

ACURA PHARMACEUTICALS, INC  
Form 10-Q  
July 28, 2011

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, 2011

or

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

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

Commission File Number 1-10113

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Acura Pharmaceuticals, Inc.  
(Exact name of registrant as specified in its charter)

New York  
(State or other Jurisdiction of  
incorporation or organization)

11-0853640  
(I.R.S. Employer Identification No.)

616 N. North Court, Suite 120  
Palatine, Illinois  
(Address of Principal Executive Offices)

60067  
(Zip Code)

847 705 7709  
(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 S-T (§232.405 of this

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charter) during the preceding 12 months (or to such shorter period that the registrant was required to submit and post such files).

Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

As of July 27, 2011 the registrant had 45,315,112 shares of common stock, \$.01 par value, outstanding.

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ACURA PHARMACEUTICALS, INC.  
AND SUBSIDIARY

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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC.  
AND SUBSIDIARY

## CONSOLIDATED BALANCE SHEETS

UNAUDITED

(in thousands, except par value)

	June 30, 2011	December 31, 2010
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$39,502	\$ 24,045
Collaboration revenue receivable	-	126
Prepaid expenses and other current assets	561	270
Total current assets	40,063	24,441
Property, plant and equipment, net	1,033	1,052
Total assets	\$41,096	\$ 25,493
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accrued expenses	\$954	\$ 686
Income taxes payable	278	-
Deferred program fee revenue	-	466
Total current liabilities	1,232	1,152
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock - \$.01 par value; 100,000 shares authorized; 45,315 and 43,894 shares issued and outstanding at June 30, 2011 and December 31, 2010	453	439
Additional paid-in capital	361,167	359,830
Accumulated deficit	(321,756 )	(335,928 )
Total stockholders' equity	39,864	24,341
Total liabilities and stockholders' equity	\$41,096	\$ 25,493

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC.  
AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Six Months Ended June 30,		Three Months Ended June 30,	
	2011	2010	2011	2010
<b>Revenues</b>				
Program fee revenue	\$466	\$622	\$233	\$233
Milestone revenue	20,000	-	20,000	-
Collaboration revenue	-	2,038	-	387
<b>Total revenues</b>	<b>20,466</b>	<b>2,660</b>	<b>20,233</b>	<b>620</b>
<b>Operating expenses</b>				
Research and development	2,283	4,572	1,142	1,525
Marketing, general and administrative	3,655	5,309	1,729	2,281
<b>Total operating expenses</b>	<b>5,938</b>	<b>9,881</b>	<b>2,871</b>	<b>3,806</b>
Income (loss) from operations	14,528	(7,221 )	17,362	(3,186 )
Other (expense) income, net	(15 )	2	5	(3 )
Income (loss) before income tax	14,513	(7,219 )	17,367	(3,189 )
Income tax expense	341	8	338	3
<b>Net income (loss)</b>	<b>\$14,172</b>	<b>\$(7,227 )</b>	<b>\$17,029</b>	<b>\$(3,192 )</b>
<b>Income (loss) per share</b>				
Basic	\$0.30	\$(0.15 )	\$0.36	\$(0.07 )
Diluted	\$0.30	\$(0.15 )	\$0.35	\$(0.07 )
<b>Weighted average shares</b>				
Basic	47,183	46,937	47,364	47,016
Diluted	47,547	46,937	48,009	47,016

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC.  
AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

SIX MONTHS ENDED JUNE 30, 2011

UNAUDITED

(in thousands, except par value)

	Common Stock \$0.01 Par Value		Additional Paid - in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance at December 31, 2010	43,894	\$439	\$359,830	\$ (335,928 )	\$24,341
Net income	-	-	-	14,172	14,172
Share-based compensation	-	-	1,883	-	1,883
Distribution of common stock pursuant to restricted stock unit award plan	540	5	(953 )	-	(948 )
Issuance of common stock pursuant to exercise of stock options	545	6	(666 )	-	(660 )
Issuance of common stock pursuant to exercise of common stock warrants	336	3	1,073	-	1,076
Balance at June 30, 2011	45,315	\$453	\$361,167	\$ (321,756 )	\$39,864

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)

