

ACURA PHARMACEUTICALS, INC  
Form 10-Q  
August 09, 2007

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**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20649**

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**Form 10-Q**

(Mark One)

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

**For the quarterly period ended June 30, 2007**

or

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

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

**Commission File Number 1-10113**

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**Acura Pharmaceuticals, Inc.**

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

**New York**

(State or other Jurisdiction of  
incorporation or organization)

**11-0853640**

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

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

**Palatine, Illinois**

(Address of Principal Executive Offices)

**60067**

(Zip Code)

**847 705 7709**

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (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  No

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Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of August 9, 2007 the registrant had 332,149,105 shares of Common Stock, \$.01 par value, outstanding.

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

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

	<b>June 30, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 83	\$ 228
Prepaid insurance	115	179
Prepaid expenses and other current assets	64	60
Total current assets	262	467
<b>PROPERTY, PLANT &amp; EQUIPMENT, NET</b>	<b>1,116</b>	<b>1,145</b>
<b>DEPOSITS</b>	<b>7</b>	<b>7</b>
<b>TOTAL ASSETS</b>	<b>\$ 1,385</b>	<b>\$ 1,619</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES</b>		
Senior secured convertible bridge term notes, net	\$ 9,402	\$ 7,005
Conversion features on bridge term notes	-	16,750
Secured term note	5,000	5,000
Current maturities of capital lease obligations	20	25
Accounts payable	63	-
Accrued expenses	516	328
Total current liabilities	15,001	29,108
<b>COMMON STOCK WARRANTS</b>	<b>-</b>	<b>10,784</b>
<b>CAPITAL LEASE OBLIGATIONS, less current maturities</b>	<b>-</b>	<b>7</b>
<b>TOTAL LIABILITIES</b>	<b>15,001</b>	<b>39,899</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' DEFICIT</b>		
Common stock - \$.01 par value; 650,000 shares authorized; 332,149 and 330,998 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively	3,321	3,310
Convertible preferred stock - \$.01 par value; 72,027 shares authorized and available for issuance	-	-
Additional paid-in capital	311,967	275,953
Accumulated deficit	(328,904)	(317,543)

<b>STOCKHOLDERS' DEFICIT</b>		(13,616)		(38,280)
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	\$	1,385	\$	1,619

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 six months ended June 30,		For the three months ended June 30,	
	2007	2006	2007	2006
Research and development	\$ 1,948	\$ 2,544	\$ 752	\$ 1,038
Marketing, general and administrative	1,366	3,724	588	1,303
<b>LOSS FROM OPERATIONS</b>	<b>(3,314)</b>	<b>(6,268)</b>	<b>(1,340)</b>	<b>(2,341)</b>
<b>OTHER INCOME (EXPENSE)</b>				
Interest expense	(819)	(495)	(452)	(270)
Interest income	10	10	5	6
Amortization of debt discount	(2,102)	-	(410)	-
Loss on fair value change of conversion features	(3,483)	-	-	-
Loss on fair value change of common stock warrants	(1,668)	-	-	-
Gain (loss) on asset disposals	20	(17)	-	(10)
Other	(2)	-	(2)	-
<b>TOTAL OTHER EXPENSE</b>	<b>(8,044)</b>	<b>(502)</b>	<b>(859)</b>	<b>(274)</b>
<b>NET LOSS</b>	<b>\$ (11,358)</b>	<b>\$ (6,770)</b>	<b>\$ (2,199)</b>	<b>\$ (2,615)</b>
Basic and diluted loss per share allocable to common stockholders (Note 7)				
	\$ (0.03)	\$ (0.02)	\$ (0.01)	\$ (0.01)
Weighted average shares used in computing basic and diluted loss per share allocable to common stockholders (Note 7)				
	354,036	342,039	355,404	343,507

See accompanying notes to the consolidated financial statements.

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

**SIX MONTHS ENDED JUNE 30, 2007**

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

	<b>Common Stock \$0.01 Par Value Shares</b>	<b>Common Stock \$0.01 Par Value Amount</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
<b>Balance at December 31, 2006</b>	330,998	\$ 3,310	\$ 275,953	\$ (317,543)	\$ (38,280)
Net loss for six months ended June 30, 2007	-	-	-	(11,358)	(11,358)
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	-	-	952	-	952
Stock based compensation	-	-	722	-	722
Issuance of common stock for interest	837	8	804	-	812
Issuance of common stock for cashless exercise of common stock warrants	314	3	(3)	-	-
<b>Balance at June 30, 2007</b>	332,149	\$ 3,321	\$ 311,967	\$ (328,904)	\$ (13,616)

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30,

UNAUDITED

(in thousands, except supplemental disclosures)

	2007	2006
<b>Cash flows from Operating Activities:</b>		
Net loss	\$ (11,358)	\$ (6,770)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	61	60
Amortization of debt discount	2,102	-
Loss on fair value change of conversion features	3,483	-
Loss on fair value change of common stock warrants	1,668	-
Common stock issued for interest	812	303
Non-cash stock compensation expense	722	4,077
(Gain) loss on asset disposals	(20)	17
Changes in assets and liabilities		
Prepaid expenses and other current assets	60	(224)
Accounts payable	63	-
Accrued expenses	188	52
Total adjustments	9,139	4,285
Net cash used in operating activities	(2,219)	(2,485)
<b>Cash flows from Investing Activities:</b>		
Capital expenditures	(29)	(8)
Proceeds from asset disposals	20	62
Net cash (used in) provide by investing activities	(9)	54
<b>Cash flows from Financing Activities:</b>		
Proceeds from issuance of senior secured term notes payable	2,096	2,635
Proceeds from the exercise of stock options	-	43
Payments on capital lease obligations	(13)	(15)
Net cash provided by financing activities	2,083	2,663
(Decrease) increase in cash and cash equivalents	(145)	232
Cash and cash equivalents at beginning of period	228	260
<b>Cash and cash equivalents at end of period</b>	<b>\$ 83</b>	<b>\$ 492</b>
Cash paid for interest	\$ 6	\$ 192

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)**

**Six Months ended June 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 \$1,296,000 Senior Secured Convertible Bridge Term Notes included conversion features measured at \$1,188,000, which resulted in an equal amount of debt discount. The change in all separated conversion feature's fair value through March 30, 2007 resulted in a loss of \$3,483,000. Due to a debt agreement modification on March 30, 2007, the then current conversion feature fair value of \$21,086,000 was reclassified from liabilities to equity.
5. 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.

