

ACURA PHARMACEUTICALS, INC  
Form 10-Q  
April 30, 2008

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20649

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Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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

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**Acura Pharmaceuticals, Inc.**

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

**New York**

*(State or other Jurisdiction of  
incorporation or organization)*

**11-0853640**

*(I.R.S. Employer  
Identification No.)*

**616 N. North Court, Suite 120**

**Palatine, Illinois**

*(Address of Principal Executive Offices)*

**60067**

*(Zip Code)*

**847 705 7709**

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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

As of April 30, 2008 the registrant had 42,723,254 shares of Common Stock, \$.01 par value, outstanding.

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**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY**

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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS**

**UNAUDITED**  
(in thousands, except par values)

	<b>March 31</b>	<b>December 31,</b>
	<b>2008</b>	<b>2007</b>
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 26,002	\$ 31,368
Collaboration revenue receivable	3,376	2,977
Short-term investments	4,000	-
Prepaid clinical study costs	-	388
Prepaid insurance	172	202
Prepaid expense and other current assets	233	47
Deferred income taxes	4,620	9,600
Total current assets	38,403	44,582
Property, plant and equipment, net	1,063	1,046
Total assets	\$ 39,466	\$ 45,628
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities		
Deferred program fee revenue - current portion	\$ 9,497	\$ 21,942
Accrued expenses	311	334
Total current liabilities	9,808	22,276
Non-current liabilities		
Deferred program fee revenue - non current portion	3,368	4,632
Total liabilities	13,176	26,908
Commitments and contingencies		
Stockholders' equity		
Common stock - \$.01 par value; 650,000 shares authorized; 42,706 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively	427	427
Additional paid-in capital	340,274	340,153
Accumulated deficit	(314,411)	(321,860)
Total stockholders' equity	26,290	18,720
Total liabilities and stockholders' equity	\$ 39,466	\$ 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)

	<b>For the Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Revenues</b>		
Program fee revenue	\$ 13,707	\$ -
Collaboration revenue	3,377	-
Total revenue	17,084	-
<b>Operating expenses</b>		
Research and development expenses	4,082	1,196
Marketing, general and administrative expenses	870	778
Total operating expenses	4,952	1,974
Operating income (loss)	12,132	(1,974)
<b>Other income (expense)</b>		
Interest income (expense), net	297	(362)
Amortization of debt discount	-	(1,692)
Loss on fair value change of conversion features	-	(3,483)
Loss on fair value change of common stock warrants	-	(1,668)
Gain on asset disposals	-	20
Total other income (expense)	297	(7,185)
Income (loss) before income tax expense	12,429	(9,159)
Income tax expense	4,980	-
Net income (loss)	7,449	(9,159)
<b>Earnings (loss) per share:</b>		
Basic	\$ 0.16	\$ (0.26)
Diluted	\$ 0.15	\$ (0.26)
<b>Weighted average shares used in computing :</b>		
Basic	45,657	35,229
Diluted	49,439	35,229

See accompanying notes to the consolidated financial statements.

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

**THREE MONTHS ENDED MARCH 31, 2008**

**UNAUDITED**  
(in thousands, except par values)

	<b>Common Stock \$0.01 Par Value - Shares</b>	<b>Common Stock \$0.01 Par Value - Amount</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
<b>Balance at December 31, 2007</b>	42,706	\$ 427	\$ 340,153	\$ (321,860)	\$ 18,720
Net income	-	-	-	7,449	7,449
Stock based compensation	-	-	121	-	121
<b>Balance at March 31, 2008</b>	42,706	\$ 427	\$ 340,274	\$ (314,411)	\$ 26,290

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31,

UNAUDITED

(in thousands, except supplemental disclosures)

	2008	2007
Cash flows from Operating Activities:		
Net income (loss)	\$ 7,449	\$ (9,159)
Adjustments to reconcile net income (loss) to net cash used in operating activities		
Depreciation and amortization	42	29
Amortization of debt discount	-	1,692
Loss on fair value change of conversion features	-	3,483
Loss on fair value change of common stock warrants	-	1,668
Common stock issued for interest	-	364
Non-cash stock compensation expense	121	442
Gain on asset disposals	-	(20)
Deferred income taxes	4,980	-
Impairment reserve against fixed assets	(51)	-
Changes in assets and liabilities		
Collaboration revenue receivable	(400)	-
Prepaid expenses and other current assets	232	81
Accrued expenses	(24)	430
Deferred program fee revenue	(13,708)	-
Net cash used in operating activities	(1,359)	(990)
Cash flows from Investing Activities:		
Purchase of investments	(4,000)	-
Capital expenditures	(7)	(27)
Proceeds from asset disposals	-	20
Net cash used in investing activities	(4,007)	(7)
Cash flows from Financing Activities:		
Proceeds from issuance of senior secured term notes payable	-	1,296
Payments on capital lease obligations	-	(6)
Net cash provided by financing activities	-	1,290
(Decrease) increase in cash and cash equivalents	(5,366)	293
Cash and cash equivalents at beginning of period	31,368	228
Cash and cash equivalents at end of period	\$ 26,002	\$ 521
Cash paid during the period for interest	\$ -	\$ 2

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)**

**Three Months ended March 31, 2008**

1. Fixed assets with a net book value of \$51,000 under the impairment reserve were disposed.

**Three Months ended March 31, 2007**

2. The Company issued 24,723 shares of common stock as payment of \$207,000 of Senior Secured Convertible Bridge Term Notes Payable accrued interest.
3. The Company issued 18,569 shares of common stock as payment of \$157,000 of Secured Term Note Payable accrued interest.
4. Warrants to purchase aggregate 41,009 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 16,533 shares of common stock.
5. The issuance of \$1,296,000 Senior Secured Convertible Bridge Term Notes included conversion features measured at \$1,188,000, which resulted in an equal amount of debt discount. 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 change in the common stock warrants' fair value through March 30, 2007 resulted in a loss of \$1,668,000. Due to a debt agreement modification on March 30, 2007, the then current fair value of all 1,592,100 outstanding common stock warrants of \$12,307,000 was reclassified from liabilities to equity.

See accompanying notes to the consolidated financial statements.

**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**MARCH 31, 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 March 31, 2008 and results of operations and cash flows for the three months ended March 31, 2008 have been made. The results of operations for the three month period ended March 31, 2008 are not necessarily indicative of the 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 share and per share data. The equity amounts and all share and per share data of the Company have been retroactively adjusted to reflect a one-for-ten reverse stock split which occurred on December 5, 2007.

**NOTE 2 - NEW ACCOUNTING PRONOUNCEMENTS**

**Derivative Instruments and Hedging Activities**

In March 2008, Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 161 "Disclosures about Derivative Instruments and Hedging Activities" ("SFAS 161"). SFAS No. 161 is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. SFAS No. 161 also improves transparency about the location and amounts of derivative instruments in an entity's financial statements; how derivative instruments and related hedged items are accounted for under Statement 133; and how derivative instruments and related hedged items affect its financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. The Company is evaluating the impact of the adoption of SFAS 157 on its financial statements but believes the adoption of SFAS 161 will not have a material effect on our results of operations or financial position.

**Noncontrolling Interests in Consolidated Statements**

In December 2007, the FASB issued SFAS No. 160 "Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51" ("SFAS 160"). SFAS 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of ARB No. 51's consolidation procedures for consistency with the requirements of SFAS 41 (revised 2007), Business Combinations. SFAS 160 is effective for fiscal years and interim periods within those fiscal years beginning on or after December 15, 2008. Earlier adoption is prohibited. SFAS 160 shall be applied prospectively as of the beginning of the fiscal year in which the Statement is adopted, except for the presentation and disclosure

requirements. The presentation and disclosure requirements shall be applied retrospectively for all periods presented.

**Business Combinations**

In December 2007, the FASB issued SFAS No. 141 (revised 2007) “Business Combinations” (“SFAS (141R)”). SFAS 141R retains the fundamental requirements of the original pronouncement requiring that the purchase method be used for all business combinations. SFAS 141R defines the acquirer as the entity that obtains control of one or more businesses in the business combination, establishes the acquisition date as the date the acquirer achieves control and requires the acquirer to recognize the assets and liabilities assumed and any non-controlling interest at their fair values as of the acquisition date. SFAS 141R requires, among other things, that the acquisition related costs be recognized separately from the acquisition. SFAS 141R is applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009.