	2011	2010
<b>Cash flows provided by (used in) operating activities:</b>		
Net income (loss)	\$ 14,172	\$(7,227 )
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>		
Depreciation	69	68
Non-cash share-based compensation expense	1,883	4,349
Loss on disposal of property and equipment	3	14
<b>Changes in operating assets and liabilities:</b>		
Collaboration revenue receivable	126	(29 )
Prepaid expenses and other current assets	(291 )	(220 )
Accrued expenses	268	131
Income taxes payable	278	-
Deferred program fee revenue	(466 )	(622 )
Net cash provided by (used in) operating activities	16,042	(3,536 )
Cash flows used in investing activities – purchase of property and equipment	(53 )	(16 )
<b>Cash flows provided by (used in) financing activities:</b>		
Exercise of stock options	217	-
Distribution of restricted stock units	5	-
Net proceeds from warrant exercise	1,076	392
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(1,830 )	-
Net cash provided by (used in) finance activities	(532 )	392
Net increase (decrease) in cash and cash equivalents	15,457	(3,160 )
Cash and cash equivalents at beginning of period	24,045	30,174
Cash and cash equivalents at end of period	\$39,502	\$27,014
<b>Supplemental cash flow information</b>		
<b>Cash paid for:</b>		
Interest	\$26	\$-
Income taxes	\$51	\$3

Supplemental Disclosure of Noncash Financing Activities (in thousands):

Six Months Ended June 30, 2011

1. On the cashless exercises of stock options to acquire 923 shares of common stock, we issued 377 shares and withheld 547 shares both for the exercise costs and for \$882 of statutory minimum withholding taxes paid on behalf of the stock option holders.
2. On the distribution of 735 restricted stock units, we issued 446 shares of common stock and withheld 289 shares both for the common stock par values and for \$953 of statutory minimum withholding taxes paid on behalf of the

recipients.

Six Months Ended June 30, 2010

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

See accompanying notes to the consolidated financial statements.



ACURA PHARMACEUTICALS, INC.  
AND SUBSIDIARY

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2011 AND 2010

NOTE 1 BASIS OF PRESENTATION

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the “Company”, “We”, or “Our”) is a specialty pharmaceutical company engaged in research, development and commercialization of product candidates intended to provide abuse deterrent features and benefits utilizing our proprietary Aversion® and Impede™ Technologies.

The accompanying unaudited consolidated financial statements of the Company were prepared in accordance with generally accepted accounting principles for interim financial information and instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments considered necessary to present fairly the Company’s financial position, results of operations and cash flows have been made. The results of operations for the six months ended June 30, 2011 are not necessarily indicative of results expected for the full year ending December 31, 2011. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto for the year ended December 31, 2010 included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission. The 2010 year-end consolidated balance sheet presented in this Report was derived from the Company’s 2010 year-end audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles. Amounts presented in the financial statements and footnotes are rounded to the nearest thousands, except per share data and par values.

NOTE 2 RESEARCH AND DEVELOPMENT

Research and Development (“R&D”) expenses include internal R&D activities, external Contract Research Organization (“CRO”) services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. We make payments to the CRO’s based on agreed upon terms and may include payments in advance of a study starting date. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

NOTE 3 REVENUE RECOGNITION AND DEFERRED PROGRAM FEE REVENUE

We recognize revenue when there is persuasive evidence that an agreement exists, performance specified in the agreement has occurred, the price is fixed and determinable, and collection is reasonably assured. In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 (the “Pfizer Agreement”) with King Pharmaceuticals Research and Development, Inc. (“King”), a subsidiary of Pfizer, Inc. (“Pfizer”), we recognize program fee revenue, collaboration revenue and milestone revenue.

Program fee revenue is derived from amortized upfront payments, such as the \$30.0 million upfront payment under the Pfizer Agreement received in December 2007, and license fees, such as the \$3.0 million option exercise fee paid to us in each of May and December 2008 upon the exercise of Pfizer's option to license a third and fourth opioid analgesic product candidate under the Pfizer Agreement. We have assigned an equal portion of the \$30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. The recognition of the program fee revenue for two of the three product candidates was completed by June 2008. During the second quarter 2011, we recognized the remaining program fee revenue which was assigned to the third product candidate under the Pfizer Agreement.

Collaboration revenue is derived from reimbursement of R&D expenses, which are invoiced quarterly in arrears, and are recognized when costs are incurred pursuant to the Pfizer Agreement. The ongoing R&D services being provided to Pfizer under the Pfizer Agreement are priced at fair value based upon the reimbursement of expenses incurred pursuant to the Pfizer Agreement.