**Six Months ended June 30, 2006**

1. The Company issued 452,175 shares of common stock as payment of \$303,000 of Secured Term Note Payable accrued interest.
2. Warrants to purchase aggregate 196,632 shares of common stock were exercised at exercise prices of \$0.48 and \$0.47 per share in a series of cashless exercise transactions resulting in the issuance of aggregate 23,794 shares of common stock.

See accompanying notes to the consolidated financial statements.

**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 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, results of operations and cash flows for the six months ended June 30, 2007, assuming that the Company will continue as a going concern, have been made. The results of operations for the six month period ended June 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 financial statements have been prepared assuming the Company will continue as a going concern. At June 30, 2007, the Company had unrestricted cash and cash equivalents of \$0.1 million, a working capital deficit of \$14.7 million, and an accumulated deficit of \$328.9 million. At December 31, 2006, the Company had cash and cash equivalents of \$0.2 million, a working capital deficit of \$28.6 million and an accumulated deficit of \$317.5 million. The Company incurred a loss from operations of \$3.3 million and a net loss of \$11.4 million during the six months ended June 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 and until such time as its product candidates are commercialized, of which no assurance can be given, the Company will continue incurring losses. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

On August 9, 2007, the Company had cash and cash equivalents of approximately \$80,000, which included the proceeds from an additional Bridge Loan funded in July 2007. The Company estimates that its current cash reserves will fund operating activities through mid to late August 2007. To fund further operations and product development activities, the Company must raise additional financing, or enter into alliances or collaboration agreements with third parties resulting in cash payments to the Company relating to its Aversion® Technology. The Company is seeking to secure working capital providing gross proceeds to the Company in the range of approximately \$15 million to \$20 million through the private offering of the Company's securities. The terms of any such securities offering, including, without limitation, the type of equity securities (or securities convertible into equity securities) and the price per share, have not been determined and will, in large part, be determined based upon negotiations between the Company and prospective investors in such private offering. No assurance can be given that the Company will be successful in obtaining any such financing or in securing collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or collaborative agreements will provide for cash payments to the Company sufficient to continue to fund operations. In the absence of such financing or third-party collaborative agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws.

Even assuming the Company is successful in securing additional sources of financing, there can be no assurance that the Company's development efforts will result in commercially viable products or that it will succeed in entering into alliances or collaboration agreements with third parties resulting in payments to the Company. The Company's failure to successfully develop the Aversion® Technology in a timely manner, to obtain issued U.S. patents relating to the Aversion® Technology and to avoid infringing third-party patents and other intellectual property rights 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 adjustment 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.

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

#### **Uncertainty in Income Taxes**

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"), which defines 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 open tax years of 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 them due to uncertainties associated with the realization of those tax benefits (Note 5).

The recognition and measurement of certain tax benefits includes estimates and judgment by 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 would establish a contingent tax liability reserve, interest and penalties related to uncertain tax positions would be classified in general and administrative expenses.

#### **Fair Value Measurements**

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.

### **NOTE 4 - RESEARCH AND DEVELOPMENT**

Research and Development ("R&D") expenses include internal R&D activities and external Contract Research Organization activities ("CRO"). Internal R&D expenses include facility overhead, maintenance, repair and depreciation, laboratory supplies, pre-clinical laboratory experiments, equipment maintenance, repairs and depreciation, salaries, benefits, incentive compensation and other administrative expenses. CRO expenses include preclinical laboratory experiments, clinical trials, clinical trial and regulatory consulting, regulatory counsel and patent counsel. R&D expenses are charged to operations as incurred. The Company reviews and accrues clinical trial expenses based on work performed and relies on an estimate of the costs applicable to the stage of completion of a clinical trial as provided by the CRO. Accrued clinical 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.

### **NOTE 5 - INCOME TAXES**

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 both June 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.

## **NOTE 6 - STOCK-BASED COMPENSATION**

The Company has several stock-based compensation plans covering 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 results for the six months ended June 30, 2007 and 2006 are \$0.7 million and \$4.1 million of stock-based compensation expense relating to the February 2006 grant of restricted stock units to the Company’s independent directors and stock based compensation expenses relating to vesting of stock options and restricted stock units granted to Company employees prior to 2006. No options or restricted stock units have been issued since February 2006.

### **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.

The RSU Plan is administered by the Company’s Board of Directors or a Committee appointed by the Board of Directors. RSUs granted under the 2005 RSU Plan vest on a schedule determined by the Board of Directors or such Committee as set forth in a restricted stock unit award agreement. Unless otherwise set forth in such award agreement, the RSUs fully vest upon a change in control of the Company (as defined in the 2005 RSU Plan) or upon termination of an employee’s employment with the Company without cause or due to death or disability, and in the case of a non-employee director, such person’s death or disability or if such person is not renominated as a director (other than for “cause” or refusal to stand for re-election) or is not elected by the Company’s stockholders, if nominated. Vesting of an RSU entitles the holder thereof to receive a share of common stock of the Company on a distribution date (after payment of the \$0.01 par value per share).

