ACURA PHARMACEUTICALS, INC Form 10-Q November 02, 2007

(Exact name of registrant as specified in its charter)

New York 11-0853640

(State or other Jurisdiction of incorporation or organization)

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

616 N. North Court, Suite 120 Palatine, Illinois

60067

(Address of Principal Executive Offices)

(Zip Code)

#### 847 705 7709

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Ac	Ir	ndicate b	check mar	k whether	the registra	int is a	n accelerated	filer (a	s defined in	Rule 1	2b-2 of the	e Exchange	e Act	(1
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Yes o No þ

As of November 2, 2007 the registrant had 427,056,493 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)

	September 30, 2007	J	December 31, 2006
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents	\$ 12,045	\$	228
Prepaid clinical study costs	1,249		-
Prepaid insurance	202		179
Prepaid expenses and other current assets	11		60
Total current assets	13,507		467
PROPERTY, PLANT & EQUIPMENT, NET	1,090		1,145
DEPOSITS	7		7
TOTAL ASSETS	\$ 14,604	\$	1,619
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES			
Senior secured convertible bridge term notes, net	\$ -	\$	7,005
Conversion features on bridge term notes	-		16,750
Secured term note	-		5,000
Current maturities of capital lease obligations	13		25
Accrued expenses	412		328
Total current liabilities	425		29,108
SECURED TERM NOTE	4,992		-
DEFERRED INTEREST PAYABLE	145		-
COMMON STOCK WARRANTS	-		10,784
CAPITAL LEASE OBLIGATIONS, less current maturities	-		7
TOTAL LIADILITIES	5.562		20.900
TOTAL LIABILITIES	5,562		39,899
COMMITMENTS AND CONTINGENCIES			
STOCKHOLDERS' EQUITY (DEFICIT)			
Common stock - \$.01 par value; 650,000 shares authorized; 426,756			
and 330,998 shares issued and outstanding at September 30, 2007 and			
December 31, 2006, respectively	4,268		3,310
Convertible preferred stock - \$.01 par value; 72,027 shares authorized	4,200		3,310
and available for issuance			
Additional paid-in capital	336,154		275,953
Accumulated deficit	(331,380)		(317,543)
Accumulated deficit	(331,360)		(317,343)

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STOCKHOLDERS' EQUITY (DEFICIT)	9,042	(38,280)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 14,604 \$	1,619
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See accompanying notes to the consolidated financial statements.

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# ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

#### CONSOLIDATED STATEMENTS OF OPERATIONS

# UNAUDITED (in thousands, except per share data)

	For the nine months ended September 30, 2007 2006		For the thr ended Sept 2007			
Research and development	\$ 2,775	\$	4,174 \$	827	\$	1,630
Marketing, general and administrative	1,959		4,754	593		1,031
LOSS FROM OPERATIONS	(4,734)		(8,928)	(1,420)		(2,661)
Other Income (Expense)						
Interest expense	(1,113)		(800)	(294)		(305)
Interest income	80		14	70		4
Amortization of debt discount	(2,700)		-	(598)		-
Loss on fair value change of						
conversion features	(3,483)		-	-		-
Loss on fair value change of common						
stock warrants	(1,904)		-	(236)		-
Gain (loss) on asset disposals	22		(10)	2		7
Other expense	(2)		(142)	-		(142)
TOTAL OTHER EXPENSE	(9,100)		(938)	(1,056)		(436)
NET LOSS	\$ (13,834)	\$	(9,866) \$	(2,476)	\$	(3,097)
Basic and diluted loss per share allocable to common stockholders						
(Note 7)	\$ (0.04)	\$	(0.03) \$	(0.01)	\$	(0.01)
Weighted average shares used in computing basic and diluted loss per share allocable to common						
stockholders (Note 7)	369,982		342,039	401,553		346,354

See accompanying notes to the consolidated financial statements.

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## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY or (DEFICIT)

## NINE MONTHS ENDED SEPTEMBER 30, 2007

# UNAUDITED (in thousands, except par values)

	Common Stock	Common Stock			
		\$0.01 Par	Additional		
	Value -	Value -	Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2006	330,998 \$	3,310 \$	275,953	\$ (317,543)\$	(38,280)
Net loss	-	-	-	(13,834)	(13,834)
Deemed dividend related to debt					
modification	-	-	-	(3)	(3)
Reclassification of conversion feature					
value	-	-	21,086	-	21,086
Reclassification of common stock					
warrant value	-	-	12,453	-	12,453
Conversion feature value of issued debt	-	-	1,788	-	1,788
Stock based compensation	-	-	874	-	874
Net proceeds from unit offering	55,555	556	13,590	-	14,146
Conversion of bridge loan notes					
payable, net	39,052	391	9,609	-	10,000
Issuance of common stock for interest	837	8	804	-	812
Issuance of common stock for cashless					
exercise of common stock warrants	314	3	(3)	-	-
Balance at September 30, 2007	426,756 \$	4,268 \$	336,154	\$ (331,380)\$	9,042

See accompanying notes to the consolidated financial statements.

# ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF CASH FLOWS

# FOR THE NINE MONTHS ENDED SEPTEMBER 30,

# UNAUDITED (in thousands, except supplemental disclosures)

Cash flows from Operating Activities:Net loss\$ (13,834) \$ (9,866)Adjustments to reconcile net loss to net cash used in operating activitiesDepreciation and amortization8789Amortization of debt discount2,700-Loss on fair value change of conversion features3,483-Loss on fair value change of common stock warrants1,904-Common stock issued for interest812596Non-cash stock compensation expense8745,096(Gain) loss on asset disposals(22)10Changes in assets and liabilitiesPrepaid expenses and other current assets(1,223)(58)Accrued expenses231430Total adjustments8,8466,163Net cash used in operating activities(4,988)(3,703)Cash flows from Investing Activities:Capital expenditures(32)(21)
Adjustments to reconcile net loss to net cash used in operating activities  Depreciation and amortization 87 89  Amortization of debt discount 2,700 - Loss on fair value change of conversion features 3,483 - Loss on fair value change of common stock warrants 1,904 - Common stock issued for interest 812 596  Non-cash stock compensation expense 874 5,096  (Gain) loss on asset disposals (22) 10  Changes in assets and liabilities  Prepaid expenses and other current assets (1,223) (58)  Accrued expenses 231 430  Total adjustments 8,846 6,163  Net cash used in operating activities (4,988) (3,703)
Depreciation and amortization         87         89           Amortization of debt discount         2,700         -           Loss on fair value change of conversion features         3,483         -           Loss on fair value change of common stock warrants         1,904         -           Common stock issued for interest         812         596           Non-cash stock compensation expense         874         5,096           (Gain) loss on asset disposals         (22)         10           Changes in assets and liabilities         -         -           Prepaid expenses and other current assets         (1,223)         (58)           Accrued expenses         231         430           Total adjustments         8,846         6,163           Net cash used in operating activities         (4,988)         (3,703)    Cash flows from Investing Activities:
Amortization of debt discount  Loss on fair value change of conversion features  Loss on fair value change of common stock warrants  Common stock issued for interest  Non-cash stock compensation expense  (Gain) loss on asset disposals  Changes in assets and liabilities  Prepaid expenses and other current assets  Accrued expenses  Total adjustments  Net cash used in operating activities:  2,700  - 3,483  - 4,904  - 5,906  (Gain) loss on asset disposals  (22)  10  Changes in assets and liabilities  Prepaid expenses and other current assets  (1,223)  (58)  Accrued expenses  231  430  Total adjustments  8,846  6,163  Net cash used in operating activities:
Loss on fair value change of conversion features3,483-Loss on fair value change of common stock warrants1,904-Common stock issued for interest812596Non-cash stock compensation expense8745,096(Gain) loss on asset disposals(22)10Changes in assets and liabilitiesPrepaid expenses and other current assets(1,223)(58)Accrued expenses231430Total adjustments8,8466,163Net cash used in operating activities(4,988)(3,703)
Loss on fair value change of common stock warrants  Common stock issued for interest  Non-cash stock compensation expense  (Gain) loss on asset disposals  (Changes in assets and liabilities  Prepaid expenses and other current assets  Accrued expenses  Total adjustments  Net cash used in operating activities:  1,904  596  812  596  (7,906  (1,223)  (1,223)  (1,223)  (1,223)  (22)  (38)  (4,988)  (3,703)  Cash flows from Investing Activities:
Common stock issued for interest812596Non-cash stock compensation expense8745,096(Gain) loss on asset disposals(22)10Changes in assets and liabilitiesPrepaid expenses and other current assets(1,223)(58)Accrued expenses231430Total adjustments8,8466,163Net cash used in operating activities(4,988)(3,703)Cash flows from Investing Activities:
Non-cash stock compensation expense 874 5,096 (Gain) loss on asset disposals (22) 10 Changes in assets and liabilities Prepaid expenses and other current assets (1,223) (58) Accrued expenses 231 430 Total adjustments 8,846 6,163 Net cash used in operating activities (4,988) (3,703)  Cash flows from Investing Activities:
(Gain) loss on asset disposals(22)10Changes in assets and liabilitiesPrepaid expenses and other current assets(1,223)(58)Accrued expenses231430Total adjustments8,8466,163Net cash used in operating activities(4,988)(3,703)Cash flows from Investing Activities:
Changes in assets and liabilities  Prepaid expenses and other current assets  Accrued expenses  Total adjustments  Net cash used in operating activities  Cash flows from Investing Activities:
Prepaid expenses and other current assets  Accrued expenses  231 430 Total adjustments  8,846 6,163 Net cash used in operating activities  (4,988)  (3,703)  Cash flows from Investing Activities:
Accrued expenses 231 430 Total adjustments 8,846 6,163 Net cash used in operating activities (4,988) (3,703)  Cash flows from Investing Activities:
Total adjustments 8,846 6,163 Net cash used in operating activities (4,988) (3,703)  Cash flows from Investing Activities:
Net cash used in operating activities (4,988) (3,703)  Cash flows from Investing Activities:
Cash flows from Investing Activities:
Capital expenditures (21)
Capital expenditures (52)
Proceeds from asset disposals 22 69
Net cash (used in) provided by investing activities (10) 48
Cash flows from Financing Activities:
Proceeds from issuance of senior secured term notes payable 2,696 3,574
Proceeds from the exercise of stock options - 72
Proceeds (net) from the unit offering
Repayments of bridge loans (8) -
Payments on capital lease obligations (19) (23)
Net cash provided by financing activities 16,815 3,623
Increase (decrease) in cash and cash equivalents 11,817 (32)
Cash and cash equivalents at beginning of period 228 260
Cash and cash equivalents at end of period \$ 12,045 \$ 228
Cash paid for interest \$ 156 \$ 201

See accompanying notes to the consolidated financial statements.

#### ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

#### CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

# SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES

#### **UNAUDITED**

(in thousands, except supplemental disclosures)

#### Nine Months ended September 30, 2007

- 1. The Company issued 475,522 shares of common stock valued at \$460,000 as payment of Senior Secured Convertible Bridge Term Notes Payable accrued interest.
- 2. The Company issued 361,505 shares of common stock valued at \$352,000 as payment of Secured Term Note Payable accrued interest.
- 3. Warrants to purchase an aggregate 580,092 shares of common stock were exercised at exercise prices between \$0.12 and \$0.66 per share in a series of cashless exercise transactions resulting in the issuance of aggregate 313,616 shares of common stock.
- 4. The issuance of \$896,000 Senior Secured Convertible Bridge term Notes during the period January 1, 2007 through March 29, 2007 included conversion features measured at \$849,000, which resulted in the recording of an equal amount of debt discount and conversion feature liabilities.
- 5. The change in all separated conversion feature's fair value through March 30, 2007 resulted in a loss of \$3,483,000. Due to a debt agreement modification on March 30, 2007, the then current conversion feature fair value of \$21,086,000 was reclassified from liabilities to equity.
- 6. The issuance of \$1,800,000 of Senior Secured Bridge Term Notes included conversion features measured at \$1,552,000, which resulted in a recording of an equal amount of debt discount to equity.
- 7. The change in the common stock warrants' fair value through the earlier of their exercise date or March 30, 2007 resulted in a loss of 1,668,000. Due to a debt agreement modification on March 30, 2007, the then current fair value of all 15,921,000 outstanding common stock warrants of \$12,307,000 was reclassified from liabilities to equity, as was \$146,000 of such value related to warrants exercised during the period.
- 8. Anti-dilution provisions in certain warrant grants were triggered resulting in a loss of \$236,000 with an equal amount recorded against equity.
- 9. Senior Secured Convertible Bridge Term Notes Payable of \$10,544,000, less unamortized debt discount of \$544,000 was converted into 39,051,844 shares of common stock.

#### Nine Months ended September 30, 2006

1. The Company issued 653,284 shares of Common Stock as payment of \$463,000 of Secured Term Note Payable accrued interest.

- 2. The Company issued 193,447 shares of Common Stock as payment of \$133,000 of Bridge Loan accrued interest.
- 3. Warrants to purchase 165,934 shares of Common Stock were exercised in March 2006 at an exercise price of \$0.48 per share in a cashless exercise transaction resulting in the issuance of 19,065 shares of Common Stock.
- 4. Warrants to purchase 30,698 shares of Common Stock were exercised in May 2006 at an exercise price of \$0.47 per share in a cashless exercise transaction resulting in the issuance of 4,729 shares of Common Stock.
- 5. A warrant to purchase 150,000 shares of Common Stock was modified due to its anti-dilution clause resulting in a \$142,000 stock compensation expense.

See accompanying notes to the consolidated financial statements.

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#### ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### **SEPTEMBER 30, 2007 AND 2006**

#### **NOTE 1 - BASIS OF PRESENTATION**

The accompanying unaudited consolidated financial statements of Acura Pharmaceuticals, Inc. and subsidiary (the "Company") have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accrual adjustments, considered necessary to present fairly the financial position as of September 30, 2007 and results of operations and cash flows for the three and nine months ended September 30, 2007, assuming that the Company will continue as a going concern, have been made. The results of operations for the three and nine month period ended September 30, 2007 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2007. The unaudited consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2006 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.

#### **NOTE 2 - LIQUIDITY MATTERS**

The accompanying unaudited financial statements have been prepared assuming the Company will continue as a going concern. On August 20, 2007, the Company entered into a Securities Purchase Agreement with the investors named therein and issued to such investors an aggregate of 23,605,551 units at a price of \$1.08 per unit (the "Unit Offering"). See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Unit Offering" for a description of the Unit Offering. Giving effect to the Unit Offering, at September 30, 2007, the Company had cash and cash equivalents of \$12.0 million, working capital of \$13.1 million, and an accumulated deficit of \$331.1 million. At December 31, 2006, the Company had cash and cash equivalents of \$0.2 million, working capital deficit of \$28.6 million and an accumulated deficit of \$317.5 million. The Company incurred a loss from operations of \$4.7 million and a net loss of \$13.6 million during the nine months ended September 30, 2007 and a loss from operations of \$10.8 million and a net loss of \$6.0 million during the year ended December 31, 2006. Historically, the Company has incurred significant losses.

On October 30, 2007, the Company and King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc., entered into a License, Development and Commercialization Agreement (the "Agreement"). Among other things, the Agreement provides that the Company will receive an upfront non-refundable cash payment of \$30 million upon closing of the transaction. Closing of the transaction is subject to the receipt of approval under the Hart-Scott-Rodino Antitrust Improvements Act. See Note 12 of this Report under the caption "King Agreement" for a description of the Agreement and related risks and uncertainties.

On November 1, 2007, the Company had cash and cash equivalents of approximately \$11.3 million, including the proceeds from a July 2007 Bridge Loan and the Unit Offering. The Company estimates that current cash reserves will fund operating activities through September 2008. To fund further operations and product development activities, the Company must complete the closing of the transaction contemplated by the Agreement with King and receive the \$30 million upfront payment contemplated by such Agreement. As of the date of this Report, the conditions to closing

have not been satisfied and no payments had been received by the Company under the Agreement. Notwithstanding the execution of the Agreement with King there can be no assurance that the Company's product development efforts will result in commercially viable products or that the conditions to the Company's receipt of the payments provided for in the Agreement will be satisfied. The Company's failure to successfully develop the Aversion® Technology in a timely manner and to avoid infringing patents and other intellectual property rights of third parties will have a material adverse impact on its financial condition and results of operations.

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#### **NOTE 3 - NEW ACCOUNTING PRONOUNCEMENTS**

In July 2006, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 48 regarding "Accounting for Uncertainty in Income Taxes," an interpretation of FASB Statement No. 109 ("FIN 48"), defining the threshold for recognizing the benefits of tax-return positions in the financial statements as "more-likely-than-not" to be sustained by the taxing authorities. The Company has reviewed its tax positions for tax years 2003 through 2005 and the adoption of FIN 48 on January 1, 2007 did not result in establishing a contingent tax liability reserve or a corresponding charge to retained earnings. The Company has substantial tax benefits derived from its net operating loss carryforwards but has provided 100% valuation allowances against such tax benefits as described in Note 5.

In September 2006, the FASB issued Statement of Financial Accounting Standards 157, "Fair Value Measurements ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently evaluating the impact the adoption of this statement could have on its financial condition, results of operations and cash flows.

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"), which permits companies to measure many financial instruments and certain other items at fair value at specified election dates. Unrealized gains and losses on these items will be reported in earnings at each subsequent reporting date. The fair value option may be applied instrument by instrument (with a few exceptions), is irrevocable and is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the impact of SFAS No. 159 on its financial statements.

#### **NOTE 4 - 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, incentive compensation, and other administrative 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 CRO's based on agreed upon terms including payments in advance of the study starting date. The Company reviews and accrues CRO and clinical trial study expenses based on work performed and relies on estimates of the 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 a CRO clinical trial agreement with an estimated cost of \$5.9 million against which the Company has made payments of \$1,589,000. Of such payments, \$1,249,000 was prepaid at September 30, 2007. The unfunded CRO commitment of \$4,303,000 is expected to be incurred as subjects are enrolled into the clinical study.

#### **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 109"), "Accounting for Income Taxes." Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, income tax credit carryforwards are reported as deferred income tax assets. At December 31, 2006, the Company has gross Federal, state, and city operating loss carryforwards aggregating \$141.2 million, \$101.0 million, and \$46.3 million, respectively, expiring during the years 2009 through 2026. The tax loss carryforwards of the Company and its subsidiary may be subject to limitation by Section 382 of the Internal Revenue Code with respect to the amount utilizable each year. This limitation reduces the Company's ability to utilize net operating loss carryforwards each year. The amount of the limitation has not been quantified. SFAS 109 requires a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. At September 30, 2007 and December 31, 2006, a valuation allowance equal to 100% of the net deferred income tax assets was used and primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards. In the event the Company were to determine that it would be able to realize some or all its deferred income tax assets in the future, an adjustment to the deferred income tax asset would increase income in the period such determination was made.

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#### **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 nine months ended September 30, 2006 is \$0.1 million of share-based compensation expense relating to a dilution adjustment on a previously issued warrant to a former Company employee pursuant to dilution protections contained in such warrant.

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

On December 22, 2005, the Board of Directors approved the Company's 2005 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 30 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 27,500,000 RSUs were granted to the Company's employees. In February 2006, an aggregate of 2,000,000 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 will vest on a straight-line monthly basis through December 2007. During the nine months ended September 30, 2007, 7,374,000 RSUs vested. Of the RSU awards granted, 27,042,000 and 19,667,000 were vested as of September 30, 2007 and December 31, 2006, respectively, and 2,458,000 and 9,833,000 were nonvested as of September 30, 2007 and December 31, 2006, respectively.