Milestone revenue is contingent upon the achievement of certain pre-defined events in the Pfizer Agreement. Milestone payments received under the Pfizer Agreement are recognized as revenue upon achievement of the “at risk” milestone events. Milestone payments are triggered either by the results of our R&D efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones were substantially at risk at the inception of the Pfizer Agreement and the amounts of the revenue correspond to the milestone payments set forth in the Pfizer Agreement. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone. Milestone revenue is non-refundable and non-creditable upon payment. On June 30, 2011, we received a \$20.0 million milestone payment from Pfizer as a result of the FDA approval of Oxecta.

#### NOTE 4 INCOME TAXES

The Company accounts for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities and are accounted for using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss (“NOL”) and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. During June 2011, we decreased our valuation allowance on our deferred income tax assets by \$5.0 million. We recorded a benefit from income taxes of \$5.0 million against our current six month period income tax provision. At June 30, 2011 we continue to maintain a full valuation on our remaining deferred income tax assets due to uncertainties with respect to future utilization of them. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

#### NOTE 5 ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	Jun 30, 2011	Dec 31, 2010
Compensation and benefits	\$ 391	\$ 95
Professional services	306	193
Franchise taxes	33	12
Property taxes	18	19
Clinical and regulatory services	145	307
Other fees and services	61	60
<b>Total</b>	<b>\$ 954</b>	<b>\$ 686</b>

#### NOTE 6 SHARE-BASED COMPENSATION

The Company has share-based compensation plans including stock options and restricted stock units (“RSUs”) for its employees and directors. The Company accounts for compensation cost related to share-based payments based on fair value of the stock options and RSUs when awarded to an employee or director. The value of the portion of the award that is ultimately expected to vest is recognized as expense in the relevant accounting periods in the Company’s

consolidated financial statement. The Company uses the straight line amortization method for calculating share-based compensation expense. The Company determines the estimated fair value of share-based stock option awards using the Black-Scholes option pricing model. Option valuation models require the input of assumptions including the expected volatility of the market price of the Company's common stock, risk-free interest rate and expected dividend yields. The Company uses historical public market closing price volatility and does not consider implied volatility because there are no options traded in its stock. The risk – free interest rate assumption is based on observed interest rates appropriate for the estimated term of the employee stock options. The dividend yield assumption is based on the Company's history and current expectation of dividend payouts on common stock. The expected term of the award represents the period that the employees and directors are expected to hold the award before exercise and issuance using historical exercise activity. The Company's accounting for share-based compensation for RSUs is also based on the fair-value method. The fair value of the RSUs is based on the closing market price of the Company's common stock on the date of the RSU award.

Our non-cash share-based compensation expense comprises the following:

	Six Months Ended June 30,		Three Months Ended June 30,	
	2011	2010	2011	2010
<b>Research and development</b>				
Stock options	\$ 355	\$ 884	\$ 110	\$ 386
RSUs	75	139	17	70
	430	1,023	127	456
<b>General and administrative</b>				
Stock options	1,225	2,983	400	1,291
RSUs	228	342	57	171
	1,453	3,325	457	1,462
<b>Total</b>	<b>\$ 1,883</b>	<b>\$ 4,349</b>	<b>\$ 584</b>	<b>\$ 1,918</b>

#### Stock Option Award Plans

At June 30, 2011, the Company has stock options issued and outstanding under three stock option plans. The Company's 1995 Stock Option Plan and 1998 Stock Option Plan have each expired but stock options awarded under such plans remain outstanding under the terms of those plans. The Company's 2008 Stock Option Plan remains in effect. Under each of the 1998 Stock Option Plan and the 2008 Stock Option Plan, only one-fourth of vested non-incentive stock option ("NonISO") may be exercised during each of calendar years 2011, 2012, 2013 and 2014.