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. No dividends accrue on the shares underlying the RSUs prior to issuance by the Company. The recipients of RSU awards need not be employees or directors of the Company on a distribution date. RSUs may generally not be transferred, except recipients of RSUs may designate beneficiaries to inherit their RSUs upon their death.



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 six months ended June 30, 2007, 4,916,000 RSUs vested. Of the RSU awards granted, 24,583,000 and 19,667,000 were vested as of June 30, 2007 and December 31, 2006, respectively, and 4,917,000 and 9,833,000 were nonvested as of June 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 stock-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 for the six months ending June 30, 2006 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 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 the earlier years than to the later years. At June 30, 2007, the total remaining unrecognized compensation expense related to the nonvested December 2005 RSU awards was \$179,000. This amount will be recognized over the next 6 months. The Company recognized compensation expense from the RSU awards of \$5,264,000 and \$4,261,000, during the years ended December 31, 2006 and 2005, respectively. No related tax benefits were recorded in calendar year 2006 and 2005. As of June 30, 2007 and December 31, 2006, the aggregate intrinsic value of the RSU awards outstanding and vested was \$27,041,000 and \$14,357,000, respectively. As discussed above, the RSU awards are distributable only upon the occurrence of certain events or beginning January 1, 2011.

As of June 30, 2007, the total remaining unrecognized compensation expense relating to unvested outstanding stock options was \$20,000.

#### **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 June 30, 2007 and 2006 are 77.4 million and 50.4 million, respectively, of potentially dilutive securities, as the effect of including them would be antidilutive. Accordingly, the loss per share is the same result from both basic and diluted computations.

Net loss used in the Company's earnings (loss) per share computations includes the impact in 2007 of dividends deemed to have been issued to certain common shareholders as a result of modifications to debt agreements with those shareholders, as further described in Note 9.

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	Six months ended June 30,		Three months ended June 30,	
	2007	2006	2007	2006
(in thousands, except per share data)				
Numerator:				
Net loss	\$ (11,358)	\$ (6,770)	\$ (2,199)	\$ (2,615)
Deemed dividend from modification of debt	(3)	-	-	-
Net loss allocable to common stockholders	\$ (11,361)	\$ (6,770)	\$ (2,199)	\$ (2,615)
Denominator:				
Common shares (weighted)	331,386	329,443	331,641	329,577
Vested restricted stock units (weighted)	22,650	12,596	23,763	13,930
Weighted average shares used in computing basic and diluted loss per share allocable to common stockholders	354,036	342,039	355,404	343,507
Basic and diluted loss per share allocable to common stockholders	\$ (0.03)	\$ (0.02)	\$ (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	19,634	18,995	19,634
Nonvested restricted stock units	4,917	14,750	4,917	14,750
Common stock warrants	15,751	16,045	15,751	16,045
Convertible bridge term notes	37,702	-	37,702	-
Total excluded dilutive common stock equivalents	77,365	50,430	77,365	50,430

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

**NOTE 8 - ACCRUED EXPENSES**

Accrued expenses are summarized as follows (in thousands):

	Jun 30, 2007	Dec 31, 2006
Payroll, payroll taxes and benefits	\$ 85	\$ 62
Legal fees	35	19
Audit examination and tax preparation fees	45	70
Franchise taxes	23	15

Property taxes	66	52
Clinical, regulatory and patent consulting fees	50	60
Clinical trials	162	-
Other fees and services	50	50
	\$ 516	\$ 328

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

Notes payable are summarized as follows (in thousands):

	Jun 30, 2007	Dec 31, 2006
Senior secured convertible bridge term notes (a):		
Face value	\$ 9,944	\$ 7,848
Debt discount	(542)	(843)
	9,402	7,005
Conversion feature value	-	16,750
	\$ 9,402	\$ 23,755
Secured term note (b)	\$ 5,000	\$ 5,000
Capital lease obligations	\$ 20	\$ 32

**(a) Senior Secured Convertible Bridge Term Notes**

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 Company has borrowed \$9.944 million and \$10.544 million as of June 30, 2007 and August 9, 2007, respectively (the "Bridge Loans"). The proceeds from the Bridge Loans have been and continue to be used by the Company to develop its Aversion® Technology and fund related operating expenses. The Bridge Loans carry an interest rate of 10%, payable quarterly which, pursuant a November 2006 amendment, is payable, at the Company's option, with shares of its Common Stock. The Bridge Loans, as amended in March 2007, mature on September 30, 2007.

The Bridge Loans are secured by a lien on all of the Company's assets, senior in right to all other Company indebtedness and restrict its ability to issue any shares of the Company's currently authorized Series A, B or C convertible preferred stock without the prior consent of the bridge lenders, and grants the bridge lenders preemptive rights relating to the issuance of the Company's Series A, B and C convertible preferred stock. The Bridge Loans contain cross default provisions with the 2004 Secured Term Note (described in (b) below) and each of the outstanding Bridge Loans. The Bridge Loans also contain normal and customary affirmative and negative covenants, including restrictions on the Company's ability to incur additional debt or grant any lien on the Company's assets or the assets of its subsidiary, subject to certain permitted exclusions. Additionally, the Bridge Notes require immediate prepayment upon a qualifying common stock equity or debt financing or any sale, transfer license or similar arrangement pursuant to which the Company sells, licenses or otherwise grant rights in any material portion of the Company's intellectual property to any third party, provided that the consummation of any such transaction results in certain minimum amounts of cash proceeds to the Company, net of all costs and expenses.