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### **Fair Value Option for Financial Assets and Financial Liabilities**

In February 2007, the FASB issued SFAS No. 159 “The Fair Value Option for Financial Assets and Financial Liabilities -Including an Amendment of FASB Statement No. 115” (“SFAS 159”). SFAS 159 permits an entity to elect to measure eligible items at fair value (“fair value option”) including many financial instruments. The provisions of SFAS 159 are effective for the Company as of January 1, 2008. If the fair value option is elected, the Company will report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. Upfront costs and fees related to an item for which the fair value option is elected shall be recognized in earnings as incurred and not deferred. The fair value option may be applied for a single eligible item without electing it for other identical items, with certain exceptions, and must be applied to the entire eligible item and not to a portion of the eligible item. The Company did not elect the fair value option.

### **Fair Value Measurements**

In September 2006, the FASB issued SFAS No. 157 “Fair Value Measurements” (“SFAS 157”), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for the Company beginning on January 1, 2008. The requirements of SFAS 157 will be applied prospectively except for certain derivative instruments that would be adjusted through the opening balance of retained earnings in the period of adoption. In February 2008, the FASB issued Staff Position No. FAS 157-2 which provides for a one-year deferral of the effective date of SFAS 157 for non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is evaluating the impact of the adoption of SFAS 157 on its financial statements.

### **NOTE 3 - RESEARCH AND DEVELOPMENT**

Research and Development (“R&D”) expenses include internal R&D activities, external contract research organization (“CRO”) activities, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, depreciation, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and incentive compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include clinical trial studies and regulatory consulting, regulatory counsel, and patent counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. The Company makes payments to the 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 rely 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 March 31, 2008 and December 31, 2007, respectively. Unfunded CRO commitments were \$2,404,000 and \$3,991,000 at March 31, 2008 and December 31, 2007, respectively, and are expected to be incurred as patients or subjects are enrolled into the clinical studies.

### **NOTE 4 - 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 the King Agreement, we recognize program fee revenue, collaboration revenue and milestone revenue. Program fee revenue is derived from the \$30.0 million upfront payment from King received in December 2007. We have assigned a portion of the program fee revenue to each product candidate identified in the King Agreement and recognize the program fee ratably over our estimate of the development period for each identified product candidate. Collaboration revenues from reimbursement of development expenses, which are invoiced quarterly in arrears, 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<sup>TM</sup> Tablets and other product candidates licensed to King under the King Agreement. We recognize milestone payments from King as revenue when we achieve the underlying developmental milestone as the milestone payments are not dependent upon any other future activities or achievement of any other future milestones and the achievement of each of the developmental milestones were substantively at risk and contingent at the effective date of the collaboration. Substantial effort is involved in achieving each of the developmental milestones. These milestones represent the culmination of discrete earnings processes and the amount of each milestone payment is reasonable in relation with the level of effort associated with the achievement of the milestone. 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.. We recognized \$13.7 million of program fee revenue, \$3.4 million of collaboration revenue and \$0 of milestone revenue during the three months ended March 31, 2008.

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## **NOTE 5 - INCOME TAXES**

The recognition and measurement of certain tax benefits includes estimates and judgment by Company management and inherently includes subjectivity. Changes in estimates may create volatility in the Company's effective tax rate in future periods from obtaining new information about particular tax positions that may cause management to change its estimates. If the Company establishes a contingent tax liability reserve, interest and penalties related to uncertain tax positions would be classified in general and administrative expenses.

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, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. 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. During the year ended December 31, 2007, 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 a \$9.6 million adjustment to the deferred income tax asset valuation allowance. This adjustment recognized a benefit from income taxes in our income for such period and provided a current deferred income tax asset. During the three months ended March 31, 2008, the Company recorded a \$4.9 million tax provision and reduced its deferred income tax asset for the same amount. At both March 31, 2008 and December 31, 2007, a valuation allowance equal to 100% of the remaining net deferred income tax assets was used and primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

## **NOTE 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 necessarily provide a reliable single measure of the fair value of its employee stock options. Included in the three months ended March 31, 2008 and 2007 is \$121,000 and \$442,000, 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 3.0 million shares of common stock are authorized for issuance under the 2005 RSU Plan. The Company believed that the 2005 RSU Plan did not require shareholder approval. Nevertheless, the Company’s shareholders ratified the 2005 RSU Plan at its December, 2006 Annual Shareholders’ Meeting.

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 the Company’s employees. In February 2006, an aggregate of 200,000 RSUs were granted to the Company’s two independent directors. Of the RSU awards granted, approximately one third vested upon grant and the other two thirds vested using on a straight-line monthly basis through December 2007.

The weighted average fair value of both RSU grants is \$3.50 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 Company recognized no share-based compensation expense from the RSU awards during the three months ended March 31, 2008 and \$0.4 million during the three months ended March 31, 2007. As of March 31, 2008 and December 31, 2007, the aggregate intrinsic value of the RSU awards outstanding and vested was \$25.8 million and \$18.0 million, respectively.

### **Stock Option Plans**

The Company has stock options outstanding under both a 1995 Stock Option Plan and a 1998 Stock Option Plan. The 1995 Stock Option Plan expired in May 2005 and the 1998 stock Option Plan expired in April 2008 but options granted under such plans remain outstanding. On April 30, 2008 the 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 1,905,000 and 1,858,000 shares with a weighted-average exercise price of \$2.32 and \$2.54 were outstanding at March 31, 2008 and December 31, 2007, respectively, of which 1,838,000 and 1,827,000 options were vested at March 31, 2008 and December 31, 2007, respectively. During the three months ended March 31, 2008, stock options to purchase an aggregate 90,000 shares having exercise prices of \$6.50 were granted, options to purchase 44,000 shares expired, and no options were exercised.

As of March 31, 2008 the Company had \$457,000 of unrecognized share-based compensation expense, net of estimated forfeitures, related to stock option grants, which will be recognized over the remaining weighted average period of nine months. Total intrinsic value of stock options outstanding and exercisable at March 31, 2008 and December 31, 2007 was \$12.8 million and \$8.1 million, respectively.

**NOTE 7- 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 March 31, 2007 are 7.8 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.

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Net loss used in the Company's earnings (loss) per share computations includes 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)	Three months ended March 31,	
	2008	2007
Basic earnings (loss) per share		
Numerator:		
Net income (loss)	\$ 7,449	\$ (9,159)
Deemed dividend from modification of debt	-	(3)
Net loss allocable to common stockholders	\$ 7,449	\$ (9,162)
Denominator:		
Common shares (weighted)	42,707	33,108
Vested restricted stock units (weighted)	2,950	2,121
Weighted average shares used in computing basic earnings (loss) per share allocable to common shareholder	45,657	35,229
Basic earnings (loss) per share allocable to common shareholder	\$ 0.16	\$ (0.26)
Diluted earnings per share		
Denominator:		
Common shares (weighted)	42,707	-
Vested restricted stock units (weighted)	2,950	-
Stock options	1,448	-
Common stock warrants	2,334	-
Weighted average shares used in computing diluted earnings per share allocable to common shareholder	49,439	-
Diluted earnings (loss) per share allocable to common shareholder	\$ 0.15	\$ (0.26)
Excluded potentially dilutive securities:		
Common stock issuable (see #1 below):		
Stock options (vested and nonvested)	86	1,900
Nonvested restricted stock units	-	737
Common stock warrants	47	1,592
Convertible term bridge notes	-	3,596
Total excluded dilutive common stock equivalents	133	7,825

(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 8 - ACCRUED EXPENSES**

Accrued expenses are summarized as follows (in thousands):

	Mar 31, 2008	Dec 31, 2007
Payroll, payroll taxes and benefits	\$ 117	\$ 63
Legal fees	40	35
Audit examination and tax preparation fees	61	120
Franchise taxes	19	15
Property taxes	39	34
Clinical, regulatory, trademarks, and patent consulting fees	35	50
Other fees and services	-	17
	\$ 311	\$ 334

**NOTE 9 - COMMON STOCK WARRANTS**

At March 31, 2008, the Company had outstanding common stock purchase warrants, exercisable for an aggregate of approximately 3,972,000 shares of common stock, all of which contained cashless exercise features. No warrants were exercised during the three month period ended March 31, 2008. During the three months ended March 31, 2007, warrants to purchase aggregate 41,009 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 16,500 shares of common stock. At March 31, 2008, outstanding common stock purchase warrants of 47,000, 409,000, 81,000 and 3,435,000 will expire if unexercised during the 2008, 2009, 2010 and years thereafter, respectively, and have a weighted average remaining term of 5.5 years. The exercise prices of these warrants range from \$1.20 to \$9.90 per share, with a weighted average exercise price of \$3.24.