The weighted average fair value of both RSU grants is \$0.35 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 \$680,000 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 \$9,724,000 and is being amortized using a graded vesting method which treats the December 2005 RSU grant as a series of awards rather than a single award and attributes 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. At September 30, 2007, the total remaining unrecognized share-based compensation expense related to the nonvested December 2005

RSU awards was \$34,000, which will be amortized to compensation expense in the fourth quarter of 2007. The Company recognized share-based compensation expense from the RSU awards of \$0.9 million and \$5.0 million during the nine months ended September 30, 2007 and 2006, respectively, and of \$0.2 million and \$0.9 million during the three months ended September 30, 2007 and 2006, respectively. No RSUs have been granted since February 2006. As of September 30, 2007 and December 31, 2006, the aggregate intrinsic value of the RSU awards outstanding and vested was \$45,431,000 and \$14,357,000, respectively.

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#### **Stock Option Plans**

The Company has stock options outstanding under a 1995 Stock Option Plan and a 1998 Stock Option Plan. The 1995 Stock Option Plan expired in May 2005 but options granted under such plan remain outstanding.

Stock options to purchase 18,995,000 shares with a weighted-average exercise price of \$0.26 were outstanding at September 30, 2007 and December 31, 2006, of which 18,373,000 options were vested at December 31, 2006. During the nine months ended September 30, 2007, stock options to purchase an additional 311,000 options having an exercise price of \$0.13 vested, bringing the total vested options outstanding at September 30, 2007 to 18,684,000. No stock options were granted, exercised or expired during the nine months ended September 30, 2007.

As of September 30, 2007, the Company had \$13,000 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 six months. Total intrinsic value of stock options outstanding and exercisable at September 30, 2007 and December 31, 2006 was \$26,741,000 and \$10,253,000, 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 September 30, 2007 and 2006 are 61.2 million and 47.5 million, respectively, of potentially dilutive securities, as the effect of including them would be antidilutive. Accordingly, the loss per share is the same result for both basic and diluted computations.

Net loss used in the Company's earnings (loss) per share 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, as described in Note 9.

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	Nine months ended September 30,			Three months ended September 30,			
(in thousands, except per share data) Numerator:		2007		2006	2007		2006
Net loss	\$	(13,598)	\$	(9,866) \$	(2,240)	\$	(3,097)
Deemed dividend from modification of debt		(3)		(774)	-		(774)
Net loss allocable to common stockholders	\$	(13,601)	\$	(10,640) \$	(2,240)	\$	(3,871)
Denominator:							
Common shares (weighted)		346,198		329,443	375,340		329,974
Vested restricted stock units (weighted)		23,784		12,596	26,213		16,380
Weighted average shares used in computing basic and diluted loss per share allocable to common stockholders		369,982		342,039	401,553		346,354
stockholders		309,982		342,039	401,333		340,334
Basic and diluted loss per share allocable to common stockholders	\$	(0.04)	\$	(0.03) \$	(0.01)	\$	(0.01)
Potentially dilutive securities as of period end:							
Common stock issuable (see #1 below):							
Vested and nonvested employee and							
director stock options		18,995		19,195	18,995		19,195
Nonvested restricted stock units		2,458		12,292	2,458		12,292
Common stock warrants		39,716		16,021	39,716		16,021
Total excluded dilutive common stock							
equivalents		61,169		47,508	61,169		47,508

<sup>(1)</sup> 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):

	S	Sept 30, 2007	Dec 31, 2006
Payroll, payroll taxes and benefits	\$	79 \$	62
Legal fees		85	19
Accounting and tax service fees		88	70
Franchise taxes		11	15
Property taxes		73	52
Clinical, regulatory and patent consulting fees		70	60
Other fees and services		6	50

\$ 412 \$ 328

#### NOTE 9 - NOTES PAYABLE AND BRIDGE LOAN AGREEMENTS

Notes payable are summarized as follows (in thousands):

Senior secured convertible bridge term notes (a):		Sept 30, 2007		Dec 31, 2006
	\$		Φ	7 0 1 0
Face value	Ф	-	\$	7,848
Debt discount		-		(843)
		-		7,005
Conversion feature value		-		16,750
	\$	-	\$	23,755
Secured term note (b)	\$	4,992	\$	5,000
Capital lease obligations	\$	13	\$	32
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#### (a) Senior Secured Convertible Bridge Term Notes

As of August 19, 2007, the Company had borrowed \$10.544 million pursuant to a series of loan agreements between the Company, Galen Partners III, L.P. and its affiliates, Care Capital Investments II, LP and its affiliate, and Essex Woodlands Health Ventures V, L.P. (collectively, the "VC Investors"), and certain other shareholders of the Company dating from June 2005 to January 2006 - all as amended through July 2007 (the "Bridge Loans). The proceeds from the Bridge Loans were used by the Company to develop its Aversion® Technology and fund related operating expenses. The Bridge Loans carried an interest rate of 10%, payable quarterly which, pursuant a November 2006 amendment, was payable, at the Company's option, with shares of its Common Stock. The Bridge Loans, as amended in March 2007, had a scheduled maturity date of September 30, 2007.

As described in "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Unit Offering", the entire \$10.544 million principal amount of the Bridge Loans was converted into the Company's Units in the Unit Offering pursuant to the terms of the Securities Purchase Agreement dated August 20, 2007 between the Company and each of the investors listed therein.

Through August 2006, the Bridge Loans did not include conversion provisions. An amendment to the Bridge Loans effected in August 2006 added a conversion feature which allowed, at the lenders' option, the Bridge Loans to be converted into the Company's Common Stock upon a qualifying equity financing at a conversion price equal to the per share price implicit in such equity financing. The Company did not assign any value to the new conversion feature as it did not provide the lenders with an opportunity to receive value in a conversion in excess of the face value of the debt regardless of the per share price of that equity financing.

In November 2006 and March 2007, the conversion feature of the Bridge Loans was further amended to allow the bridge loan lenders to convert the Bridge Loans into the Company's common stock, upon the completion of a third-party equity financing providing gross proceeds to the Company in the aggregate amount of at least \$5.0 million (a "Third Party Equity Financing"), a Change of Control Transaction or upon the maturity date of the Bridge Loans (each a "Triggering Event"). Upon the occurrence of a Triggering Event, the bridge lenders could convert \$3.8 million (as of August 9, 2007) of Bridge Loans into the Company's common stock at a conversion price equal to (A) in the case of the completion of a Third Party Equity Financing, the lesser of (i) 80% of the average closing bid and asked prices of the Company's common stock for the twenty trading days immediately preceding the public announcement of the Third Party Investor Financing, but not less than \$0.21 per share (ii) the average price of the securities sold by the Company in such Third Party Equity Financing (80% of such average price in the case of \$1.8 million of Bridge Loans), and (iii) \$0.44 per share for \$2.0 million of Bridge Loans and \$0.46 per share for \$1.8 million of Bridge Loans and (B) in the case of a Change of Control Transaction or upon the maturity date of the Bridge Loans, the lesser of (i) 80% of the average closing bid and asked prices of the Company's common stock for the twenty trading days immediately preceding the public announcement of the Change of Control Transaction or the maturity date, as applicable, but not less than \$0.21 per share, and (ii) \$0.44 per share for \$2.0 million of Bridge Loans and \$0.46 per share for \$1.8 million of Bridge Loans. In addition, upon a Triggering Event, the bridge lenders could convert \$2.55 million of Bridge Loans into the Company's common stock at a conversion price of \$0.20 per share, \$2.3 million of Bridge Loans at a conversion price of \$0.225 per share and \$1.894 million of Bridge Loans at a conversion price of \$0.25 per share.

The November and December 2006 issuances of Bridge Loans for an aggregate face value of \$1,104,000 included this amended conversion feature which the Company valued at an aggregate of \$1,034,000. This value was recorded as a liability with an offsetting \$1,025,000 debt discount (which was amortized over the term of the Bridge Loans) and \$9,000 of issuance loss. However, as the debt was issued to shareholders who control the Company, this loss was recorded as a non-cash deemed dividend rather than effecting net loss. Additional issuances of \$896,000 of Bridge Loans in January and February 2007 similarly had aggregate conversion feature value of \$849,000 and a loss upon issuance of \$3,000, which was recorded as a non-cash deemed dividend rather than effecting net loss.

The November 2006 amendment of the conversion feature on all of the then outstanding Bridge Loans, coupled with the requirement under current accounting guidance to separate the value of the conversion feature from the debt, required the Company to record the value of the amended conversion feature on that outstanding debt as a liability and a loss on the modification of debt. The Company assigned a value of \$19.951 million to these conversion features at date of modification and reflected that loss as non-cash deemed dividend.

Upon revaluing the aggregate conversion features on all outstanding Bridge Loans as of March 30, 2007 (the date immediately before further amendment to the Bridge Loans), the Company recorded the resulting increase in value as a \$3.483 million loss. The increase in the Company's common stock trading price from December 31, 2006 to March 30, 2007 resulted in the increase in the value of the conversion liability. The Bridge Loan amendment on March 30, 2007 limited the conversion price of the post-October 2006 loans to no lower than \$0.21 per share. With this limit in place, the outstanding conversion feature no longer had to be reflected as Company liabilities. As such, the Company recorded a \$21.1 million reclassification of that liability to additional paid-in capital.

To compute the estimated value of the conversion features just prior to the reclassification described above and at the previous year end, the Company used the Black-Scholes option-pricing model with the following assumptions on these dates:

	Mar 30, 2007	Dec 31, 2006
Company stock	\$ 0.85	\$ 0.74
price		
Exercise price	(see #1 below)	(see #1 below)
Expected dividend	0.0%	0.0%
Risk -free interest	5.07%	5.0%
rate		
Expected volatility	none	88.8%
Contracted term	1 day	3 months

(1) The conversion price per share used to estimate fair value of the Bridge Loan conversion rights was equal to the fixed conversion price per share set forth above for each of the specified Bridge Loan amounts. While the Bridge Loan Agreements provide for other than fixed conversion prices under certain circumstances, the Company has judged that the fixed conversion prices will most likely be the lowest price per share under any of the circumstances and the lender would therefore select such fixed price for their conversion.