Through August 2006, the terms of the Bridge Loans did not include any conversion provisions. An August 2006 amendment 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 may 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 Registrant'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 may 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.

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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.

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:

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

Note: 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, \$444,000 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.



**(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, carries a floating rate of interest equal to the prime rate plus 4.5% and matures on September 30, 2007. An amendment to extend the maturity date of such notes from June 30, 2007 to September 30, 2007 occurred on June 28, 2007. The carrying interest rate at June 30, 2007 and December 31, 2006 was 12.75%. The 2004 Secured Term Note contains cross default provisions with each of the outstanding Bridge Loans. The majority holders of the Bridge Loans also are the majority holders of the 2004 Secured Term Note. To the extent cash is not available to the Company to pay this near-term debt obligation upon maturity, the Company expects to negotiate with its lenders to arrange for alternative means to settle the obligation, including, without limitation, the possible additional extension of maturity or conversion of the 2004 Secured Term Note into equity.

**NOTE 10 - COMMON STOCK WARRANTS**

At June 30, 2007, the Company had outstanding common stock purchase warrants, all containing cashless exercise features, exercisable for an aggregate of 15,751,000 shares of common stock. Of such outstanding warrants, 4,884,000 were issued in connection with the issuance of bridge loans and financing commitments from 2001 through 2003, 10,701,000 were issued to Watson in connection with their agreement to amend the Watson Notes at December 20, 2002, and 166,000 were issued in 2003 as part of the settlement terms with a former executive officer of the Company. During the six months ended June 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 314,000 shares of Common Stock. At June 30, 2007, outstanding common stock purchase warrants of 154,000, 4,085,000 and 11,512,000 will expire if unexercised during the years 2008, 2009 and thereafter, respectively, with a weighted average remaining term of 5.0 years. The exercise prices of the warrants range from \$0.12 to \$0.34 per share, with a weighted average price of \$0.33.

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 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 no longer had to be reflected as Company liabilities. As such, the Company recorded a \$12.3 million reclassification of that liability to additional paid-in capital in addition to a \$146,000 reclass related to warrants exercised during the first quarter of 2007. To compute the estimated value of the warrant liability 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:

	March 30, 2007	December 31, 2006
Company stock price	\$ 0.85	\$ 0.74
Exercise price	\$ 0.12 - \$ 0.34	\$ 0.12 - \$ 0.66
Expected dividend	0.0%	0.0%
Risk-free interest rate	4.54% - 4.70%	4.7% - 5.0%
Expected volatility	114.3% - 135.8%	48.4% - 143.5%
Weighted -average volatility	127.7%	127.7%

Contractual term	1.4 years - 6.8 years	38 days - 6.8 years
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## **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 Acura Pharmaceuticals, Inc. (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 enter into contractual arrangements with qualified pharmaceutical partners to license, develop and commercialize the Company's Aversion® (abuse deterrent) Technology and related product candidates, 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. is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® (abuse deterrent) 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. OxyADF Tablets, 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 OxyADF Tablets and other product candidates under the direction of the Company.

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 United States Food and Drug Administration (“FDA”) and other regulatory authorities and commercialize such products.

The Company was historically engaged in development of novel manufacturing processes (the "Opioid Synthesis Technologies") intended for use in the commercial manufacture of certain bulk opioid active pharmaceutical ingredients. In early 2005, the Company announced the suspension of activities relating to the Opioid Synthesis Technologies pending the deputy DEA Administrator's determination relating to the Company's pending application for registration to import narcotic raw materials (the "Narcotic Raw Materials Import Application") filed with the DEA in early 2001. In late 2006, the Company notified the DEA that it was withdrawing the Narcotic Raw Materials Import Application and subsequently, the Company has discontinued all activities relating to the Opioid Synthesis Technologies. The withdrawal of the Narcotic Raw Material Import Application and the discontinuation of all activities relating to the Opioid Synthesis Technologies allows the Company to focus all of its resources on developing and commercializing its Aversion® (abuse deterrent) Technology and related product candidates.

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

At June 30, 2007, the Company had unrestricted cash and cash equivalents of \$0.1 million compared to \$0.2 million at December 31, 2006. The Company had a working capital deficit of \$14.7 million and \$28.6 million at June 30, 2007 and December 31, 2006, respectively. The Company had an accumulated deficit of \$328.9 million and \$317.5 million at June 30, 2007 and December 31, 2006, respectively. The Company incurred a loss from operations of \$3.3 million and a net loss of \$11.4 million during the six months ended June 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 August 9, 2007, the Company had cash and cash equivalents of approximately \$80,000 which included the proceeds from an additional Bridge Loan funded in July 2007. The Company estimates that its current cash reserves will fund operating activities through mid to late August 2007.

The Company has incurred net losses since 1992 and the Company's consolidated financial statements for each of the years ended December 31, 2006, 2005, 2004 and 2003 were prepared on a going-concern basis, expressing substantial doubt about the Company's ability to continue as a going-concern as a result of recurring losses and negative cash flows. The Company's future profitability will depend on several factors, including (i) the Company's ability to secure additional financing to fund continued operations; (ii) the successful completion of the formulation development, clinical testing and acceptable regulatory review of product candidates utilizing the Aversion® Technology; (iii) the Company's ability to negotiate and execute appropriate licensing, development and commercialization agreements with interested third parties relating to the Company's product candidates; and, (iv) the successful commercialization by licensees of products incorporating the Aversion® Technology without infringing the patents and other intellectual property rights of third parties.

### ***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 opioid analgesics and other abuseable drugs. Additionally, the Company has seven U.S. patents issued and one U.S. patent application pending related to its Opioid Synthesis Technologies.