**NOTE 10 - COMMITMENTS AND CONTINGENCIES****Employment Contracts**

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.

**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.

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## NOTE 11 - RECENT EVENTS

### *King Agreement*

In December, 2007, the Company and King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc., closed a License, Development and Commercialization Agreement (the "King Agreement") to develop and commercialize in the United States, Canada and Mexico (the "Territory") certain opioid analgesic products utilizing the Company's proprietary Aversion® (abuse deterrent) Technology including ACUROX™ Tablets. The King Agreement provides King with an exclusive license in the Territory for ACUROX™ Tablets and another undisclosed opioid analgesic product candidate utilizing Acura's Aversion® Technology. In addition, the King Agreement provides King with an option to license in the Territory all future opioid analgesic products developed utilizing Acura's Aversion® Technology.

Under the terms of the King Agreement, King made an upfront cash payment to Acura of \$30.0 million. Depending on the achievement of certain development and regulatory milestones, King could also make additional cash payments to Acura of up to \$28 million relating to ACUROX™ Tablets and similar amounts with respect to each subsequent Aversion® Technology product developed under the King Agreement. King will reimburse Acura for all research and development expenses incurred beginning from September 19, 2007 for ACUROX™ Tablets and all research and development expenses related to future products after King's exercise of its option to an exclusive license for each future product. King will record net sales of all products. Commencing one year after the first commercial sale of the first product commercialized, King will pay us a royalty ranging from 5% to 25% based on the level of combined annual net sales for all products commercialized subject to the King Agreement. King will also make a one-time cash payment to us of \$50 million in the first year in which the combined annual net sales of all products exceed \$750 million.

Pursuant to the King Agreement, King and Acura have formed a joint steering committee to coordinate development and commercialization strategies. With King's oversight, Acura will conduct all ACUROX™ Tablet development activities through approval of a New Drug Application ("NDA") and thereafter King will commercialize ACUROX™ in the U.S. With respect to all other products subject to the King Agreement, King will be responsible for development and regulatory activities following either acceptance of an Investigational New Drug Application by the U.S. Food and Drug Administration ("FDA") or Acura's demonstration of certain stability and pharmacokinetic characteristics for each future product candidate. All products developed pursuant to the King Agreement will be manufactured by King or a third party contract manufacturer under the direction of King. Subject to the King Agreement, King will have final decision making authority with respect to all development and commercialization activities for all products licensed.

The foregoing description of the Agreement contains forward-looking statements about the revenue generating potential of ACUROX™ Tablets and other opioid analgesic products developed pursuant to the 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 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 the Company by King will materialize. For further discussion of other risks and uncertainties associated with the Company, see the Company's Annual Report on Form 10-K for the year ended December 31, 2007, under the heading "Risks Factors".

### *Reverse Stock Split*

On October 30, 2007, the Company's Board of Directors approved an Amendment to the Company's Restated Certificate of Incorporation to affect a 1 for 10 reverse stock split. The reverse stock split took effect on December 5, 2007.

**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 that may occur in future periods.

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

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. The most significant of such factors include, but are not limited to, our ability and the ability of King Pharmaceuticals Research and Development, Inc. ("King") and other pharmaceutical companies, if any, to whom we may license our Aversion® Technology, to obtain necessary regulatory approvals and commercialize products utilizing the 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 highly skilled personnel; our ability to secure and protect our patents, trademarks and 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 of 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 are intended to identify forward-looking statements.

### ***Company Overview***

We are a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® Technology and related product candidates. Product candidates developed with Aversion® Technology and containing opioid analgesic active ingredients are intended to effectively relieve pain and also discourage the most common methods of pharmaceutical product misuse and abuse including; (i) intravenous injection of dissolved tablets or capsules, (ii) nasal snorting of crushed tablets or capsules and (iii) intentional swallowing of excessive numbers of tablets or capsules. Acurox™ Tablets, our lead product candidate utilizing Aversion® Technology, is being developed pursuant to an active investigational new drug application ("IND") on file with the U.S. Food and Drug Administration ("FDA"). Aversion® Technology is our patented platform technology for developing next-generation pharmaceutical products containing potentially abuseable drugs including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, tramadol, propoxyphene, and many others. Additional Aversion® Technology patents are pending encompassing a wide range of abuseable drugs including stimulants, tranquilizers and sedatives. Aversion® Technology is applicable to orally administered tablets and capsules. In addition to the active ingredient, Aversion® Technology utilizes certain patented compositions of pharmaceutical product inactive excipients and active ingredients intended to discourage or deter pharmaceutical product abuse.

We conduct internal research, development, laboratory, manufacturing and warehousing activities for Aversion® Technology at our Culver, Indiana facility. The 28,000 square foot facility is registered by the U.S. Drug Enforcement Administration ("DEA") to perform research, development and manufacture of certain Schedule II - V finished dosage

form products. In addition to internal capabilities and activities, we engage numerous contract research organizations (“CROs”) with expertise in regulatory affairs, clinical trial design and monitoring, clinical data management, biostatistics, medical writing, laboratory testing and related services. Such CROs perform development services for Acurox™ Tablets and other Aversion® product candidates under our direction.

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We are focused on:

- research and development of product candidates utilizing our Aversion® Technology;
- manufacture, quality assurance testing and release, and stability studies of clinical trial supplies and NDA submission batches of certain finished dosage form product candidates utilizing Aversion® Technology;
- prosecution of our patent applications relating to Aversion® Technology with the United States Patent and Trademark Office (“USPTO”) and foreign equivalents; and
- negotiation and execution of license and development agreements with pharmaceutical company partners providing that such licensees will further develop certain finished dosage product candidates utilizing the Aversion® Technology and file for regulatory approval with the FDA and other regulatory authorities and commercialize such products.

### ***Company’s Present Financial Condition***

At March 31, 2008 we had cash and cash equivalents of \$26.0 million and \$4.0 million of short term investments compared to \$31.4 million in aggregate cash, cash equivalents and no short term investments at December 31, 2007. We had working capital of \$28.6 million and \$22.3 million at March 31, 2008 and December 31, 2007, respectively. We had an accumulated deficit of \$314.4 and \$321.9 million at March 31, 2008 and December 31, 2007, respectively. We had operating income of \$12.1 million and net income of \$7.5 million for the three months ended March 31, 2008 and a loss from operations of approximately \$4.9 million and a net loss of approximately \$4.3 million for the year ended December 31, 2007.

At April 30, 2008, we had cash and cash equivalents of approximately \$30.0 million. We estimate that our current cash reserves will be sufficient to fund the development of the Aversion® Technology and related operating expenses through at least the next 12 months.

As described in Note 11 - Recent Events, in December, 2007, we and 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 three months ended December 31, 2007, we recognized revenue of \$6.4 million derived from the \$30.0 million non-refundable upfront cash payment received from King in December, 2007 under the King Agreement and billed King for reimbursement of our development expenses. During the three months ended March 31, 2008, we recognized revenues of \$17.1 million derived from the \$30.0 million upfront cash payment from King and billed King for reimbursement of our 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 and expand the scope of our intellectual property, and hire additional personnel.

### ***Company Strategy***

Our goal is to become a leading specialty pharmaceutical company focused on addressing the growing societal problem of prescription drug abuse by developing a portfolio of pharmaceutical products with abuse deterrent features. Specifically we intend to:



*Capitalize on our Experience and Expertise in the Research and Development of Abuse Deterrent Pharmaceutical Products.* Our approach is to utilize existing active pharmaceutical ingredients with proven safety and efficacy profiles that have known potential for abuse, and develop new products utilizing our proprietary Aversion® (“abuse deterrent”) Technology. We believe that in most cases the FDA’s 505(b)(2) NDA approval process may be used with these product candidates. While there can be no assurance, we believe the use of the 505(b)(2) NDA approval process may allow for more efficient and timely approvals as compared to standard NDA filings. The 505(b)(2) NDA regulatory pathway is being utilized in the development of Acurox™ Tablets, our lead product candidate utilizing Aversion® Technology. In addition to Acurox™ Tablets, as of the date of this Report we are engaged in the development of several additional product candidates incorporating Aversion® Technology, including hydrocodone bitartrate with acetaminophen tablets (marketed generically and by others under the brand names Vicodin®, Lortab®, and Lorcet®), hydromorphone HCl tablets (marketed generically and by Abbott Laboratories under the brand name Dilaudid®) and oxycodone HCl with acetaminophen (marketed generically and by others under the brand names of Percocet®, Tylox®, Endocet®, and Roxicet®). We expect to file an IND for our second Aversion® Technology opioid product candidate in the first half of 2008.