The conversion features related to \$1.8 million Bridge Note issuances (dated March 30, 2007, April 2, 2007, May 17, 2007, and July 10, 2007) were not required to be separated and accounted for at fair value. However, based on the conversion price of those notes, the issuances did include beneficial conversion features whereby the common stock to be issued upon conversion would be worth more than the underlying debt if converted upon issuance. That incremental value, computed as \$339,000, \$170,000, \$443,000 and \$600,000, respectively, was recorded as additional paid in capital and as debt discount, which will be amortized over the term of the notes. Upon conversion of the Bridge Loans into Units of the Unit Offering dated August 20, 2007, \$544,000 of unamortized beneficial conversion features reflected as debt discount was recorded as a reduction to additional paid in capital.

#### (b) Secured Term Note

The Company is a party to a certain loan agreement with each of the VC Investors and certain other shareholders of the Company dated February 10, 2004 (the "2004 Secured Term Note"). The 2004 Secured Term Note is in the principal amount of \$5.0 million and is secured by a lien on all of the Company's and its subsidiary's' assets. On June 28, 2007, the 2004 Secured Term Note was amended to extend the maturity date from June 30, 2007 to September 30, 2007 and further amended on August 20, 2007 to extend the maturity date from September 30, 2007 to December 31,

2008. In addition, the August 20, 2007 amendment to the 2004 Secured Term Note reduced the interest rate from a variable rate of prime plus 4.5%, to a fixed rate of 10.0% per annum and to provide for interest payments in the form of cash instead of the Company's common stock. During September 2007 approximately \$8,000 of principal was repaid under the 2004 Secured Term Note leaving a principal balance of \$4,992,000. Simultaneous with the Company's receipt of the \$30 million upfront cash payment anticipated to be received pursuant to the closing of the Agreement with King described in Note 12 of this Report under the caption "King Agreement" the Company will prepay the principal amount plus unpaid interest relating to the 2004 Secured Term Note.

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On September 24, 2007, the 2004 Secured Term Note was further amended to provide for the accrual and deferral of accrued interest payments until the earlier of (i) the December 31, 2008 maturity date of the Note, or (ii) Company's receipt of proceeds in excess of \$5.0 million from a third party pharmaceutical company or companies pursuant to which the Company, in one or more transactions, grants such pharmaceutical company or companies rights to any of the Company's products or product candidates or rights to the Company's Aversion® Technology, with such proceeds including any up front payments, progress payments, milestone payments, license fees, royalties and similar payments, but excluding fees for services, reimbursements or advances for costs and expenses. Deferred interest is due on the maturity date, or if earlier, ten days after the occurrence of an event described in (ii) above. Upon the occurrence of an event described in (ii) above, all future interest payments are to be paid in cash on a quarterly basis. The carrying interest rate at September 30, 2007 was 10.0% and at December 31, 2006 was 12.75%. At September 30, 2007, interest of \$145,000 had been deferred under the 2004 Secured Term Note.

#### NOTE 10 - COMMON STOCK WARRANTS

At September 30, 2007, the Company had outstanding common stock purchase warrants, exercisable for an aggregate of approximately 39,716,000 shares of common stock, all of which contained cashless exercise features. Of such outstanding warrants, (i) 13,889,000 were issued in connection with the Company's August 2007 Unit Offering (See "Item 2. Management's Discussion Analysis of Financial Condition and Results of Operations - Unit Offering and description of the Unit Offering), (ii) 9,763,000 were issued in upon conversion of \$10.544 million in principal amount under the Company's outstanding Bridge Loans into Units as part of the Company's August 2007 Unit Offering, (iii) 5,197,000 were issued in connection with the issuance of bridge loans and financing commitments from 2001 through 2003, (iv) 10,701,000 were issued to Watson Pharmaceuticals, Inc. in connection with their agreement to amend the Watson Notes at December 20, 2002, and (v) 166,000 were issued in 2003 as part of the settlement terms with a former executive officer of the Company. In August 2007, a warrant issued in 2003 in connection with the issuance of a bridge loan, was increased by 313,000 shares as result of the anti-dilution provision of such warrant. The outstanding warrants have a weighted average remaining term of 6.0 years with exercise prices ranging from \$0.12 to \$0.99 per share, and a weighted average exercise price of \$0.32.

During the nine months ended September 30, 2007, warrants to purchase an aggregate 580,092 shares of Common Stock were exercised at exercise prices between \$0.12 and \$0.66 per share in a series of cashless exercise transactions resulting in the issuance of aggregate 313,616 shares of Common Stock. At September 30, 2007, outstanding common stock purchase warrants exercisable for 467,000, 4,085,000, 811,000 and 34,353,000 shares of the Company's common stock will expire if unexercised during the years 2008, 2009, 2010 and thereafter, respectively.

As a result of the November 2006 amendment to the Bridge Loans, the Company's outstanding common stock purchase warrants commenced being accounted for as mark-to-market liabilities with a recorded value of \$10.784 million at December 31, 2006. Upon revaluing the warrants just before their exercise or as of March 30, 2007 (the date immediately before further amendment to the Bridge Loans), the Company recorded the resulting increase in value as a \$1.668 million loss. The increase in the Company's common stock trading price from December 31, 2006 to March 30, 2007 resulted in the increase in the value of the warrant liability. The Bridge Loan amendment on March 30, 2007 limited the conversion price of the post-October 2006 loans to no lower than \$0.21 per share. With this limit in place, the outstanding warrants were no longer required to be reflected as Company liabilities. As such, the Company recorded a \$12.307 million reclassification of that liability to additional paid-in capital in addition to a \$146,000 reclassification related to warrants exercised during the first quarter of 2007.

#### **NOTE 11 - COMMITMENTS AND CONTINGENCIES**

#### **Employment Contracts**

The employment agreements of the Company's officers Andrew D. Reddick, Ron J. Spivey, Ph.D., and Peter A. Clemens were automatically renewed on October 2, 2007, each for a term expiring December 31, 2008. The term of each of the employment agreements provides for automatic one year renewals in the absence of written notice to the contrary from the Company or such Officer at least ninety days prior to the expiration of any one-year renewal period.

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#### **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.

#### **NOTE 12 - RECENT EVENTS**

#### King Agreement

On October 30, 2007, the Company and King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc., entered into a License, Development and Commercialization Agreement (the "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<sup>TM</sup> Tablets (formerly known as OxyADF). The Agreement provides King with an exclusive license in the Territory for ACUROX<sup>TM</sup> Tablets and another undisclosed opioid product utilizing Acura's Aversion® Technology. In addition, the 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 Agreement, King will make an upfront cash payment to Acura of \$30 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<sup>TM</sup> Tablets and similar amounts with respect to each subsequent Aversion® Technology product developed under the Agreement. King will reimburse Acura for all research and development expenses incurred beginning from September 19, 2007 for ACUROX<sup>TM</sup> 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 and pay Acura a royalty ranging from 5% to 25% based on the level of combined annual net sales for all products subject to the Agreement. King will also make a one-time cash payment to Acura of \$50 million in the first year in which the combined annual net sales of all products exceed \$750 million.

King and Acura will form a joint steering committee to coordinate development and commercialization strategies. With King's oversight, Acura will conduct all ACUROX<sup>TM</sup> Tablet development activities through approval of a New Drug Application ("NDA") and thereafter King will commercialize ACUROX<sup>TM</sup> in the U.S. With respect to all other products subject to the 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. All products developed pursuant to the Agreement will be manufactured by King or a third party contract manufacturer under the direction of King. Subject to the Agreement, King will have final decision making authority with respect to all development and commercialization activities for all products licensed.

The Agreement closing is subject to antitrust review under the Hart-Scott-Rodino Antitrust Improvements Act.

The foregoing description of the Agreement contains forward-looking statements about the revenue generating potential of ACUROX<sup>TM</sup> 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 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, 2006, under the heading "Risks Factors".

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#### 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 effect a 1 for 10 reverse stock split. The reverse stock split will take effect on or about December 5, 2007, subject to compliance with OTC Bulletin Board requirements.

#### 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.

#### 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 the actual results, performance or achievements of the Company 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, the Company's ability to secure additional financing to fund continued product development and operations, the Company's ability to successfully close and fulfill its obligations under the Agreement with King Pharmaceuticals Research and Development, Inc described in Note 12 of this Report under the caption "King Agreement"., and the Company's ability to fulfill the U.S. Food and Drug Administration's ("FDA") requirements for approving the Company's product candidates for commercial 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 the Company's product candidates, the adequacy of the development program for the Company's product candidates, changes in regulatory requirements, adverse safety findings relating to the Company's product candidates, the risk that the FDA may not agree with the Company's analysis of its 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 or otherwise of the studies, the risk that further studies of the Company's product candidates 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: the Company's ability to attract and retain highly skilled personnel; its ability to secure and protect its patents, trademarks and proprietary rights; its ability to avoid infringement of patents, trademarks and other proprietary rights or trade secrets of third parties; litigation or regulatory action that could require the Company to pay significant damages or change the way it conducts its business; the Company's ability to compete successfully against current and future competitors; its dependence on third-party suppliers of raw materials; its ability to secure U.S. Drug Enforcement Administration ("DEA") quotas and source controlled substances that constitute the active ingredients of the Company's products in development; difficulties or delays in clinical trials for Company products or in the manufacture of Company products; and other risks and uncertainties detailed in this Report. The Company is at development stage and may not ever have any products or technologies that generate revenue. 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

Acura Pharmaceuticals, Inc. (the "Company") is 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 treat pain and also discourage the three 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<sup>TM</sup> Tablets (formerly known as OxyADF), the Company's 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"). The Company conducts internal research, development, laboratory, manufacturing and warehousing activities for Aversion® Technology at its 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, the Company engages numerous of pharmaceutical product 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<sup>TM</sup> Tablets and other product candidates under the direction of the Company.

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The Company is focused on (i) development and evaluation, in concert with CROs, of product candidates utilizing the Company's Aversion® Technology; (ii) 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; (iii) prosecution of the Company's patent applications relating to Aversion® Technology with the United States Patent and Trademark Office ("USPTO") and foreign equivalents; and (iv) 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 September 30, 2007, the Company had unrestricted cash and cash equivalents of \$12.0 million compared to \$0.2 million at December 31, 2006. The Company had working capital of \$13.1 million at September 30, 2007 and a working capital deficit of \$28.6 million at December 31, 2006. The Company had an accumulated deficit of \$331.1 million and \$317.5 million at September 30, 2007 and December 31, 2006, respectively. The Company incurred a loss from operations of \$4.7 million and a net loss of \$13.6 million during the nine months ended September 30, 2007 and a loss from operations of \$10.8 million and a net loss of \$6.0 million during the year ended December 31, 2006.