As of the date of this Report, the Company retained ownership of all intellectual property and commercial rights to its product candidates and technologies.

***Status of Strategy with Commercial Partners***

To generate revenue the Company plans to enter into 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 expects to receive milestone payments and a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Aversion® Technology. Future revenue, if any, will be derived from milestone payments and a share of profits and/or royalty payments relating to such collaborative partners' sale of products incorporating the Aversion® Technology. As of the date of this Report, the Company did not have any executed collaborative agreements with Partners, nor can there be any assurance that the Company will successfully enter into such collaborative agreements in the future.

***OxyADF Tablets Development Status***

OxyADF (oxycodone HCl/niacin) Tablets, the 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 and a sub therapeutic amount of niacin. The Company intends to file a 505(b)(2) NDA for OxyADF Tablets with an anticipated indication for treating moderate to moderately severe pain. OxyADF 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. OxyADF Tablets are being developed pursuant to an active investigational new drug application ("IND") on file with the FDA. The FDA has provided written guidance to the Company stating that OxyADF Tablets are an appropriate product candidate for submission as a 505(b)(2) NDA and has confirmed in writing to the Company that no additional toxicology studies are required prior to submission of such NDA.

**OxyADF Tablets: Technical and Pre-Clinical Development and Regulatory Affairs Program**

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

<b>Technical and Pre-Clinical Development</b>	<b>Status</b>
Formulation development	Complete
Pilot bioequivalence study	Complete
Pivotal oxycodone extraction study	Complete (results summarized below)
Viscosity and syringability of dissolved tablets in various solvents	Study results pending and intended to support product labeling
Tablet stability for NDA submission	Testing in process. 18 month real time data demonstrates stability acceptable for NDA submission
Toxicology studies	Not required per FDA written guidance to the Company
<b>Regulatory Affairs</b>	<b>Status</b>

Investigational New Drug Application (IND)	Active
End of Phase II meeting with FDA	Completed Q1-06
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 distribution in the U.S.	OxyADF 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

**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, OxyADF 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 OxyADF Tablets using any generally available solvent, including water or alcohol, into a volume and form suitable for I.V. injection, the tablet converts into a viscous gel matrix 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 OxyADF Tablet. As described below, the Company has compared the relative difficulty of extracting oxycodone from OxyADF 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 OxyADF 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 intravenous (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 OxyADF (oxycodone HCl/niacin) Tablets, OxyContin® (oxycodone HCl Controlled-Release) Tablets, generic oxycodone HCl 5mg Tablets, and Percocet® (oxycodone HCl/acetaminophen, 5mg/325mg) 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. OxyADF 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 OxyADF 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	<u>Difficulty Rating</u>
			1 = Easy to 10 = Difficult
OxyContin® Tablets 1x 40mg tablet Purdue Pharma	3 minutes	3 steps ~92% Yield	1
	6 minutes	3 Steps	2

Oxycodone HCl Tablets 8 x 5mg tablets, Mallinckrodt		~71% Yield	
Percocet® Tablets 8 x 5/325mg tablets Endo Labs	<10 minutes with vacuum assisted filtration	3 Steps ~75% Yield	3-4
OxyADF 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. OxyADF Tablets have three mechanisms intended to discourage nasal snorting. First, OxyADF 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 OxyADF 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 OxyADF 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 OxyADF Tablet nasal abuse characteristics in laboratory, animal, and phase I clinical studies.

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

OxyADF 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 OxyADF 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 OxyADF Tablet. When OxyADF 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 OxyADF 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 OxyADF Tablets. However, we anticipate that inclusion of niacin in OxyADF 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 OxyADF 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 OxyADF 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 OxyADF 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 OxyADF Tablets. Instead, the Company is seeking an indication for OxyADF 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 OxyADF

Tablet product label. In this regard, the Company intends to seek FDA approval of language in the OxyADF 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 OxyADF Tablets and other product candidates utilizing Aversion® Technology. At this stage there can be no assurances that the Company's product labeling strategy for OxyADF Tablets will be successful or that FDA approved product labeling, if any, will provide a viable commercialization platform.

**OxyADF Tablets Clinical Development Program: Completed and Planned Clinical Studies**

The clinical development program for OxyADF 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 OxyADF Tablets.

**OxyADF Tablets Clinical Development Program**

<b>Clinical Study Number</b>	<b>Clinical Study Description</b>	<b>Status</b>
<b>Phase I</b>		
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. OxyADF 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)	Received FDA written guidance for protocol design
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 initial FDA written guidance for protocol design
<b>Phase II</b>		
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
<b>Phase III</b>		
AP-ADF-105	Pivotal efficacy and safety	Special Protocol Assessment (SPA) agreed by FDA

**Summary of OxyADF 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 (DRQS). As an additional measure of subjective effects, subjects completed a 40 item short form of an Addiction Research Inventory (ARCI) that yielded three scale scores - the Morphine Benzodrine Group Scale (MBG), the LSD Specific Scale (LSD) and the Pentobarbital Chlorpromazine Alcohol Group Scale (PCAG). After completion of the study, subjects responded to a Treatment Enjoyment Assessment Questionnaire to select which of the treatments they would take again. Prior to initiating the study, the hypothesis was that the addition of niacin to oxycodone would produce effects that are disliked by subjects with a history of opioid abuse. The maximum scale response to the question "Do you dislike the drug effect you are feeling now?" (i.e. the "Disliking Score"), was designated as the primary efficacy variable. Statistical analysis (maximum dislike response in comparison to 0 mg niacin) was conducted for DRQS, ARCI scales and vital signs. Study results were as follows:

- (1) In the fasting state, all three doses of niacin (240mg, 480mg and 600mg) in combination with oxycodone 40mg produced significant ( $p \leq .05$ ) disliking scores compared to oxycodone 40mg alone. The linear regression across niacin dose was not significant. No other subjective measure was significantly affected by the niacin addition to oxycodone.
- (2) The high fat meal eliminated the niacin effect on oxycodone 40 mg. The high fat meal also delayed the time to oxycodone peak blood levels.
- (3) The addition of niacin to oxycodone alters the subjective response to oxycodone as indicated by the significant responses on the disliking scale. This observation in conjunction with the results from the Treatment Enjoyment Questionnaire indicates that the addition of niacin reduces the attractiveness of oxycodone to opiate abusers.
- (4) There were no serious adverse events. Niacin produced a dose related attenuation of pupillary constriction, diastolic blood pressure increase and probably systolic blood pressure increase produced by oxycodone. The alterations by niacin on the vital sign responses to oxycodone 40 mg were minimal, were seen primarily with the 600 mg niacin dose and were not clinically significant.

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 Study AP-ADF-102 in its 505(b)(2) NDA submission for OxyADF 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 OxyADF (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 OxyADF Tablets (with or without niacin) and post-treatment safety and tolerability assessments. Efficacy (the tolerability of OxyADF) was evaluated with a Side Effects and Symptoms Questionnaire (SESQ) and an OxyADF 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 OxyADF Tablets with and without niacin. The mean post-dose SESQ total score during the run-in phase was very low in all groups (highest possible score = 33; Group results = 0.84 - 1.6) indicating that OxyADF 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 OxyADF 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 OxyADF 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 OxyADF 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 96% of subjects reporting either "no effect" or "easy to tolerate". Niacin was also well tolerated at doses of 90 mg, with 86% of Fasted subjects reporting either "no effect" or "easy to tolerate" and 14% reporting "mildly unpleasant, but tolerable". The absence of any notable effects at low doses suggests that niacin will be well tolerated up to 60 mg per dose and will likely be well tolerated at 90 mg per dose. As niacin doses escalated from 120 to 360 mg, a transition occurred resulting in a larger proportion of Fasted subjects (22% to 73%) reporting mildly unpleasant, unpleasant, or intolerable effects. At doses of 480 and 600 mg, most Fasted subjects (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 OxyADF Tablets.

#### **Additional OxyADF Tablets Clinical Studies Planned**

The FDA has requested that the Company complete certain additional clinical studies for OxyADF 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 OxyADF (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

unionectomy 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 OxyADF Tablets.

**Study AP-ADF-106:** This will be a phase I clinical study, for use in product labeling, evaluating the nasal irritating characteristics of crushed OxyADF 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.

### **Estimated Timing for submission of a 505(b)(2) NDA for OxyADF Tablets**

Estimating the dates of initiation and completion of clinical studies and the costs to complete development of the Company's product candidates, including OxyADF 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 OxyADF 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 Six Months Ended June 30, 2007 and June 30, 2006**

The Company is a specialty pharmaceutical development company engaged in development of innovative Aversion® (abuse deterrent) Technology and related product candidates. To generate revenue, the Company plans to enter into 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 six months ended June 30, 2007 and 2006 and relied upon bridge loans provided by its current primary shareholders to fund operations and development activities.

### **Research and Development Expenses**

The Company's research and development expenses for the six months ended June 30, 2007 and 2006 were as follows (in thousands):

<b>6 MONTHS ENDED 6/30/07 R&amp;D EXPENSES</b>	<b>6 MONTHS ENDED 6/30/06 R&amp;D EXPENSES</b>	<b>6 MONTHS ENDED 6/30/07 and 6/30/06 R&amp;D EXPENSES CHANGE (\$)</b>	<b>6 MONTHS ENDED 6/30/07 and 6/30/06 R&amp;D EXPENSES CHANGE (%)</b>
\$1,948	\$2,544	(\$596)	(23%)

Research and development expense in the six months ended June 30, 2007 and 2006 consisted of development of 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 \$293 and \$1,453, respectively. Excluding the stock-based compensation expense, there is a \$564 increase in overall expenses primarily attributable to a) incurring clinical study costs of \$396 for study AP-ADF-102 which was completed in the second quarter 2007 and study AP-ADF-105 which was only initiated in its start-up phase in the second quarter of 2007, and b) \$168 of insurance costs which was realigned from our general and administrative operations and assigned to our research and development operations. The decrease in stock-compensation expense of \$1,160 (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.

Marketing, General and Administrative Expenses

Marketing, general and administrative expenses for the six months ended June 30, 2007 and 2006 were as follows (in thousands):

<b>6 MONTHS ENDED 6/30/07 MARKETING, G&amp;A EXPENSES</b>	<b>6 MONTHS ENDED 6/30/06 MARKETING, G&amp;A EXPENSES</b>	<b>6 MONTHS ENDED 6/30/07 and 6/30/06 MARKETING, G&amp;A EXPENSES CHANGE (\$)</b>	<b>6 MONTHS ENDED 6/30/07 and 6/30/06 MARKETING, G&amp;A EXPENSES CHANGE (%)</b>
\$1,366	\$3,724	(\$2,358)	(63%)

During the six months ended June 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 \$429 and \$2,624, respectively. Excluding the stock-based compensation expense, the expenses decreased \$163 which is attributable to a) \$87 reduction in general legal services, b) \$168 reduction of insurance costs from the realignment of these costs from our general and administrative operations to our research and development operations, and c) offset by \$92 increase in marketing studies conducted by the Company. The decrease in stock-compensation expense of \$2,195 (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 \$480 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.