- *Maximize Commercial Value of our Product Candidates Through Out-Licensing to Strategically Focused Pharmaceutical Partners.* On October 30, 2007, we and King entered into a License, Development and Commercialization Agreement (the "King Agreement") to develop and commercialize in the United States, Canada and Mexico (the "King Territory") opioid analgesic products utilizing Aversion® Technology including Acurox™ Tablets. We believe opportunities exist to enter into similar agreements with other commercial partners for these same opioid products outside the King Territory and in the United States and worldwide for developing additional Aversion® Technology product candidates for other abuseable drugs including tranquilizers, stimulants and sedatives. By partnering with strategically focused companies with expertise and infrastructure in commercialization of pharmaceuticals, we are able to leverage our expertise, intellectual property rights and Aversion® Technology without the need to build costly sales and manufacturing infrastructure. We anticipate that our future revenue, if any, will be derived from milestone and royalty payments related to the commercialization of products utilizing our Aversion® Technology.
- *Expand the Aversion® Technology Intellectual Property Portfolio.* We believe our patent granted by the United States Patent and Trademark Office ("USPTO") in April 2007 for Aversion® Technology provides protection in the U.S. against potential generic product competition through March 2025 and is a key element for the appeal of our product candidates to King for opioid analgesic product candidates and other potential commercial partners for non-opioid product candidates. We have filed additional patent applications with the USPTO which, if issued, will compliment and broaden the scope of our granted patent claims. In addition, we have filed corresponding Aversion® Technology patent applications internationally. All of the Aversion® Technology intellectual property, including all pending and issued patents was developed internally by the Company and as of the date of this Report we believe no enabling licenses from others will be required.
- *Remain focused on Research, Development and Achieving Proof of Concept for Product Candidates Incorporating the Aversion® Technology while Minimizing Internal Fixed Costs through Outsourcing High Fixed Cost Elements of the Development Process.* We maintain a streamlined corporate infrastructure focused on:
  - selection, formulation development, laboratory evaluation, manufacture, quality assurance and stability testing of certain finished dosage form product candidates;
  - development and prosecution of our patent applications; and
- negotiation and execution of license and development agreements with strategically focused pharmaceutical partners. While we expect to expand our internal staff to enable us to more rapidly develop multiple product candidates, as of the date of this Report we have only 15 employees, 9 of whom are engaged in the research, development and manufacture of product candidates utilizing the Aversion® Technology. We contract with CROs with expertise in regulatory affairs, clinical trial design and monitoring, clinical data management, biostatistics, medical writing, laboratory testing and related services. Such CROs perform development services for Acurox™ Tablets and other Aversion® product candidates under our direction. By outsourcing the high fixed cost elements of our product development process, we believe that we substantially reduce fixed overhead and capital investment and thereby reduce our business risk.

#### ***Status of Patent Applications, Patent Publications, and Issued Patents***

In April 2007, the United States Patent and Trademark Office (the "USPTO") issued to us U.S. Patent No. 7,201,920 titled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms". The 54 allowed patent claims encompass pharmaceutical compositions intended to reduce or discourage the most common methods of prescription opioid analgesic product misuse and abuse. The opioid analgesics in the issued patent claims include oxycodone, hydrocodone, hydromorphone, morphine, codeine, tramadol, propoxyphene and many others.



In addition to issued U.S. Patent No. 7,201,920, as of the date of this report, we have five U.S. non-provisional pending patent applications, three WO/PCT pending patent applications and multiple additional U.S. provisional and international patent filings relating to compositions containing abuseable drugs.

As of the date of this report, except for those rights conferred in the King Agreement, we have retained all of the intellectual property rights to our Aversion® Technology and related product candidates.

### **Aversion® Technology Overview**

Aversion® Technology is a patented platform for developing pharmaceutical products containing potentially abuseable drugs including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, tramadol, propoxyphene, and many other opioid analgesics. We believe this platform technology is also applicable to non-opioid products that are subject to abuse and which fall into two broad categories, central nervous system ("CNS") depressants (including tranquilizers and sedatives) and stimulants. Aversion® Technology is applicable to orally administered tablets and capsules. In addition to the active ingredient, Aversion® Technology utilizes certain proprietary combinations of inactive excipients and active ingredients intended to discourage the most common methods of pharmaceutical product misuse and abuse including; (i) intravenous injection of dissolved tablets or capsules, (ii) nasal snorting of crushed tablets or capsules and (iii) intentional swallowing of excess quantities of tablets or capsules.

### **Intended to Deter I.V. Injection of Opioids Extracted from Dissolved Tablets**

Prospective drug abusers or recreational drug users may attempt to dissolve currently marketed opioid-containing tablets in water, alcohol, or other common solvents, filter the dissolved solution, and then inject the resulting fluid intravenously to obtain euphoric effects. In addition to its two active ingredients, Acurox™ Tablets also contains a unique combination of inactive ingredients. These "functional" inactive ingredients are commonly used pharmaceutical excipients which elicit no therapeutic effect but which have specific non-therapeutic functions. If a person attempts to extract oxycodone from Acurox™ Tablets using any generally available solvent, including water or alcohol, into a volume and form suitable for intravenous ("I.V.") injection, the tablet converts into a viscous gel mixture and effectively traps the oxycodone HCl in the gel. Based on controlled in-vitro experiments, we believe it is not possible, without extraordinary difficulty, to draw this viscous gel through a needle into a syringe for I.V. injection. We believe that this gel forming feature will discourage prospective I.V. drug abusers or recreational drug users from extracting oxycodone from an Acurox™ Tablet. As described below under the caption "Pivotal Oxycodone Extraction Study", we have compared the relative difficulty of extracting oxycodone from Acurox™ Tablets to several currently marketed oxycodone-containing products.

### **Intended to Deter Nasal Snorting**

In addition to potential intravenous or oral abuse, prospective drug abusers may crush or grind currently marketed oxycodone-containing tablet or capsule products. The resultant powder may then be nasally snorted and the oxycodone in the powder is absorbed through the lining of the nasal passages often resulting in a rapid onset of euphoric effects. Acurox™ Tablets have three mechanisms intended to discourage nasal snorting;

- *Mild burning and irritation* -if the tablets are crushed and the prospective drug abuser attempts to snort the crushed tablets a mild burning and irritation of the nasal passages is expected to occur
- *Viscous gel traps active ingredient* -when Acurox™ Tablets are crushed and snorted, we expect the moisture in the nasal passages will form a viscous gel with the crushed tablet powder thereby trapping the oxycodone in the gel and reducing the amount of oxycodone available for absorption through the lining of the nasal passages

- *Gelatinous mass* - we believe that the viscous gel formed in the nasal passages will result in a sticky mass producing an unpleasant sensation in the nasal passages of the prospective abuser

Therefore, we expect potential nasal abusers of Acurox™ Tablets to experience mild burning and irritation of the nasal passages, a lower level of oxycodone available for nasal absorption and a physically unpleasant gelatinous mass to form in the nasal passages. We have evaluated the potential for reducing nasal absorption using a standard in-vitro experimental process. As discussed in the section below regarding Acurox™ Tablets, we intend to further evaluate Acurox™ Tablets nasal abuse characteristics in laboratory and Phase I clinical studies.

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### **Intended to Deter Swallowing Excess Quantities of Tablets**

We have included a sub-therapeutic amount of niacin in each tablet of Acurox™ Tablets. We believe that should a person swallow excess quantities of Acurox™ Tablets they will experience an unpleasant combination of symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort. It is expected that these dysphoric symptoms will begin approximately 10-15 minutes after the excess dose is swallowed and self-resolve approximately 75-90 minutes later. We believe that healthcare providers, (including physicians, nurses, and pharmacists) generally understand and recognize that niacin, when administered orally in immediate release tablets in amounts exceeding by several fold the amount in each Acurox™ Tablet, may cause a combination of unpleasant symptoms. In addition, it is generally recognized that niacin has a well established safety profile in long term administration at doses far exceeding the amounts in each Acurox™ Tablet. When Acurox™ Tablets are administered at the anticipated recommended maximum dose of 2 tablets every 6 hours it is intended that legitimate pain patients will receive effective analgesic effects and not be aware of the potential dysphoric effects of niacin. Acurox™ Tablets are not intended for patients requiring opioid dose escalation due to the possibility of niacin induced flushing as the dose is increased.