On November 1, 2007, the Company had cash and cash equivalents of approximately \$11.3 million, including the proceeds from a Bridge Loan funded in July 2007 and the net proceeds from the Company's August 2007 Unit Offering described below under the caption "Unit Offering". The Company estimates that its current cash reserves will fund operating activities through September 2008.

The Company has incurred net losses since 1992 and the Company's consolidated financial statements for each of the years ended December 31, 2003 through 2006 were prepared on a going-concern basis, expressing substantial doubt about the Company's ability to continue as a going-concern. The Company's future profitability will depend on several factors, including (i) the Company's ability to successfully close and fulfill its obligations pursuant to the Agreement with King Pharmaceuticals Research and Development, Inc. ("King") as more fully described in Note 12 of this report under the caption Recent Events, "King Agreement" and (ii) the successful commercialization by King and other future potential licensees (if any) of products incorporating Aversion® Technology.

#### **Unit Offering**

On August 20, 2007 the Company entered into a Securities Purchase Agreement with the investors named therein (the "Investors"). Pursuant to the Agreement, the Investors purchased, in the aggregate, 23,651,847 Units ("Units") of the Company, at a price of \$1.08 per Unit (the "Unit Offering"). Each Unit consisted of four shares of common stock, \$0.01 par value ("Common Stock") and a warrant to purchase one share of common stock (the "Warrants"). 13,888,886 of the Units issued under the Securities Purchase Agreement were issued for cash, with the balance of 9,962,961 Units issued in consideration of the conversion of an aggregate of \$10.544 million in principal amount under the Company's outstanding Bridge Loan. The net cash proceeds to the Company after expenses of the Unit Offering were approximately \$14.2 million.

The Warrants are immediately exercisable at a price of \$0.34 per share and expire August 20, 2014. The Warrants may be exercised for cash, or on a cashless basis commencing 180 days after the closing if at the time of exercise the shares underlying the Warrants are not covered by an effective registration statement filed with the U.S. Securities and Exchange Commission ("SEC").

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The Common Stock and shares of Common Stock underlying the Warrants sold pursuant to the Unit Offering have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States in the absence of an effective registration statement or exemption from registration requirements. Pursuant to the Securities Purchase Agreement, the Company was required to file a registration statement within 60 days after the closing of the Unit Offering for purposes of registering the resale of the shares of Common Stock issued and the shares of Common Stock issuable upon exercise of the Warrants (the "Registration Statement"). On October 1, 2007, the Company filed the Registration Statement. Subject to certain exceptions, the Company is required to cause the Registration Statement to be declared effective by the SEC within one hundred eighty (180) days after the August 20, 2007 closing date of the Securities Purchase Agreement. The Company must exercise best efforts to keep the Registration Statement effective until the earlier of (i) the date that all shares of Common Stock and shares of Common Stock underlying Warrants covered by such Registration Statement have been sold, or (ii) the fifth anniversary of the Registration Statement, provided that the period during which the Registration Statement must be kept effective can be shortened to not less than two years by agreement of holders of registrable securities. Shares of Common Stock eligible for sale under Rule 144(k) of the Securities Act of 1933, as amended, need not be included in the Registration Statement. Under certain circumstances, if shares are excluded from the Registration Statement by the SEC, the Company may be required to file one or more additional Registration Statements for the excluded shares.

Subject to certain exceptions, for each day that the Company misses the foregoing deadlines or fails to keep the Registration Statement effective, it must pay each Investor 0.05% of the purchase price of securities covered by the Registration Statement and held by the Investor at such time, up to a maximum of 9.9% of the amount paid by an Investor for the Units. Interest on unpaid amount accrues at 1% per month.

The requirement in the Securities Purchase Agreement to file the Registration Statement triggered the piggyback registration rights granted to certain holders of shares of Common Stock and warrants exercisable for Common Stock pursuant to an Amended and Restated Registration Rights Agreement dated as of February 6, 2004, as amended. GCE Holdings LLC, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP and Essex Woodlands Health Ventures V, L.P. have exercised their piggyback registration rights and have requested that an aggregate of 265,840,164 shares of Common Stock and shares underlying warrants be included in the Registration Statement pursuant to such piggyback registration rights.

As part of the completion of the transactions contemplated in the Securities Purchase Agreement, each of GCE Holdings LLC and the other bridge lenders converted the entire \$10.544 million principal amount under the Bridge Loans into Units issued pursuant to the Securities Purchase Agreement in full and complete satisfaction of the Company's obligations under the outstanding Bridge Loans. As a result of the conversion of the Bridge Loans into Units, the Bridge Loan Agreements and related security agreements and guarantees were terminated.

#### Status of Strategy with Commercial Partners

On October 30, 2007 the Company entered into a License, Development and Commercialization Agreement (the "Agreement") with King Pharmaceuticals Research and Development Inc., ("King") as more fully described in Note 12, of this Report under the caption "King Agreement" Pursuant to the Agreement, the Company and King will develop and commercialize certain opioid analgesic products utilizing the Company's Aversion® (abuse deterrent) Technology including ACUROX<sup>TM</sup> Tablets (formerly known as OxyADF). The closing of the transaction contemplated by the Agreement is subject to receipt of approval under the Hart-Scott-Rodino Antitrust Improvements Act. The Company's future revenue, if any, will be derived from milestone and royalty payments relating to the Agreement and other milestone and royalty payments, if any, derived from agreements anticipated to be potentially negotiated and executed by the Company with other pharmaceutical company partners. No assurance can be given that the conditions to the closing of the Agreement with King will be satisfied, that the Company will receive the milestone and royalty payments provided for in such Agreement, or that the Company will be successful in entering into similar agreements

 $with other pharmaceutical \ partners \ to \ develop \ and \ commercialize \ products \ incorporating \ the \ Aversion \textcircled{\$} \ Technology.$ 

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

In April 2007, the United States Patent and Trademark Office (the "USPTO") granted to the Company U.S. Patent No. 7,201,920 titled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms". The allowed patent claims encompass pharmaceutical compositions intended to reduce or discourage the three most common methods of prescription opioid analgesic product misuse and abuse including; (i) intravenous injection of dissolved tablets or capsules; (ii) snorting of crushed tablets or capsules and; (iii) intentionally swallowing excess quantities of tablets or capsules. The opioid analgesics in the allowed 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, the Company has pending five U.S. non-provisional patent applications, three WO/PCT patent applications and multiple additional U.S. provisional and international patent filings relating to compositions containing abuseable drugs. Additionally, the Company has seven U.S. issued patents and one U.S. patent application pending related to its Opioid Synthesis Technologies.

#### ACUROX<sup>TM</sup> Tablets (formerly known as OxyADF) Development Status

ACUROX<sup>TM</sup> Company's lead product candidate with Aversion® (abuse deterrent) 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 composition of function inactive ingredients. The Company and King intend to file a 505(b)(2) NDA for ACUROX<sup>TM</sup> Tablets with an anticipated indication for treating moderate to moderately severe pain. ACUROX<sup>TM</sup> Tablets are intended to effectively treat moderate to moderately severe pain while also discouraging or deterring the three 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 excessive numbers of tablets. ACUROX<sup>TM</sup> Tablets are being developed pursuant to an active investigational new drug application ("IND") on file with the FDA.

#### ACUROX™ Tablets: Technical and Pre-Clinical Development Program and Regulatory Strategy and Status

The technical and pre-clinical development program and regulatory strategy and status for ACUROX<sup>TM</sup> 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<sup>TM</sup> Tablets regulatory requirements prior to their acceptance for filing of a 505(b)(2) NDA submission for ACUROX<sup>TM</sup> Tablets.

Technical and Pre-Clinical	Status
Development	
Formulation development	Complete
Pilot bioequivalence study	Complete
Pivotal oxycodone extraction study	Complete (results summarized below)
Viscosity and syringability of dissolved	Complete
tablets in various solvents	-
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 the Company
Regulatory Affairs	Status
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

Company

Product labeling Strategy and concepts discussed with FDA. Written

guidance provided by FDA to the Company

Regulatory submission for commercial

ACUROX<sup>TM</sup> Tablets are eligible for submission as a

505(b)(2) NDA per FDA written guidance to

Company

Phase III pivotal clinical trial

A single phase III efficacy and safety trial is

required per FDA written guidance to Company

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distribution in the U.S.

#### Aversion® Technology: 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 oxycodone-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<sup>TM</sup> 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<sup>TM</sup> 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, the Company believes 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 substantially discourage prospective I.V. drug abusers or recreational drug users from extracting oxycodone from an ACUROX<sup>TM</sup> Tablet. As described below, the Company has compared the relative difficulty of extracting oxycodone from ACUROX<sup>TM</sup> Tablets to several currently marketed oxycodone-containing products.

#### **Pivotal Oxycodone Extraction Study:**

The Company, in concert with a leading pharmaceutical laboratory CRO (the "Laboratory CRO"), completed a pivotal study to assess certain properties of ACUROX<sup>TM</sup> using tablets from batches manufactured by the Company at its 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<sup>TM</sup> (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<sup>TM</sup> Tablets resulted in a "trace" of oxycodone HCl extracted in 355 minutes and was rated 10 in relative difficulty. The Company intends to utilize the data and results from this pivotal laboratory study in its 505(b)(2) NDA submission for ACUROX<sup>TM</sup> Tablets to the FDA.