Interest Expense, net of Interest Income

The Company's interest expense, net of interest income for the six months ended June 30, 2007 and 2006 was as follows (in thousands):

<b>6 MONTHS ENDED 6/30/07 INTEREST EXPENSE, NET OF INTEREST INCOME</b>	<b>6 MONTHS ENDED 6/30/06 INTEREST EXPENSE, NET OF INTEREST INCOME</b>	<b>6 MONTHS ENDED 6/30/07 and 6/30/06 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (\$)</b>	<b>6 MONTHS ENDED 6/30/07 and 6/30/06 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (%)</b>
\$809	\$485	\$324	67%

The Company incurs interest at the prime interest rate plus 4.5%, payable quarterly in common stock, on its \$5.0 million Secured Term Note and incurs 10% interest, payable quarterly, on its \$9,944 Secured Senior Convertible Bridge Term Notes (“Bridge Loans”). 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. All such interest under the \$5.0 million Secured Term Note since February 2004 is paid in the Company’s common stock. The increase in net interest expense in 2007 primarily resulted from the addition of \$4,759 of Bridge Loans since June 30, 2006 and increases in the prime interest rate. In addition to the net interest expense reflected above, in 2007 the Company also incurred \$2,102 of amortization expense related to debt discounts recorded upon issuance of certain debt agreements in latter 2006 and during 2007. The 2006 period had no such expense.

### Net Loss

The Company’s net loss for the six months ended June 30, 2007 and 2006 was as follows (in thousands):

<b>6 MONTHS ENDED 6/30/07 NET LOSS</b>	<b>6 MONTHS ENDED 6/30/06 NET LOSS</b>	<b>6 MONTHS ENDED 6/30/07 and 6/30/06 NET LOSS CHANGE (\$)</b>	<b>6 MONTHS ENDED 6/30/07 and 6/30/06 NET LOSS CHANGE (%)</b>
\$11,358	\$6,770	\$4,588	68%

Included in the net loss for the six months ended June 30, 2007 are non cash stock-based compensation charges of \$722 and \$4,077 for the six months ended June 30, 2007 and 2006, respectively.

The November and December 2006 issuances of 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 a 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.

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.

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 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 \$21,086 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 reclass relating to warrants exercised during the first quarter of 2007.

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

The Company had no revenues for the three months ended June 30, 2007 and 2006 and relied upon bridge loans provided by its current primary shareholders to fund operations and development activities.

### **Research and Development Expenses**

The Company's research and development expenses for the three months ended June 30, 2007 and 2006 were as follows (in thousands):

<b>3 MONTHS ENDED 6/30/07 R&amp;D EXPENSES</b>	<b>3 MONTHS ENDED 6/30/06 R&amp;D EXPENSES</b>	<b>3 MONTHS ENDED 6/30/07 and 6/30/06 R&amp;D EXPENSES CHANGE (\$)</b>	<b>3 MONTHS ENDED 6/30/07 and 6/30/06 R&amp;D EXPENSES CHANGE (%)</b>
\$752	\$1,038	(\$286)	(28%)

Research and development expense in the three months ended June 30, 2007 and 2006 consisted of development of 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 \$114 and \$504, respectively. Excluding the stock-based compensation expense, there is a \$104 increase in overall expenses primarily attributable to \$24 of additional clinical study costs and \$80 of insurance costs realigned from our general and administrative operations and assigned to our research and development operations. The decrease in stock-compensation expense of \$390 (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.

Marketing, General and Administrative Expenses

Marketing, general and administrative expenses for the three months ended June 30, 2007 and 2006 were as follows (in thousands):

<b>3 MONTHS ENDED 6/30/07 MARKETING, G&amp;A EXPENSES</b>	<b>3 MONTHS ENDED 6/30/06 MARKETING, G&amp;A EXPENSES</b>	<b>3 MONTHS ENDED 6/30/07 and 6/30/06 MARKETING, G&amp;A EXPENSES CHANGE (\$)</b>	<b>3 MONTHS ENDED 6/30/07 and 6/30/06 MARKETING, G&amp;A EXPENSES CHANGE (%)</b>
\$588	\$1,303	(\$715)	(55%)

During the three months ended June 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 \$55 and \$751, respectively. Excluding the stock-based compensation expense, the decrease of \$19 in overall expenses is attributable to a) \$52 increase in general legal services, b) \$80 reduction in insurance costs from the realignment of these costs from our general and administrative operations to our research and development operations, and c) \$9 increase in marketing studies conducted by the Company. The decrease in stock-compensation expense of \$696 (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.

Interest Expense, net of Interest Income

The Company's interest expense, net of interest income for the three months ended June 30, 2007 and 2006 was as follows (in thousands):

<b>3 MONTHS ENDED 6/30/07 INTEREST EXPENSE, NET OF INTEREST INCOME</b>	<b>3 MONTHS ENDED 6/30/06 INTEREST EXPENSE, NET OF INTEREST INCOME</b>	<b>3 MONTHS ENDED 6/30/07 and 6/30/06 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (\$)</b>	<b>3 MONTHS ENDED 6/30/07 and 6/30/06 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (%)</b>
\$447	\$264	\$183	69%

The Company incurs interest at the prime interest rate plus 4.5%, payable quarterly in common stock, on its \$5.0 million Secured Term Note and incurs 10% interest, payable quarterly, on its \$9,944 Secured Senior Convertible Bridge Term Notes ("Bridge Loans"). 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. The increase in net interest expense in 2007 primarily resulted from the addition of \$4,759 of Bridge Loans since June 30, 2006 and increases in the prime interest rate.

In addition to the net interest expense reflected above, in 2007 the Company also incurred \$410 of amortization expense related to debt discounts recorded upon issuance of certain debt agreements in latter 2006 and during 2007.

The 2006 period had no such expense.