We do not expect that the undesirable niacin effects will be “fool-proof” in discouraging swallowing excess quantities of Acurox™ Tablets. However, we anticipate that inclusion of niacin in Acurox™ Tablets and in other Aversion® Technology product candidates will deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of Acurox™ Tablets. We anticipate that most potential drug abusers or recreational drug users will seek alternative opioid analgesic products that are generally much easier to abuse than Acurox™ Tablets and do not have the potential to cause these undesirable niacin effects. As described below under the caption “Status and Expectations For Acurox™ Tablets Clinical Development Program,” we have evaluated the effects of niacin in a number of Phase I and Phase II clinical studies in subjects with and without a history of opioid abuse.

### **U.S. Market for Opioid Analgesic Products Incorporating Aversion® Technology**

Primary market research conducted by us indicates that U.S. based physicians perceive that nearly one out of six prescriptions for oxycodone and hydrocodone containing opioid analgesics may be abused. Such market research also revealed that nearly all physicians questioned reported being the victim of opioid prescription forgeries in the previous year. Physicians believe that drug abusers seeking prescriptions for opioid containing products present a legal and professional risk to their practices. In addition, the results of a survey of over 1,500 adults conducted by the market research firm of Schulman, Ronca and Bucuvalas, Inc. and published in 2006, revealed that 37% of those surveyed know someone personally who has abused opioid painkillers. Of those reporting knowing someone who has abused opioid painkillers, 10% percent indicated that they personally had abused these products. Nearly 20% percent of the abusers were identified as coworkers, with the balance identified as family members or acquaintances. We believe that healthcare providers are generally unable to determine which, if any, of their prescriptions for opioid analgesics will ultimately be abused by their patients or diverted for abuse by others. The uncertainty about which, if any, prescriptions for opioid analgesic products will be abused or diverted implies that certain segments of the U.S. market represent a major opportunity for products incorporating our Aversion® Technology. The table below lists several commonly prescribed opioid analgesics in the U.S that are subject to potential misuse or abuse.

<b>Opioid Active Ingredients (Generic Names)</b>	<b>Frequently Prescribed Opioid Analgesics (Common Brand Names)</b>
Oxycodone	Percocet®, OxyContin®, Roxicet®, Tylox®, Endocet®
Hydrocodone	Vicodin®, Lortab®, Lorcet®
Morphine	Avinza®, Kadian®, MSContin®
Hydromorphone	Dilaudid®
Codeine	Tylenol® with Codeine

Tramadol  
Propoxyphene

Ultram®, Ultram® ER, Ultracet®  
Darvon®, Darvocet®

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Based on market research data purchased by us from IMS Health, for the 12 months ended September 30, 2007, approximately 235 million total prescriptions (brands and generics combined) were dispensed in the U.S. for immediate release and extended release tablet and capsule forms of the opioid analgesics listed above. Of these total dispensed prescriptions, approximately 14 million were for extended release products (usually administered every 8 to 24 hours) and 221 million were for immediate release products (usually administered every 4 to 6 hours). Extended release products are more commonly prescribed for relief of chronic pain for durations ranging from several weeks to several months or longer. Immediate release products are more commonly prescribed for relief of acute pain for durations of generally less than 30 days. According to data published in The National Survey on Drug Use and Health Report, Issue 22, 2006, immediate release opioid containing pain relievers are used non-medically approximately ten-fold more often than extended release products.

Recreational drug users, drug abusers and/or drug addicts typically obtain the opioid analgesics products (listed above) in tablet or capsule dosage forms and then crush, shear, grind, chew, dissolve and/or heat, extract or otherwise manipulate the product so that a significant amount, or even the entire amount, of the abuseable drug becomes available for rapid absorption by injection, and/or snorting, and/or oral swallowing excess quantities of tablets or capsules to achieve a "high". Abuse of pharmaceutical products is a large and growing issue in American society and there is an urgent need for a new technology to discourage and deter misuse and abuse of opioid analgesic tablets and capsules.

### U.S. Market for Non-Opioid Products Incorporating Aversion® Technology

Aversion® Technology is a platform technology which we believe is also applicable to non-opioid products that are subject to abuse and that are administered in tablet or capsule form. Non-opioid abuseable drugs fall into two broad categories, central nervous system ("CNS") depressants (including tranquilizers and sedatives) and stimulants. According to data published in The National Survey on Drug Use and Health Report, Issue 22, 2006, the estimated number of people in the U.S. aged 12 and over who have abused drugs in these categories is as follows:

Category	During Lifetime (millions)	During Past Year (millions)	Frequently Prescribed (Common Brand Names)
C N S Depressants	30.1	6.0	Valium®, Xanax®, Halcion®, Klonopin®, Ativan®, Nembutal®
Stimulants	20.1	3.4	Dexadrine®, Adderall®, Ritalin®, Concerta®

To date we have devoted limited resources to the development of non-opioid product candidates and can not provide any assurance that future efforts, if any, to develop non-opioid products incorporating the Aversion® Technology will be successful or will result in viable commercial products.

### Acurox™ Tablets Development Status and Clinical Trials

Acurox™ Tablets, our lead product candidate with Aversion® Technology, is an orally administered immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient, a sub therapeutic amount of niacin, and a unique composition of functional inactive ingredients. Acurox™ Tablets will have an anticipated indication for relief of moderate to severe pain and will also have anticipated features to discourage or deter the most common methods of misuse and abuse including (i) intravenous injection of dissolved tablets, (ii) nasal snorting of crushed tablets and (iii) intentional swallowing of excess quantities of tablets. Acurox™ Tablets are being developed pursuant to an active investigational new drug application ("IND") on file with the FDA. We and King intend to file a 505(b)(2) NDA for Acurox™ Tablets. The FDA has confirmed in writing to us that the proposed NDA would qualify for a Section



505(b)(2) submission.

In September, 2007 we began enrolling patients in clinical Study AP-ADF-105, our pivotal phase III efficacy and safety study being conducted pursuant to a Special Protocol Assessment agreed with the FDA (see description of this study below under the caption "Study AP-ADF-105"). Patient enrollment in this study is now complete and Top-line results are anticipated in July 2008. We currently expect to submit a 505(b)(2) NDA for Acurox™ Tablets prior to the end of 2008. At the time of NDA submission we intend to request a priority review of the application by the FDA. The FDA has publicly indicated a willingness to consider such action for product candidates incorporating abuse deterrence features. No assurance however can be provided that the FDA will grant a priority review of our 505(b)(2) NDA submission.

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**Acurox™ Tablets: Technical and Pre-Clinical Development Program and Regulatory Affairs Strategy**

The technical and pre-clinical development program and regulatory strategy and status for Acurox™ Tablets are summarized below. At this stage, we can not provide any assurance that FDA will not require additional pre-clinical studies not listed below, or revise the Acurox™ Tablets regulatory requirements prior to their acceptance for filing of a 505(b)(2) NDA submission for Acurox™ Tablets.