# Summary Results of Pivotal Laboratory Oxycodone Extraction Study (described above)

Product Tested, Oxycodone HCl Strength and Product Supplier	Approximate laboratory time required to produce a form suitable for intravenous injection	Extraction Scheme and Yield	Difficulty Rating 1 = Easy to 10 = Difficult
OxyContin® Tablets 1x 40mg tablet Purdue Pharma	3 minutes	3 steps ~92% Yield	1
Oxycodone HCl Tablets 8 x 5mg tablets,	6 minutes	3 Steps ~71% Yield	2

# Mallinckrodt

Percocet® Tablets 8 x 5/325mg tablets Endo Labs	<10 minutes with vacuum assisted filtration	3 Steps ~75% Yield	3-4	
ACUROX <sup>TM</sup> Tablets 8 x 5/30mg tablets Acura Pharmaceuticals	355 minutes with no success	23 Steps ~0% Yield	10	
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# Aversion® Technology: Intended to Deter Nasal Snorting

In addition to potential intravenous or oral abuse, prospective drug abusers may easily crush or grind currently marketed oxycodone-containing tablet or capsule products. The crushed 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<sup>TM</sup> Tablets have three mechanisms intended to discourage nasal snorting. First, ACUROX<sup>TM</sup> Tablets are formulated with a functional excipient intended to induce mild burning and irritation of the nasal passages if the tablets are crushed and the prospective drug abuser attempts to snort the crushed tablets. Second, when ACUROX<sup>TM</sup> Tablets are crushed and snorted, the Company expects the moisture in the nasal passages will form a viscous gel with the crushed tablet powder, trapping the oxycodone in the gel and reducing the amount of oxycodone available for absorption through the lining of the nasal passages. Third, the Company expects 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, the Company expects potential nasal abusers of ACUROX<sup>TM</sup> 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. The Company has evaluated the potential for reducing nasal absorption using a standard in-vitro experimental process. As discussed below, the Company intends to further evaluate ACUROX<sup>TM</sup> Tablet nasal abuse characteristics in laboratory, animal, and phase I clinical studies.

### Aversion® Technology: Intended to Deter Swallowing Excess Quantities of Tablets

ACUROX<sup>TM</sup> Tablets contain two active ingredients. In each tablet, oxycodone HCl is included to provide analgesic effects and niacin is included as a second active ingredient in a sub-therapeutic amount. 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 ACUROXTM Tablet, may cause a combination of unpleasant symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort. 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<sup>TM</sup> Tablet. When ACUROX<sup>TM</sup> 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 effects of niacin. However, when a person swallows excess quantities of ACUROX<sup>TM</sup> Tablets, it is intended that 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 15 minutes after the excess dose is swallowed and self-resolve approximately 90 minutes later. The Company does not expect that the undesirable niacin effects will be "fool-proof" in discouraging swallowing excessive numbers of ACUROX<sup>TM</sup> Tablets. However, we anticipate that inclusion of niacin in ACUROX<sup>TM</sup> Tablets and other Aversion® Technology product candidates will deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of ACUROX<sup>TM</sup> 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<sup>TM</sup> Tablets, and do not have the potential to cause these undesirable niacin effects. As described below, the Company has evaluated the effects of niacin in three phase II clinical studies in subjects with and without a history of opioid abuse.

# Expectations for ACUROX<sup>TM</sup> Tablets Product Labeling

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 the Company stating that an indication for abuse deterrence must be supported by data from two adequate and well-controlled clinical trials. The Company does not intend to seek an indication for abuse deterrence for ACUROX<sup>TM</sup> Tablets. Instead, the Company is seeking an indication for ACUROX<sup>TM</sup> Tablets for treatment of moderate to moderately severe pain. The FDA has also provided written guidance to the Company stating that language regarding abuse deterrence, which is supported by rigorous, scientific data, may be placed into appropriate sections of the ACUROX<sup>TM</sup>

Tablet product label. In this regard, the Company intends to seek FDA approval of language in the ACUROX<sup>TM</sup> Tablet product label describing the physical characteristics of the product and likely results if attempts are made to dissolve tablets in solvents for intravenous injection, and/or snort crushed tablets, and/or swallow excessive numbers of tablets. The Company believes this product labeling strategy will provide a viable promotional platform for the commercialization of ACUROX<sup>TM</sup> Tablets and other product candidates utilizing Aversion® Technology. At this stage there can be no assurances that the Company's product labeling strategy for ACUROX<sup>TM</sup> Tablets will be successful or that FDA approved product labeling, if any, will provide a viable commercialization platform.

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# ACUROX<sup>TM</sup> Tablets Clinical Development Program: Completed and Planned Clinical Studies

The clinical development program for ACUROX<sup>TM</sup> Tablets is summarized below. At this stage, the Company 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<sup>TM</sup> Tablets.

# **ACUROX**<sup>TM</sup> **Tablets Clinical Development Program**

Clinical Study Number	Clinical Study Description Phase I	Status
AP-ADF-101	Niacin dose-response in normal subjects	Final study report complete
AP-ADF-104	Phase I: Bioequivalence to non Aversion® Technology Reference Listed Drug	Final study report complete. ACUROX <sup>TM</sup> tablets are bioequivalent to reference listed drug
AP-ADF-106	Evaluate effects of nasal snorting	Received FDA written guidance for protocol design
AP-ADF-108	Single dose pharmacokinetics (dose linearity and food effect)	Subject enrollment in progress
AP-ADF-109	Multi-dose pharmacokinetics (dose linearity)	Received FDA written guidance for protocol design
AP-ADF-110	Single dose pharmacokinetics and bioavailability. Required if there is not dose linearity	Received FDA written guidance for protocol design
	Phase II	
AP-ADF-102	Relative dislike of oxycodone HCl/niacin versus oxycodone alone in subjects with a history of opioid abuse	Final study report complete
AP-ADF-103	Repeat dose safety and tolerability in normal subjects	Final study report complete
AP-ADF-107	Niacin dose-response in normal subjects	Final study report complete
AP-ADF-111	Abuse Liability of ACUROX™ Tablets	Study protocol drafted
	Phase III	
AP-ADF-105	Pivotal efficacy and safety	Special Protocol Assessment (SPA) agreed by FDA.

Patient enrollment in progress

# Summary of ACUROX<sup>TM</sup> Tablets Phase II Study Designs, Status and Results

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

The principal study investigator's overall conclusion was that the results of 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. The Company intends to include the data and results from StudyAP-ADF-102 in its 505(b)(2) NDA submission for ACUROX<sup>TM</sup> Tablets to the FDA.

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<sup>TM</sup> (oxycodone/niacin) Tablets in comparison to oxycodone HCl tablets without niacin, the Company 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<sup>TM</sup> Tablets (with or without niacin) and post-treatment safety and tolerability assessments. Efficacy (the tolerability of ACUROX<sup>TM</sup>) was evaluated with a Side Effects and Symptoms Questionnaire (SESQ) and an ACUROX<sup>TM</sup> 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<sup>TM</sup> Tablets with and without niacin. The mean post-dose SESO 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<sup>TM</sup> 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<sup>TM</sup> 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). The Company intends to include the data and results from Study AP-ADF-103 in its 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<sup>TM</sup> 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 standardized high-fat breakfast consisting of two fried eggs, hash browns, two fried bacon strips, toast, butter, and whole milk, 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 396% of subjects reporting either "no effect" or "easy to tolerate". Niacin was also well tolerated at doses of 90 mg, with 86% of Fasted subjects reporting either "no effect" or "easy to tolerate" and 14% reporting "mildly unpleasant, but tolerable". 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 (386%) reported mildly unpleasant, unpleasant, or intolerable effects. At least 40% of subjects dosed at 480 and 600 mg reported either "unpleasant and difficult to tolerate" or "intolerable and would never take 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 (368%) 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. The Company intends to include the data and results from Study AP-ADF-107 in its 505(b)(2) NDA submission to the FDA for ACUROX<sup>TM</sup> Tablets.

#### Additional ACUROX<sup>TM</sup> Table Slinical Studies Planned

The FDA has requested that the Company complete certain additional clinical studies for ACUROX™ Tablets prior to accepting our 505(b)(2) NDA submission including, as of the date of this Report, the following:

**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<sup>TM</sup> (oxycodone HCl and niacin) Tablets versus Placebo for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Patients." This short term phase III study is planned to enroll approximately 400 patients with moderate to severe pain following

bunionectomy surgery. The Company submitted the study protocol to the FDA and requested 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. A SPA is binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing is begun. On June 19, 2007, the Company announced that the FDA and the Company had reached agreement on the SPA for Study AP-ADF-105. The Company believes the completion of Study AP-ADF-105 is the critical time and events path to 505(b)(2) NDA submission for ACUROX<sup>TM</sup> Tablets. Patient enrollment in Study AP-ADF-105 is in progress.

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**Study AP-ADF-106:** This will be a phase I clinical study, for use in product labeling, evaluating the nasal irritating characteristics of crushed ACUROX<sup>TM</sup> Tablets (with and/or without oxycodone HCl) anticipated to enroll 12-24 normal subjects.

**Studies AP-ADF-108, AP-ADF-109, and if necessary AP-ADF-110:** These will be phase I single dose or multi-dose pharmacokinetic studies anticipated to enroll approximately 25-50 normal subjects per study. Subject enrollment in Study AP-ADF-108 is in progress.

**Study AP-ADF-111**: This will be a phase II, single-center, randomized, double-blind assessment of the abuse Liability of ACUROX<sup>TM</sup> (oxycodone HCl and niacin) Tablets in approximately 30 subjects with a history of opioid abuse. This clinical study has not been requested by FDA but is being conducted by the Company with the intent of providing clinical data in support of certain targeted ACUROX<sup>TM</sup> Tablet product label claims.

# Estimated Timing for submission of a 505(b)(2) NDA for ACUROX<sup>TM</sup> Tablets

Estimating the dates of initiation and completion of clinical studies and the costs to complete development of the Company's product candidates, including ACUROX<sup>TM</sup> Tablets, would be speculative and potentially misleading. The Company expects to reassess its future research and development plans pending review of data received from development activities currently in progress and the availability of cash resources to fund such development activities. The cost and pace of future research and development activities are linked and subject to change. At this stage there can be no assurance that any of the Company's research and development efforts, including those for ACUROX<sup>TM</sup> Tablets, will lead to a 505(b)(2) NDA submission or that if NDA submissions are made with the FDA, that any such submission will be accepted for filing or approved by the FDA.

