our product candidates, if successfully developed and commercially launched, will compete with both currently marketed and new products marketed by other companies. Health care providers may not accept or utilize any of our products. Physicians and other prescribers may not be inclined to prescribe the products utilizing our Aversion® Technology unless our products demonstrate commercially viable advantages over other products currently marketed for the same indications. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

Our success depends on our ability to protect our intellectual property.

Our success depends on our ability to obtain and maintain patent protection for products developed utilizing our Aversion® Technology, in the United States and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual questions. Notwithstanding our receipt of U.S. Patent No. 7,201,920 from the United States Patent and Trademark Office ("USPTO") for our opioid product candidates utilizing our Aversion® Technology, there is no assurance that any of our patent claims in our other pending non-provisional and provisional patent applications relating to our Aversion® Technology will issue or if issued, that any such patent claims will be valid and enforceable against third-party infringement or that our products will not infringe any third-party patent or intellectual property. Moreover, any patent claims relating to our Aversion® Technology may not be sufficiently broad to protect the products utilizing Aversion® Technology. In addition, issued patent claims may be challenged, potentially invalidated or potentially circumvented. Our patent claims may not afford us protection against competitors with similar technology or permit the commercialization of our products without infringing third-party patents or other intellectual property rights.

Our success also depends on our not infringing patents issued to others. We may become aware of patents belonging to competitors and others that could require us to obtain licenses to such patents or alter our technologies. Obtaining such licenses or altering our technology could be time consuming and costly. We may not be able to obtain a license to any technology owned by or licensed to a third party that we or our licensees require to manufacture or market one or more products utilizing our Aversion® Technology. Even if we can obtain a license, the financial and other terms may be disadvantageous.

Our success also depends on maintaining the confidentiality of our trade secrets and know-how. We seek to protect such information by entering into confidentiality agreements with employees, potential licensees, raw material suppliers, potential investors and consultants. These agreements may be breached by such parties. We may not be able to obtain an adequate, or perhaps, any remedy to such a breach. In addition, our trade secrets may otherwise become known or be independently developed by our competitors. Our inability to protect our intellectual property or to commercialize our products without infringing third-party patents or other intellectual property rights would have a material adverse affect on our operations and financial condition.

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

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

- litigation or other proceedings we may initiate against third parties to enforce our patent rights or other intellectual property rights;

- litigation or other proceedings we may initiate against third parties seeking to invalidate the patents held by such third parties or to obtain a judgment that our products do not infringe such third parties' patents;

- litigation or other proceedings third parties may initiate against us to seek to invalidate our patents or to obtain a judgment that third party products do not infringe our patents;

- if our competitors file patent applications that claim technology also claimed by us, we may be forced to participate in interference or opposition proceedings to determine the priority of invention and whether we are entitled to patent rights on such invention; and

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

Our failure to avoid infringing third-party patents and intellectual property rights in the commercialization of products utilizing the Aversion® Technology will have a material adverse affect on our operations and financial condition.

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

We are aware of one competitor who has suggested to the USPTO that the USPTO should declare an interference between that competitor's pending patent application and one of our patent applications which covers our lead product candidate. While we believe that there is no valid basis for declaring such an interference and that even if such an interference were declared that we would prevail, there can be no guarantee that such an interference will not be declared and ultimately succeed such that this competitor would obtain patent rights which could block our lead product candidate and other products.

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

Moreover, other parties could have blocking patent rights to products made utilizing the Aversion® Technology. We are aware of certain United States and international pending patent applications owned by third parties claiming abuse deterrent technologies, including pending patent applications owned by competitors which have claims encompassing our lead product candidate. While we do not expect that the claims contained in such pending patent applications will issue in their present form, there can be no assurance that such patent applications will not issue as patents with claims covering one or more of our products. If such patent applications result in valid and enforceable issued patents, containing claims in their current form or otherwise covering our products we or our licensees could be required to obtain a license to such patents, should one be available, or alternatively, alter our products so as to avoid infringing such third-party patents. If we or our licensees are unable to obtain a license on commercially reasonable terms, if at all, we or our licensees could be restricted or prevented from commercializing products utilizing the Aversion® Technology. Additionally, any alterations to our products or our Aversion® Technology could be time consuming and costly and may not result in technologies or products that are non-infringing or commercially viable. We cannot assure you that our products and/or actions in developing products utilizing our Aversion® Technology will not infringe third-party patents.

Key personnel are critical to our business, and our success depends on our ability to retain them.

We are dependent on our management and scientific team, including Andrew D. Reddick, our President and Chief Executive Officer, Robert Jones, our Senior Vice President and Chief Operating Officer, and Ron J. Spivey, Ph.D. our Senior Vice President and Chief Scientific Officer. On February 27, 2008, we announced that Mr. Reddick began a leave of absence for health reasons. On September 2, 2008 we announced that Mr. Reddick resumed his full time duties and responsibilities except that he has been advised by his physician, for the foreseeable future, to limit his travel. Commencing January 1, 2009, Dr. Spivey will reduce his employment to a part-time basis (10 weeks per year) through 2010 and will serve as our Senior Scientific Advisor. We may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. While we have employment agreements with certain employees, all of our employees are at-will employees who may terminate their employment at any time. We do not have key personnel insurance on any of our officers or employees. The loss of any of our key personnel, or the inability to attract and retain such personnel, may significantly delay or prevent the achievement of our product and technology development and business objectives and could materially adversely affect our business, financial condition and results of operations.

Prior ownership changes may limit our ability to use our tax net operating loss carryforwards.

Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of Net Operating Loss (“NOL”) carryforwards and other tax attributes. The Company determined that an ownership change did occur (as defined by IRS Section 382) as a result of the restructuring that occurred in 2004. At December 31, 2007 the Company had total NOLs of $135 million. The application of Section 382 has reduced these NOL carryforwards by $40 million leaving $95 million of Federal NOL carryforwards available to offset current and future taxable income. These NOL carryforwards expire between 2009 and 2027.

Neither the amount of our NOL carryforwards nor the amount of limitation of such carryforwards claimed by us have been audited or otherwise validated by the Internal Revenue Service, which could challenge the amount we have calculated. The recognition and measurement of our tax benefit includes estimates and judgment by our management, which includes subjectivity. Changes in estimates may create volatility in our tax rate in future periods based on new information about particular tax positions that may cause management to change its estimates. If we establish a contingent tax liability reserve, interest and penalties related to uncertain tax positions would be classified as general and administrative expenses.

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Item 6. ***Exhibits***

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

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

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

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

SIGNATURES

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

October 27, 2008

ACURA PHARMACEUTICALS, INC.

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

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