<b>Technical and Pre-Clinical Development</b>	<b>Status and Expectations</b>
Formulation development	Complete
Pilot bioequivalence study	Complete
Pivotal oxycodone laboratory extraction study	Complete (results summarized in this Report)
Tablet stability for NDA submission	Testing in process. 24 month real time data demonstrates stability acceptable for NDA submission
Toxicology studies	Not required per FDA written guidance to us
<b>Regulatory Affairs</b>	<b>Status and Expectations</b>
Investigational New Drug Application (IND)	Active
End of Phase II meeting with FDA	Complete
Factorial design clinical studies	Not required per FDA written guidance to us
Phase III pivotal clinical trial	A single phase III efficacy and safety trial is required per FDA written guidance to us. Refer to status summary for Study AP-ADF-105 in this Report.
Type of regulatory submission for U.S. regulatory approval and commercial distribution in the U.S.	Acurox™ Tablets are eligible for submission as a 505(b)(2) NDA per FDA written guidance to us
505(b)(2) NDA submission	Anticipate submission prior to the end of 2008

**Pivotal Oxycodone Extraction Study:**

We, in concert with a leading pharmaceutical laboratory CRO (the “Laboratory CRO”), completed a pivotal study to assess certain properties of Acurox™ Tablets using tablets from batches manufactured by us at our Culver Facility at a scale of sufficient size to fulfill the FDA’s requirements for a 505(b)(2) NDA submission. The Laboratory CRO was contracted to quantitatively and qualitatively measure the relative difficulty of extracting oxycodone HCl for purposes of I.V. injection from tablet products containing oxycodone HCl. The Laboratory 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, OxyContin®

(oxycodone HCl) Controlled-Release Tablets, generic oxycodone HCl Tablets, and Percocet® (oxycodone HCl/acetaminophen) Tablets. As set forth in the table below, results were reported as (i) percent of drug extracted, (ii) time to extract drug and (iii) difficulty to extract drug on a scale of 1-10, 1 being easy and 10 being extremely difficult. OxyContin® Tablets and generic oxycodone HCl tablets resulted in 71-92% drug extracted in 3-6 minutes and were rated 1-2 in relative difficulty. Percocet® Tablets resulted in 75% oxycodone HCl extracted in 10 minutes (with vacuum assisted filtration) and was rated 3-4 in relative difficulty. Acurox™ Tablets resulted in a “trace” of oxycodone HCl extracted in 355 minutes and was rated 10 in relative difficulty. We intend to utilize the data and results from this pivotal laboratory study in our 505(b)(2) NDA submission to the FDA for Acurox™ Tablets.

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

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

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**Status and Expectations for Acurox™ Tablets Clinical Development Program**

The clinical development program for Acurox™ Tablets is summarized below. At this stage, we cannot provide any assurance that FDA will not require additional clinical studies prior to their acceptance for filing of a 505(b)(2) NDA submission for Acurox™ Tablets.

<b>Clinical Studies to Evaluate Pharmacokinetics in Normal Subjects</b>		<b>Status and Expectations</b>
AP-ADF-104	Phase I: Bioequivalence to non Aversion® Technology Reference Listed Drug	Final study report complete. Acurox™ Tablets are bioequivalent to the Reference Listed Drug
AP-ADF-108	Phase I: Single dose linearity and food effect	Final study report complete. Acurox™ Tablets demonstrate single dose linearity. Absorption is delayed by food.
AP-ADF-109	Phase I: Multi-dose linearity	Subject enrollment complete
AP-ADF-110	Phase I: Required only if there is not dose linearity in Study AP-ADF-108 and Study AP-ADF-109	As of the date of this Report, we do not anticipate this study will be required

**Studies AP-ADF-108, AP-ADF-109, and if necessary AP-ADF-110:** These are Phase I single dose or multi-dose pharmacokinetic studies anticipated to enroll approximately 25-50 normal subjects per study. Study AP-ADF-108 confirmed that Acurox™ Tablets demonstrate single dose linearity and that absorption is delayed by food. Patient enrollment in Study AP-ADF-109 is complete and we are awaiting the study results. Based on Study AP-ADF-108 study results, we currently do not believe that Study AP-ADF-110 will be necessary.

<b>Clinical Studies to Evaluate Niacin Dose Response in Normal Subjects</b>		<b>Status and Expectations</b>
AP-ADF-101	Phase I: Niacin dose-response (0-75mg)	Final study report complete
AP-ADF-103	Phase II: Repeat dose safety and tolerability	Final study report complete. Refer to summary in this Report
AP-ADF-107	Phase II: Niacin dose-response (0-600mg)	Final study report complete. Refer to summary in this Report

**Study AP-ADF-103:** This study is titled, "A Phase II Single-Center, Randomized, Double-Blind, Multiple-Dose Study in Healthy Volunteers to Evaluate the Safety and Tolerability of Niacin in Combination with 5 mg of an Opioid vs. 5 mg of an Opioid Alone." To assess the safety and tolerability of Acurox™ (oxycodone/niacin) Tablets in comparison to oxycodone HCl tablets without niacin, we conducted this Phase II single-center, randomized, double-blind, multiple dose study in 66 healthy adult male and female volunteers. Subjects were randomly assigned to one of three treatment groups (22 subjects per treatment group). A run-in phase was conducted on an outpatient basis for five days and included at-home dosing four times daily and adverse event and tolerability assessments. The treatment phase followed the run-in phase and was conducted on an inpatient basis for five days. The treatment phase

included dosing with Acurox™ Tablets (with or without niacin) and post-treatment safety and tolerability assessments. Efficacy (the tolerability of Acurox™) was evaluated with a Side Effects and Symptoms Questionnaire (SESQ) and an Acurox™ Tolerability Rating Scale. Safety was evaluated by adverse events and clinical laboratory and vital signs assessments were conducted periodically during the study. 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 (highest possible score = 33; Group results = 0.84 - 1.6) indicating that Acurox™ was generally well-tolerated when taken at 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 (blood pressure, heart rate, and respiratory rate). We intend to include the data and results from Study AP-ADF-103 in our 505(b)(2) NDA submission to the FDA for Acurox™ Tablets.

**Study AP-ADF-107:** This study is titled "A Phase II Single-Center, Randomized, Double-Blind Study in Fasted and Non-Fasted Healthy Volunteers to Evaluate the Dose-Response for Flushing and Safety and Tolerability of Escalating Doses of Niacin." The study objective was to evaluate the dose-response for niacin-induced flushing, safety, and tolerability of niacin in the Acurox™ Tablet matrix (excluding oxycodone HCl) at various dose levels in both fasted and fed subjects. This trial was a Phase II single-center, randomized, double-blind study in healthy, adult male and female subjects. A total of 50 subjects were enrolled. The Treatment Phase was conducted on an inpatient basis and included study drug dosing and safety and tolerability assessments. Each subject received eight doses of niacin (30, 60, 90, 120, 240, 360, 480, and 600 mg) and three doses of placebo administered orally in tablet form on eleven separate days in a random sequence. Half of the subjects (n=25) took each dose of study drug following a FDA standardized high-fat breakfast and half (n=25) remained fasted for at least 2 hours after study drug administration. Subjects were discharged from the Clinical Research Unit on Day 11, approximately 6 hours after the last dose of study drug administration. Tolerability was rated by subjects during the Treatment Phase using a Tolerability Rating Scale (TRS) completed 3 hours after each dose of study drug. Each subject's overall reaction to the study drug was recorded using the following 5-point scale: 0 = No effect; 1 = Easy to tolerate; 2 = Mildly unpleasant, but tolerable; 3 = Unpleasant and difficult to tolerate; 4 = Intolerable and would never take again. The results showed a clear niacin dose-response relationship in both Fasted and Fed subjects as assessed by the 5-point TRS. The response ranged from little or no effect at low niacin doses (30 to 90 mg) to more difficult and unpleasant symptoms at higher doses of niacin (>120 mg). With Fasted subjects, there was minimal or no effect of niacin at doses of 30 to 60 mg, with 96% 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". The absence of any notable effects at low doses suggests that niacin will be well tolerated up to 60 mg per dose and will likely be well tolerated at 90 mg per dose. 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 (86%) 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 again". The higher doses of niacin clearly produced undesirable side effects. As anticipated, niacin effects were mitigated by food. All Fed subjects (100%) receiving 30 to 240 mg niacin reported "no effect" or "easy to tolerate". Niacin was also generally well tolerated at doses of 360 to 600 mg with most Fed subjects (68%) reporting "no effect" or "easy to tolerate".

In this study there were no significant adverse events or discontinuations due to treatment-emergent adverse events (TEAEs). None of the TEAEs reported were severe in intensity. A clear niacin dose-response relationship was observed in the incidence of AEs. As expected, the most frequently reported TEAE in both Fasted and Fed subjects was flushing. Flushing occurred more frequently in Fasted subjects than in Fed subjects with higher incidence as the niacin dose increased. The majority of Fasted subjects (54% to 88%) reported flushing at doses of 240 to 600 mg; while the majority of Fed subjects (64%) reported flushing only at a dose of 600 mg. Most of the events of flushing were moderate in intensity. No other safety issues were apparent. We intend to include the data and results from Study AP-ADF-107 in our 505(b)(2) NDA submission to the FDA for Acurox™ Tablets.