# Results of Operations for the Nine Months Ended September 30, 2007 and September 30, 2006

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® Technology and related product candidates. To generate revenue, the Company plans to enter into license, development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license product candidates utilizing the Company's Aversion® Technology and further develop, register and commercialize multiple formulations and strengths of such product candidates. The Company had no revenues for the nine months ended September 30, 2007 and 2006 and relied upon the net proceeds from an offering of the Company's securities and bridge loans to fund operations and development activities.

	N	ine Months E	Cnded	l Sept 30,		Change
(\$ in thousands):		2007		2006	<b>Dollars</b>	%
Research and development expenses	\$	2,775	\$	4,174	\$ (1,3	399) (33.5)7%

Research and development expense in the nine months ended September 30, 2007 and 2006 consisted of development of 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 2007 and 2006 results are non-cash stock-based compensation charges of \$355 and \$1,811, respectively. Excluding the stock-based compensation expense, there is a \$57 increase in overall expenses primarily attributable to a) decreasing clinical study costs of \$227, b) \$254 of added insurance costs of which \$168 was reclassified from our general and administrative expenses to our research and development expenses, and c) \$30 of added legal and regulatory consulting expenses. The decrease in stock-compensation expense of \$1,456 (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.

	Nine Months Ended Sept 30,					Change		
(\$ in thousands):		2007		2006		Dollars	%	
Marketing, general & administrative								
expenses	\$	1,959	\$	4,754	\$	(2,795)	(58.8)%	
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During the nine months ended September 30, 2007, marketing expenses consisted of Aversion® Technology primary market research studies and payroll costs. The Company's general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll costs. Included in the 2007 and 2006 results are non-cash stock-based compensation charges of \$519 and \$3,143, respectively. Excluding the stock-based compensation expense, the expenses decreased \$171 which is attributable to a) \$70 reduction in general legal services, b) \$168 reduction of insurance costs from the reclassification of these costs from our general and administrative operations to our research and development expenses, and c) offset by \$67 increase in a marketing costs due to a research study conducted by the Company in 2007. The decrease in stock-compensation expense of \$2,624 (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 a nonrecurring \$680 expense immediately recorded in February 2006 on the grant of restricted stock units to the Company's independent directors, and to the vesting method used for amortization. The fair value of the awards is 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.

	Ni	ne Months I	Ended	Sept 30,	Change			
(\$ in thousands):		2007		2006	<b>Dollars</b>		%	
Interest expense, net of interest								
income	\$	1,033	\$	786	\$	247		31.4%

The Company incurred interest on its \$5.0 million Secured Term Note at the variable rate of prime plus 4.5% up to August 19, 2007 and thereafter at the fixed rate of 10% per annum. Interest on the \$5 million Secured Term Note was payable in the Company's common stock through August 19, 2007 and thereafter payable in cash. Such cash interest is deferred until the earlier of (i) the December 31, 2008 maturity date of the Secured Term Note, or (ii) the Company's receipt of proceeds in excess of \$5.0 million from a third party pharmaceutical company or companies pursuant to which the Company, in one or more transactions, grants such pharmaceutical company or companies' rights to any of the Company's products or product candidates or rights to the Company's Aversion® Technology. The Company also incurred interest on its \$10.544 million Senior Secured Convertible Bridge Notes (collectively, the "Bridge Loans") at the fixed rate of 10%. 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 the Company's common stock. On August 20, 2007, the entire \$10.544 million principal amount of the Bridge Loans was converted into the Company's Units in accordance with the Unit Offering. The increase in net interest expense in 2007 primarily resulted from the addition of \$4.420 million of Bridge Loans since September 30, 2006.

	I	Nine Months E	nded	Change		
(\$ in thousands):		2007		2006	Dollars	%
Net loss	\$	(13,834)	\$	(9,866) \$	3,968	40.2%
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The November and December 2006 Bridge Loans for an aggregate face value of \$1,104 included an amended conversion feature which the Company valued at an aggregate of \$1,034. This value was recorded as a liability with an offsetting \$1,025 debt discount (which was amortized over the term of the Bridge Loans) and \$9 of issuance loss. However, as the debt was issued to shareholders who control the Company, this loss was recorded as non-cash deemed dividend rather than effecting net loss. Additional issuances of \$896 of Bridge Loans in January and February 2007 similarly had aggregate conversion feature value of \$849 and a loss upon issuance of \$3 recorded as non-cash deemed dividend rather than effecting net loss. The November 2006 amendment of the conversion feature on all of the then outstanding Bridge Loans, coupled with the requirement under current accounting guidance to separate the value of the conversion feature from the debt, required the Company to record the value of the amended conversion feature on that outstanding debt as a liability and a loss on the modification of debt. The Company assigned a value of \$19,951 to these conversion features at date of modification and reflected that loss as non-cash deemed dividend in the fourth quarter 2006.

Upon revaluing the aggregate conversion features on all outstanding Bridge Loans as of March 30, 2007 (the date immediately before further amendment to the Bridge Loans), the Company recorded the resulting increase in value as a \$3,483 loss. The increase in the Company's common stock trading price from December 31, 2006 to March 30, 2007 resulted in the increase in the value of the conversion liability. The Bridge Loan amendment on March 30, 2007 limited the conversion price of the post-October 2006 loans to not less than \$0.21 per share. With this limit in place, the outstanding conversion feature no longer had to be reflected as Company liabilities. As such, the Company recorded a \$21,086 reclassification of that liability to additional paid-in capital.

As a result of the November 2006 amendment to the Bridge Loans, the Company's outstanding common stock purchase warrants started being accounted for as mark-to-market liabilities with a recorded value of \$10,784 at December 31, 2006. Upon revaluing the warrants just before they were exercised or as of March 30, 2007 (the date immediately before further amendment to the Bridge Loans), the Company recorded the resulting increase in value as a \$1,668 loss. The increase in the Company's common stock trading price from December 31, 2006 to March 30, 2007 resulted in the increase in the value of the warrant liability. The Bridge Loan amendment on March 30, 2007 limited the conversion price of the post-October 2006 loans to no lower than \$0.21 per share. With this limit in place, the outstanding warrants no longer had to be reflected as Company liabilities. As such, the Company recorded a \$12,307 reclassification of that liability to additional paid-in capital; in addition to a \$146 reclassification relating to warrants exercised during the first quarter of 2007.

In addition to the items discussed above, other items contributing to the Company's reported net loss for the periods were i) \$2,700 of amortization expense related to debt discounts recorded upon issuance of certain debt agreements dated in latter 2006 and throughout 2007, (the nine month period ended September 30, 2006 had no such debt amortization expense), ii) \$142 of share-based compensation expense relating to a dilution adjustment on a previously issued warrant to a former Company employee pursuant to dilution protections contained in such warrant recorded during the period ended September 30, 2006, iii) anti-dilution clauses contained in certain warrants were triggered resulting in a loss of \$236,000 with an equal amount recorded against equity and iv) disposals of capital equipment and other expenses during the periods resulted in reported income of \$20 and a expense of \$10 for the 2007 and 2006 periods, respectively.

# Results of Operations for the Three Months Ended September 30, 2007 and September 30, 2006

The Company had no revenues for the three months ended September 30, 2007 and 2006 and relied upon the net proceeds from an offering of the Company's securities and bridge loans to fund operations and development activities.

	Thre	ee Months	Ende	d Sept 30,	Chan	ge
(\$ in thousands):	2	007		2006	Dollars	<b>%</b>
Research and development expenses	\$	827	\$	1,630 \$	(803)	(49.3)%

Research and development expense in the three months ended September 30, 2007 and 2006 consisted of development of 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 2007 and 2006 results are non-cash stock-based compensation charges of \$61 and \$358, respectively. Excluding the stock-based compensation expense, there is a \$506 decreases in overall expenses primarily attributable to \$562 of reduced clinical study costs and \$56 of added insurance costs reclassified from our general and administrative operations and assigned to our research and development operations. During the three months ended September 30, 2006, the Company had various studies in progress, including studies AP-ADF-102 and AP-ADF-107. The decrease in stock-compensation expense of \$297 (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.

	Three Months Ended Sept 30,					Change		
(\$ in thousands):	200	7		2006	Dolla	ars	<b>%</b>	
Marketing, general & administrative								
expenses	\$	593	\$	1,031	\$	(440)	(42.7)7%	

During the three months ended September 30, 2007, marketing expenses consisted of Aversion® Technology primary market research studies and payroll costs. The Company's general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll costs. Included in the 2007 and 2006 results are non-cash stock-based compensation charges of \$90 and \$519, respectively. Excluding the stock-based compensation expense, the decrease of \$9 in overall expenses is attributable to a) \$72 increase in legal and accounting professional services, b) \$56 reduction in insurance costs from the reclassification of these costs from our general and administrative expense to our research and development expenses, and c) \$25 decrease in marketing research costs pertaining to studies conducted by the Company. The decrease in stock-compensation expense of \$429 (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 is 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.

	Thr	ee Months	Ended	Sept 30,	Change		
(\$ in thousands):	2	007		2006	<b>Dollars</b>	<b>%</b>	
Interest expense, net of interest							
income	\$	224	\$	301	\$ (	77) (25	(.6)%

The Company incurred interest on its \$5.0 million Secured Term Note at the variable rate of prime plus 4.5% up to August 19, 2007 and thereafter at the fixed rate of 10%. Interest on the \$5.0 million Secured Term Note was payable in the Company's common stock through August 19, 2007 and thereafter is payable in cash. Such cash interest is deferred until the earlier of (i) the December 31, 2008 maturity date of the Secured Term Note, or (ii) the Company's receipt of proceeds in excess of \$5.0 million from a third party pharmaceutical company or companies pursuant to which the Company, in one or more transactions, grants such pharmaceutical company or companies' rights to any of the Company's products or product candidates or rights to the Company's Aversion® Technology. The Company also incurred interest on its \$10.544 million Senior Secured Convertible Bridge Notes (collectively, the "Bridge Loans") at the fixed rate of 10%. 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 the Company's common stock. On August 20, 2007, the entire \$10.544 million principal amount of the Bridge Loans was converted into the

Company's Units in accordance with the Unit Offering. The Company's Bridge Loans increased by \$4.420 million since September 30, 2006, however the decrease in interest expense reflects both the reduction in the \$5.0 million Secured Term Note's interest rate and the conversion of all Bridge Loans as discussed above.