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Net Loss

The Company's net loss for the three months ended June 30, 2007 and 2006 was as follows (in thousands):

<b>3 MONTHS ENDED 6/30/07 NET LOSS</b>	<b>3 MONTHS ENDED 6/30/06 NET LOSS</b>	<b>3 MONTHS ENDED 6/30/07 and 6/30/06 NET LOSS CHANGE (\$)</b>	<b>3 MONTHS ENDED 6/30/07 and 6/30/06 NET LOSS CHANGE (%)</b>
\$2,199	\$2,615	(\$416)	(16%)

Included in the net loss for the three months ended June 30, 2007 are non cash stock-based compensation charges of \$169 and \$1,255 for the three months ended June 30, 2007 and 2006, respectively.

*Liquidity and Capital Resources*

At June 30, 2007, the Company had unrestricted cash and cash equivalents of \$0.1 million compared to \$0.2 million at December 31, 2006. The Company had a working capital deficit of \$14.7 million at June 30, 2007 compared to a working capital deficit of \$28.6 million at December 31, 2006, with the decrease primarily due to the reclassification of \$16.8 million conversion feature liabilities into additional paid in capital, offset by an increase of \$2.1 million of Bridge Loans, both as described in Note 9 of this Report.

Cash flows used in operating activities were \$2.2 million and \$2.5 million for the six months ended June 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 make up our immaterial cash flows used in investing activities for the 2007 period and generated less than \$60,000 in the 2006 period. Our financing activities of \$2.1 million and \$2.7 million for the respective six month periods are primarily from additional Bridge Loan borrowings.

### Commercial Focus, Cash Reserves and Funding Requirements

As of August 9, 2007, the Company had cash and cash equivalents of approximately \$80,000, which included the proceeds from an additional Bridge Loan funded in July 2007. Such cash reserves will be fund operating activities through mid to late August 2007. The Company's future sources of revenue, if any, will be derived from contract signing fees, milestone payments and royalties and/or profit sharing payments from licensees for the Company's Aversion® Technology. To fund further operations and product development activities the Company must raise additional financing, or enter into alliances or collaboration agreements with third parties resulting in cash payments to the Company. The Company is seeking to secure working capital providing gross proceeds to the Company in the range of approximately \$15 million to \$20 million through the private offering of the Company's securities. The terms of any such securities offering, including, without limitation, the type of equity securities (or securities convertible into equity securities) and the price per share, have not been determined and will, in large part, be determined based upon negotiations between the Company and prospective investors in such private offering. No assurance can be given that the Company will be successful in obtaining any such financing or in securing collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or collaborative agreements will provide for payments to the Company sufficient to continue to fund operations. In the absence of such financing or third-party collaborative agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. Even assuming the Company is successful in securing additional sources of financing to fund the continued development of the Aversion® Technology, or enters into alliances or collaborative agreements relating to the Aversion® Technology, there can be no assurance that the Company's development efforts will result in commercially viable products. The Company's failure to successfully develop the Aversion® Technology in a timely manner, and to avoid infringing third-party patents and other intellectual property rights 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 June 30, 2007 (in thousands):

<b>Expected cash payments on contractual obligations outstanding at June 30, 2007</b>	<b>Total</b>	<b>Due in 2007</b>	<b>Due in 2008</b>	<b>Due Thereafter</b>
Convertible bridge term notes, gross (2)	\$ 9,944	\$ 9,944	\$ -	\$ -
Interest on fixed rate debt (1)	254	254	-	-
Term note (2)	5,000	5,000	-	-
Capital leases	20	13	7	-
Operating leases	5	5	-	-
Clinical trials	160	160	-	-
Employment agreements	370	370	-	-
Total contractual cash obligations	\$ 15,753	\$ 15,746	\$ 7	\$ -
<b>Expected cash payments on contractual obligations entered into subsequent to June</b>	<b>Total</b>	<b>Due in 2007</b>	<b>Due in 2008</b>	<b>Due Thereafter</b>

**30, 2007**

Convertible bridge term notes, gross (2)	\$	600	\$	600	\$	-	\$	-
Interest on fixed rate debt (1)		14		14		-		-
Operating leases		15		10		5		-
Total contractual cash obligations	\$	629	\$	624	\$	5	\$	-

(1) At the Company's option, the \$268 of interest on the Company's fixed rate Senior Secured Convertible Bridge Term Notes is payable in either cash or Company common stock. Interest on the Company's variable rate debt is payable in Company common stock (Note 9) and is not reflected in this schedule.

- (2) To the extent cash is not available to the Company to pay this near-term debt obligation upon maturity, the Company expects to negotiate with its lenders to arrange for alternative means to settle the obligation, including, without limitation, the possible extension of maturity or conversion into equity.

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### ***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 ones 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***

There are no material changes in the Risk Factor disclosures contained in Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2006.

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

*Issuance of Common Stock.* During the quarter ended June 30, 2007, the Company issued Common Stock in the amounts of (i) 228,290 shares valued at \$253,000 as payment of interest due June 30, 2007 on the Company's Senior Secured Convertible Bridge Term Notes, (ii) 175,813 shares valued at \$195,000 as payment of interest due June 30, 2007 on the Company's Secured Term Note and (iii) 148,281 shares for the cashless exercise of 170,000 common stock purchase warrants.

*Exemption from Registration.* The Company issued the above-described Common Stock 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 shares 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.

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.

August 9, 2007

ACURA PHARMACEUTICALS, INC.

/s/ Andrew D. Reddick

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Andrew D. Reddick  
President & Chief Executive Officer

/s/ Peter A. Clemens

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Peter A. Clemens  
Senior VP & Chief Financial Officer