**Clinical Studies to Evaluate Tolerability of Nasal Snorting and Excess Oral Doses in Subjects with a History of Opioid Abuse**

		<b>Status and Expectations</b>
AP-ADF-106	Phase I: Evaluate effects of nasal snorting in subjects with a history of snorting and nasal drug abuse	Expect subject enrollment to commence in Q2-08
AP-ADF-102	Phase II: Evaluate relative dislike of oxycodone HCl/niacin versus oxycodone HCl alone	Final study report complete Refer to summary in this Report
AP-ADF-111	Phase II: Evaluate abuse liability of oxycodone HCl/niacin versus oxycodone HCl alone	Subject enrollment commenced in Q1-08



**Study AP-ADF-106:** This will be a Phase I clinical study, for use in product labeling, evaluating the characteristics of crushed Acurox™ Tablets when snorted by 12-18 subjects with a history of opioid abuse. We expect to initiate subject enrollment in this study in Q2-08.

**Study AP-ADF-102:** This study is titled, "A Phase II Single-Center, Randomized, Double-Blind Study in Subjects with a History of Opioid Abuse to Evaluate the Dose-Response for Flushing and Safety and Tolerability of Varying Doses of Niacin in Combination with 40mg of an Opioid vs. 40mg of an Opioid Alone." The study objectives were 1) to determine the dose response for niacin-induced flushing in male and female healthy, adult volunteers with a history of opioid abuse when niacin is administered in combination with 40 mg oxycodone HCl; 2) to evaluate the safety and tolerability of niacin-induced flushing following varying niacin doses in combination with 40 mg oxycodone HCl in subjects with a history of opioid abuse; 3) to confirm the appropriate strength of niacin to use in an Aversion® Technology formulation of oxycodone HCl; 4) to determine whether the flushing induced by niacin is of sufficient intensity to deter abuse in a population of subjects with a history of opioid abuse; and 5) to evaluate the effect of food on niacin-induced flushing when niacin is administered in combination with 40 mg oxycodone HCl.

This study was a single-center, double-blind, randomized, placebo-controlled, five-period crossover study conducted on an inpatient basis with 5 cohorts of 5 subjects each. Twenty-five subjects (three female and twenty-two male) were admitted for the study. One male subject completed the first drug condition but thereafter withdrew from the study stating personal reasons unrelated to the study. Twenty-four subjects received a single dose of study drug every 48 hours for 9 days. 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 HCl while the subjects were fasted on Days 1, 3, 5, and 7. On Day 9, a dose of 600 mg niacin in combination with 40 mg oxycodone HCl was administered following a standardized high-fat breakfast. Each dosing day, vital sign measures and subjective and behavioral effects were assessed before dosing and at 0.5, 1, 1.5, 2, 3, 4, 5, 6, and 12 hours after dosing. Vital signs included systolic and diastolic blood pressure, heart rate, oral temperature and respiratory rate. Subjective changes were measured by subject response to a Drug Rating Questionnaire (DRQS). As an additional measure of subjective effects, subjects completed a 40 item short form of an Addiction Research Center Inventory (ARCI) that yielded three sub-scale scores - a euphoria scale, a dysphoria scale and a sedation scale. After completion of the study, subjects responded to a Treatment Enjoyment Assessment Questionnaire to select which of the treatments they would take again. Prior to initiating the study, the hypothesis was that the addition of niacin to oxycodone would produce effects that are disliked by subjects with a history of opioid abuse. 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. Statistical analysis (maximum dislike response in comparison to 0 mg niacin) was conducted for DRQS, ARCI scales and vital signs. Study results were as follows:

- (1) In the fasting state, all three doses of niacin [240mg, 480mg and 600mg] in combination with oxycodone 40mg produced significant ( $p \leq .05$ ) disliking scores compared to oxycodone 40mg alone. The linear regression across niacin dose was not significant. No other subjective measure was significantly affected by the niacin addition to oxycodone.
- (2) The high fat meal eliminated the niacin effect on oxycodone 40 mg. The high fat meal 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 scale. 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.

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The principal study investigator's overall conclusion was that the results of this pharmacodynamic study (Study AP-ADF-102) support 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 does not alter the safety profile of oxycodone alone. We intend to include the data and results from Study AP-ADF-102 in our 505(b)(2) NDA submission for Acurox™ Tablets to the FDA.

**Study AP-ADF-111:** This is a Phase II, single-center, randomized, double-blind assessment of the abuse liability of Acurox™ (oxycodone HCl/niacin) Tablets versus oxycodone HCl alone in approximately 30 subjects with a history of opioid abuse. This clinical study has not been requested by FDA but is being conducted by us with the intent of providing additional clinical data in support of certain targeted Acurox™ Tablet product label claims. Subject enrollment in Study AP-ADF-111 commenced in Q1-08.

**Clinical Study to Evaluate Efficacy and Safety in Patients with Moderate to Severe Pain**

		<b>Status and Expectations</b>
AP-ADF-105	Phase III: Pivotal efficacy and safety	Special Protocol Assessment (SPA) agreed by FDA. Patient enrollment is complete. Top line results expected in July 2008.

**Study AP-ADF-105:** This study is titled "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." Patient enrollment in this study is now complete and Top-line results are anticipated in July 2008. The study enrolled approximately 405 patients with moderate to severe pain following bunionectomy surgery. The primary endpoint was a reduction in the sum of the pain intensity difference for 48 hours (SPID 48) for active drugs versus placebo. We submitted the study protocol to the FDA and requested and received agreement for a Special Protocol Assessment ("SPA"). Clinical protocols for Phase III trials whose data will form the primary basis for an efficacy claim are eligible for a SPA. A SPA from the FDA is an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses plan are acceptable to support regulatory approval and is binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing is begun.

**Expectations for Acurox™ Tablets Product Labeling and NDA submission**

In the U.S., every product approved for commercialization pursuant to an NDA must be marketed in accordance with its FDA approved indications and associated product labeling. The FDA has provided written guidance to us stating that an indication for abuse deterrence must be supported by data from two adequate and well-controlled clinical trials. We do not intend to seek an indication for abuse deterrence for Acurox™ Tablets. Instead, we are seeking an indication for Acurox™ Tablets for relief of moderate to severe pain. The FDA has also provided written guidance to us stating that language regarding abuse deterrence (as opposed to an indication for abuse deterrence), which is supported by rigorous, scientific data, may be placed into appropriate sections of the Acurox™ Tablet product label. In this regard, we intend to seek FDA approval of language in the Acurox™ Tablet product label describing the physical characteristics of the product and likely results if attempts are made to dissolve tablets in solvents suitable for intravenous injection, and/or snort crushed tablets, and/or swallow excess quantities of tablets. We believe this product labeling strategy will provide a viable promotional platform for the commercialization of Acurox™ Tablets and other product candidates utilizing Aversion® Technology. At this stage there can be no assurances that our product labeling strategy for Acurox™ Tablets will be successful or that FDA approved product labeling, if any, will provide a viable commercialization platform. We currently expect to submit a 505(b)(2) NDA for Acurox™ Tablets prior to the end of 2008.

**Competition**

We compete to varying degrees with numerous companies in the pharmaceutical research, development, manufacturing and commercialization fields. Most of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in research and development of their competitive technologies and products. Although a larger company with greater resources than us will not necessarily have a higher likelihood of receiving regulatory approval for a particular product or technology as compared to a smaller competitor, the company with a larger research and development expenditure will be in a position to support more development projects simultaneously, thereby improving the likelihood of obtaining regulatory approval of a commercially viable product or technology than its smaller rivals.