	Thi	ree Months	Ended	Change	e	
(\$ in thousands):	2	2007		2006	Dollars	<b>%</b>
Net loss	\$	(2,476)	\$	(3,097) \$	(621)	(20.1)%

Contributing to the Company's reported net loss for the periods were i) \$598 of amortization expense related to debt discounts recorded upon issuance of certain debt agreements dating March 30, 2007 and thereafter, recorded during the period ended September 30, 2007, (the period ended September 30, 2006 had no such debt amortization expense), ii) \$142 of share-based compensation expense relating to a dilution adjustment on a previously issued warrant to a former Company employee pursuant to dilution protections contained in such warrant recorded during the period ended September 30, 2006, iii) anti-dilution clauses contained in certain warrants were triggered resulting in a loss of \$236,000 with an equal amount recorded against equity and iv) disposals of capital equipment resulted in reported losses of \$2 and \$7 for the 2007 and 2006 periods, respectively.

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# **Liquidity and Capital Resources**

At September 30, 2007, the Company had unrestricted cash and cash equivalents of \$12.0 million compared to \$0.2 million at December 31, 2006. The Company had working capital of \$13.1 million at September 30, 2007 compared to a working capital deficit of \$28.6 million at December 31, 2006. The increase in cash and working capital at September 30, 2007 is due primarily to the net proceeds of \$14.2 million received under the Company's Unit Offering, the receipt of \$2.7 million in Bridge Loan in July 2007, and the conversion of the entire \$10.544 million principal amount of the Company's outstanding Bridge Loans into Units in the Unit Offering. Cash flows used in operating activities were \$5.0 million and \$3.7 million for the nine months ended September 30, 2007 and 2006, respectively, primarily representing our net loss for those periods less non-cash charges related to amortization of debt discount, fair value changes of conversion features and common stock warrants for the 2007 period, and stock compensation and common stock issued for interest for both 2007 and 2006 periods. Capital expenditures offset by proceeds from asset disposals include cash flows used in investing activities for the 2007 period and were less than \$50,000 in the 2006 period. Our financing activities of \$16.8 million for the 2007 nine month period related primarily to Unit Offering and additional Bridge Loan borrowings. Our financing activities of \$3.6 million for the 2006 nine month period related primarily to additional Bridge Loans.

# Commercial Focus, Cash Reserves and Funding Requirements

As of November 1, 2007, the Company had cash and cash equivalents of approximately \$11.3 million, which included the proceeds from an additional Bridge Loan funded in July 2007 and the net proceeds from the Company's Unit Offering. The Company estimates that such cash reserves will fund operations through September 2008. To fund further operations and product development activities beyond September 2008, the Company must raise additional financing, or must successfully close the Agreement described in Note 12 (Recent Events) under the caption "King Agreement" and receive the \$30 million up-front non-refundable cash payment anticipated to be received upon the closing of such Agreement. No assurance can be given that the condition to the closing of the Agreement will be satisfied, that the Company will receive the milestone and royalty payments provided for in the Agreement, or that the Company will be successful in entering into similar agreements with other pharmaceuticals partners to develop and commercialize products incorporating the Aversion® Technology. In the absence of the Company's receipt of the upfront, milestone payment provided for in the Agreement, the receipt of payments under similar license agreements anticipated to be negotiated and executed by the Company with other pharmaceutical company partners, or the receipt of financing from other sources, the Company may be required to scale back or terminate operations and possibly seek protection under applicable bankruptcy laws. The Company's failure to successfully develop the Aversion® Technology in a timely manner, and to avoid infringing patents and other intellectual property rights of third parties will have a material adverse impact on its financial condition and results of operations.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying consolidated balance sheets is dependent upon continued operations of the Company, which in turn are dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to succeed in its future operations. The Company's financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

The following table presents the Company's expected cash requirements for contractual obligations outstanding as of September 30, 2007 (in thousands):

Expected cash payments on						
contractual obligations outstanding					Due	
at September 30, 2007	Total	<b>Due in 2007</b>	$\mathbf{D}$	Oue in 2008	Thereafter	
Term note	\$ 4,992	\$	- \$	4,992	\$	_

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Interest on term note (see #1 below)	770	-	770	-
Capital leases	13	6	7	-
Operating leases	12	7	5	-
Clinical trials	4,303	2,170	2,133	-
Employment agreements	185	185	-	-
Total contractual cash obligations	\$ 10,275 \$	2,368 \$	7,907 \$	-

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Expected cash payments on						
contractual obligations entered into						Due
subsequent to September 30, 2007	Total	Du	e in 2007	D	ue in 2008	Thereafter
Clinical trials	\$ 398	\$	172	\$	226	\$ -
Employment agreements	740		-		740	_
Total contractual cash obligations	\$ 1,138	\$	172	\$	966	\$ -

(1) The interest on the Company's fixed rate Senior Secured Term Note is payable in cash upon the earlier of (i) the maturity date of the Note or (ii) the Company's receipt of proceeds in excess of \$5.0 million from a third party company in a licensing or similar transaction relating to the Company's Aversion® Technology.

# **Critical Accounting Policies**

Note A of the Notes to Consolidated Financial Statements, in the Company's 2006 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 that Annual Report are the same as applicable to 2007.

#### Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. The Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-14 as of the end of the period covered by this Report. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including its consolidated subsidiary) required to be included in the Company's periodic Securities and Exchange Commission filings. No significant changes were made in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

Changes in Internal Control over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the period covered by this Report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

#### **PART II**

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

In addition to the Risk Factors set forth in Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2006, shareholders and prospective investors in the Company's common stock should carefully consider the following risks:

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# Any Future Sale of a Substantial Number of Shares to be included in the Company's Registration Statement Could Depress the Trading Price of our Stock, Lower our Value and Make It More Difficult for us to Raise Capital

In accordance with the terms of the Securities Purchase Agreement dated August 20, 2007 between us and the Investors named therein pursuant to which we completed our Unit Offering, we are obligated to file a registration statement with the U.S. Securities and Exchange Commission to register the shares included in the Units issued pursuant to the Securities Purchase Agreement, including shares underlying warrants included in the Units. In addition, pursuant to the exercise of previously granted piggyback registration rights, each of GCE Holdings, LLC, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP and Essex Woodlands Health Ventures V, L.P. have exercised their piggyback registration rights to include an aggregate of 265,840,164 shares in such registration statement. As a result, 384,099,399 shares (representing approximately 75% of our shares outstanding on a fully-diluted basis - including all derivative securities, whether or not currently exercisable) are proposed to be included in the registration statement for resale by selling stockholders, including 355,164,234 shares held by affiliates. If some or all of such shares proposed to be included in the registration statement are sold by affiliates and others it will likely have the effect of depressing the trading price of our common stock. In addition, such sales could lower our value and make it more difficult for us to raise capital.

There Can Be No Assurance That The Total Market Capitalization Of Our Common Stock (The Aggregate Value Of Our Common Stock At The Then Market Price) After A Reverse Stock Split Will Be Equal To Or Greater Than The Total Market Capitalization Before A Reverse Stock Split Or That The Per Share Market Price Of Our Common Stock Following A Reverse Stock Split Will Equal Or Exceed The Current Per Share Market Price

On December 14, 2006, our shareholders authorized our Board of Directors, in its discretion, to effect a reverse stock split of our common stock at one of six ratios on or prior to December 14, 2007. If our Board of Directors elects to implement the reverse stock split prior to December 14, 2007, it would be authorized to do so without need for any further shareholder action. Our Board may also affect a reverse stock split following December 14, 2007 upon receipt of the approval of our stockholders. If our Board elects to affect a reverse stock split, there can be no assurance that the market price per new share of our common stock after the reverse stock split will increase in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split. For example, if the market price of our common stock on the OTCBB before the reverse split was \$1.00 per share, and if our Board of Directors decided to implement the reverse stock split and selects a reverse stock split ratio of one-for-ten, there can be no assurance that the post-split market price of our common stock would be \$10.00 per share or greater. Further, following a reverse stock split there can be no assurance that the market price of our common stock will rise to or maintain any particular level or that we will at any time or at all times be able to meet the minimum-bid-price and other requirements for obtaining a listing of our common stock on the American Stock Exchange or the Nasdaq Capital Market and for maintaining such a listing.

# If A Reverse Stock Split Is Effected, The Resulting Per-Share Stock Price May Not Attract Institutional Investors Or Investment Funds And May Not Satisfy The Investing Guidelines Of Such Investors

There can be no assurance that a reverse stock split will result in a per-share price that will attract institutional investors or investment funds or that such share price will satisfy the investing guidelines of institutional investors or investment funds.

#### Item 2. Unregistered Sale of Equity Securities and Use of Proceeds

Issuance of Common Stock and Warrants. During the Quarter Ended September 30, 2007, as a result of the Company's Securities Purchase Agreement, the Company issued common stock and common stock warrants in the amounts of i) 55,555,544 shares and 13,888,885 warrants for cash consideration of \$15.0 million and ii) 39,051,844 shares and 9,762,962 warrants for the conversion of \$10.544 million in principal amount under the Company's outstanding Bridge Loans.

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Exemption from Registration. The Company issued the above-described Common Stock and Warrants in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended and/or Regulation D promulgated under the Securities Act of 1933. Each of the recipients of such securities represented to the Company that such holder was an accredited investor as defined in Rule 501(a) of the Securities Act of 1933 and that the securities issued pursuant thereto were being acquired for investment purposes.

#### 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.

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### **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.

November 2, 2007

ACURA PHARMACEUTICALS, INC.

/s/ Andrew D. Reddick

Andrew D. Reddick President & Chief Executive Officer

/s/ Peter A. Clemens

Peter A. Clemens Senior VP & Chief Financial Officer

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