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We believe competitors may be developing opioid abuse deterrent technologies and products. Such competitors include, but may not be limited to, Alpharma Inc. of Fort Lee, NJ, Elite Pharmaceuticals, Inc. of Northvale, NJ, Pain Therapeutics of South San Francisco, CA, (in collaboration with King Pharmaceuticals of Bristol, TN), Purdue Pharma of Stamford, CT, Endo Pharmaceuticals of Chadds Ford, PA, Neuromed Pharmaceuticals, of Vancouver, BC and Collegium Pharmaceuticals, Inc., of Cumberland, RI. These companies appear to have focused their development efforts on extended release opioid products (commonly prescribed for relief of chronic pain for durations ranging from several weeks to several months or longer) while our lead product candidate, Acurox™ Tablets, and other Aversion® Technology product candidates under development, are immediate release products (more commonly prescribed for relief of acute pain for durations of generally less than 30 days). We estimate the U.S. market for opioid analgesics, assuming brand pricing for all products, would be approximately \$14 Billion and can be segmented by immediate release versus extended release products as follows:

	<b>Immediate Release Products</b>	<b>Extended Release Products</b>
Dispensed Rx's <sup>1</sup>	221 Million	14 Million
Ratio of Dispensed Rx's <sup>2</sup>		16:1
Ratio of Abuse <sup>2</sup>		10:1
Estimated Ratio of \$ Market Potential <sup>3</sup>		4:1
Identified Competitors	Acura in collaboration with King	<ol style="list-style-type: none"> <li>1. Alpharma</li> <li>2. Pain Therapeutics</li> <li>3. Purdue</li> <li>4. Endo</li> <li>5. Elite</li> <li>6. Neuromed</li> <li>7. Collegium</li> </ol>

<sup>1</sup> IMS America 12 months ending 9/30/07.

<sup>2</sup> National Survey on Drug Use and Health Report, Issue 22, 2006

<sup>3</sup> Assuming brand pricing

**Results of Operations for the Three Months Ended March 31, 2008 and March 31, 2007**

**Revenue - Program fee revenue**

(\$ in thousands):	Three Months Ended Mar 31,		Change	
	2008	2007	Dollars	%
Revenue - Program fee revenue	\$ 13,707	\$ -	\$ 13,707	* %

King paid us a \$30.0 million upfront fee in connection with the closing of the King Agreement in December 2007. Revenue recognized in 2008 from amortization of this upfront fee was \$13.7 million. We have assigned a portion of the program fee revenue to each of the 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 the product candidates identified in the King Agreement. We currently estimate the development period for the expected product candidates to extend through December, 2009. The Company had no revenues for the three months ended March 31, 2007 and during such period relied on the net proceeds from bridge loans to fund operations and development activities.

**Revenue - Collaboration fee revenue**

	<b>Three Months Ended Mar 31,</b>	<b>Change</b>
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<b>(\$ in thousands):</b>	<b>2008</b>	<b>2007</b>	<b>Dollars</b>	<b>%</b>
Revenue - Collaboration fee revenue	\$ 3,377	\$ -	\$ 3,377	* %

Collaboration revenue recognized in 2008 was \$3.4 million. This revenue related to billed reimbursement of our development expenses incurred pursuant to the King Agreement from January 1, 2008 to March 31, 2008. We invoice King in arrears on a calendar quarter basis for our 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 revenues for the three months ended March 31, 2007 and during such period relied on the net proceeds from bridge loans to fund operations and development activities.

Research and development expenses

(\$ in thousands):	Three Months Ended Mar 31,		Change	
	2008	2007	Dollars	%
<b>Research and development expenses</b>	\$ 4,082	\$ 1,196	\$ 2,886	241%

Research and development expense during the three months ended March 31, 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 \$2 and \$179, respectively. Excluding the stock-based compensation expense, there is a \$3,063 increase in development expenses primarily attributable to increasing clinical study costs. The decrease in stock-compensation expense of \$177 (related to the fair value of stock options and restricted stock units, net of expected forfeitures, granted prior to 2006 which continue to vest and expense over the related employees requisite service periods), is due to the vesting method used for amortization. The fair value of the awards are being amortized using a graded vesting method which treats the award as if the grant was a series of awards rather than a single award and attributes a higher percentage of the reported fair value to the earlier quarters than to the later quarters of the service period. At December 31, 2007, all restricted stock units were fully vested. There were no stock options or restricted stock units granted during the three months ended March 31, 2008.

Marketing, general and administrative expenses

(\$ in thousands):	Three Months Ended Mar 31,		Change	
	2008	2007	Dollars	%
<b>Marketing, general &amp; administrative expenses</b>	\$ 870	\$ 778	\$ 92	12%

During the three months ended March 31, 2008 and 2007, marketing expenses consisted of Aversion® Technology primary market 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 \$119 and \$263, respectively. Excluding the stock-based compensation expense, the expenses increased \$236 attributable to general legal counsel costs and shareholders' communication costs associated with the company's annual shareholders' meeting. There is a decrease in stock-compensation expense of \$258 (related to the fair value of stock options and restricted stock units, net of expected forfeitures, granted prior to 2006 which continue to vest and expense over the related employees requisite service periods), is due to the vesting method used for amortization. The fair value of the awards are being amortized using a graded vesting method which treats the award as if the grant was a series of awards rather than a single award and attributes a higher percentage of the reported fair value to the earlier quarters than to the later quarters of the service period. At December 31, 2007, all restricted stock units were fully vested. There were grants of stock options to purchase an aggregate of 90,000 common shares during the three months ended March 31, 2008 for which \$114 was recorded as stock compensation expense.

Interest income (expense), net

(\$ in thousands):	Three Months Ended Mar 31,		Change	
	2008	2007	Dollars	%
<b>Interest income (expense), net</b>	\$ 297	\$ (362)	\$ 659	182%

Through August 19, 2007 we incurred interest 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 on our \$5.0 million Secured Term Note was payable in our common stock through August 19, 2007 and thereafter payable in cash.

Beginning August 20, 2007 such cash interest was deferred until we fully repaid such note on December 7, 2007. We also incurred interest 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 through June 30, 2006 was paid in cash. Commencing with interest due under such Bridge Loans at September 30, 2006, all such interest 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. The cash proceeds received pursuant to the King Agreement are primarily invested in bank commercial paper during the three months ended March 31, 2008 with maturity dates less than 12 months.

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Net income (loss)

(\$ in thousands):	Three Months Ended Mar 31,		Change	
	2008	2007	Dollars	%
<b>Net income (loss)</b>	\$ 7,449	\$ (9,159)	\$ 16,608	181%

The Company's net income or loss for the three months ended March 31, 2008 includes a provision for income taxes of \$5.0 million. The Company anticipates the utilization of its deferred tax assets to offset incomes taxes payable.

The Company's net loss for the three months ended March 31, 2007 includes a) debt discount amortization expense of \$1.7 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 and c) \$1.7 million loss on fair value changes to common stock warrants being accounted for as mark-to-market liabilities.

**Liquidity and Capital Resources**

At March 31, 2008, the Company had unrestricted cash, cash equivalents and short-term investments of \$30.0 million compared to \$31.4 million at December 31, 2007. The Company had working capital of \$28.6 million at March 31, 2008 compared to \$22.3 million at December 31, 2007. The decrease in our cash position of \$1.4 million is primarily due to the development costs of our Aversion Technology. The increase in working capital of \$6.3 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. Cash flows used in operating activities were \$1.4 million for the three month period March 31, 2008 primarily representing recognition of deferred program fee revenue offset by our utilization of net deferred tax assets, non-cash charges for stock compensation, and our net income for the 2008 period. Cash flow used in operating activities for the three month period March 31, 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 offset by proceeds from asset disposal include cash flows used investing activities for the 2007 period was less than \$10,000. Our purchase of short-term investments of \$4.0 million includes cash flows used in financing activities for the 2008 period. Our financing activities of \$1.3 million for the 2007 three month period related primarily to additional bridge loan borrowings.

At April 30, 2008, the Company had cash, cash equivalents, and short-term investments of approximately \$30.0 million. The Company estimates that such cash reserves will be sufficient to fund the development of the Aversion® Technology 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 March 31, 2008 (in thousands):

Expected cash payments on contractual obligations outstanding at March 31, 2008	Total	Due in 2008	Due in 2009	Due Thereafter	
Clinical trials	\$ 2,404	\$ 2,404	\$ -	\$ -	-
Operating leases	30	23	7	-	-
Employment agreements	663	663	-	-	-
Total contractual cash obligations	\$ 3,097	\$ 3,090	\$ 7	\$ -	-
<b>Expected cash payments on</b>	<b>Total</b>	<b>Due in 2008</b>	<b>Due in 2009</b>	<b>Due Thereafter</b>	



**contractual obligations entered into  
subsequent to March 31, 2008**

Employment agreements	\$	508	\$	218	\$	290	\$	-
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### ***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 first 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***

There are no material changes 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 those risks.

### **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.

April 30, 2008

ACURA PHARMACEUTICALS, INC.

*/s/ Andrew D. Reddick*

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Andrew D. Reddick  
President & Chief Executive Officer

*/s/ Peter A. Clemens*

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Peter A. Clemens  
Senior VP & Chief Financial Officer

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