Exercise of NonISOs by employees may require the Company to make minimum statutory withholding tax ("withholding tax") payments for such employee on any gain on such shares at the time of exercise. The employee is responsible for providing sufficient funds to the Company to make such withholding tax payments. However, under the Company's stock option plans, the employee may elect to take a partial distribution of the exercised NonISO shares and have the Company retain the balance of the exercised shares in satisfaction of the employee's withholding tax payments. In such event, the Company becomes obligated to directly pay the withholding taxes of such employee and will retain a sufficient number of exercised shares such that the fair market value of the retained shares will offset the employee's withholding taxes. The Company has not reflected this obligation as a liability in its consolidated financial statements as the withholding tax payments are contingent upon the timing and number of NonISOs exercised by employees and the closing market price of our common stock at the time of exercise. Such withholding tax will be paid and charged against additional paid in capital as the NonISOs are exercised. During the six months ended June 30, 2011, 0.23 million NonISOs shares were withheld by the Company upon our employees' election to satisfy \$0.9 million of withholding taxes relating to their stock option exercises during such time period.

As of June 30, 2011 the Company had \$1.2 million of unrecognized share-based compensation expense from stock option grants, which will be recognized in our consolidated financial statements over their remaining vesting periods. Under the stock option plans, if a change in control occurs, an acceleration of unvested shares will occur and any remaining unrecognized share-based compensation expense will be recognized in our consolidated financial statements.

Our stock option award activity during the six months ended June 30, 2011 and 2010 is as follows:

	Six Months Ended March 31,			
	2011		2010	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, beginning	4,243	\$ 5.40	3,671	\$ 5.90
Granted	90	3.46	90	5.47
Exercised	(1,091 )	1.33	-	-
Forfeited or expired	(69 )	3.38	(27 )	18.75
Outstanding, ending	3,173	\$ 6.78	3,734	\$ 5.80
Options exercisable	2,805	\$ 7.31	2,978	\$ 5.60

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

	2011		2010	
Dividend yield	0.0	%	0.0	%
Average risk-free interest rate	3.36	%	3.85	%
Average volatility	115	%	122	%
Expected forfeitures	0.0	%	0.0	%
Expected holding period	10 years		10 years	
Weighted average grant date fair value	\$ 3.26		\$ 5.23	

#### Restricted Stock Unit Award Plan

The Company has RSUs issued and outstanding under a Restricted Stock Unit Award Plan (“2005 RSU Plan”) for its employees and directors. A RSU represents the contingent obligation of the Company to deliver a share of its common stock to the holders of a vested RSU on a specified distribution date. For the 2005 RSU Plan, absent a change of control, one-fourth of vested shares of common stock underlying an RSU award will be distributed on January 1 of each of 2011, 2012, 2013 and 2014. Distribution of RSU shares to employees may require the Company to make minimum statutory withholding tax (“withholding tax”) payments for such employee on any gain on such shares at the time of distribution. The employee is responsible for providing sufficient funds to the Company to make such withholding tax payments. However, under the 2005 RSU Plan, the employee may elect to take a partial distribution of shares and have the Company retain the balance of the share distribution in satisfaction of the withholding tax payments. In such event, the Company becomes obligated to directly pay the withholding taxes of such employee and will retain a sufficient number of shares such that the fair market value of the retained shares will offset the employee’s withholding taxes. The Company has not reflected this obligation as a liability in its consolidated financial statements as the withholding tax payments are contingent upon the timing and number of RSU shares distributed to employees and the closing market price of our common stock at the time of distribution. Such withholding taxes will be paid and charged against additional paid-in capital as the RSU shares are distributed. On January 1, 2011, 0.54 million vested shares were distributed to our employees and 0.29 million shares were withheld by the Company upon our employees’ election to exchange RSUs in satisfaction of \$1.0 million withholding tax obligations relating to RSU distributions on such date.

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

	Six Months Ended June 30,	
	2011	2010

	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	3,316	3,267	3,316	3,112
Granted	-	-	-	-
Distributed	(829 )	(829 )	-	-
Vested	-	49	-	77
Forfeited or expired	-	-	-	-
Outstanding, ending	2,487	2,487	3,316	3,189

## NOTE 7 COMMON STOCK WARRANTS

At June 30, 2011, the Company had common stock warrants outstanding exercisable for 1.86 million shares of common stock at an exercise price of \$3.40 per share with an expiration date of August 2014. Warrants exercisable for 0.34 million shares of common stock were exercised during the six months ended June 30, 2011.

## NOTE 8 EARNINGS (LOSS) PER SHARE

Computation of basic earnings (loss) per share of common stock is based on the sum of the weighted average number of outstanding common shares and vested RSUs during the period. Computation of diluted earnings (loss) per share is based on the sum of the common shares and vested RSUs used in the basic earnings (loss) computation, adjusted for the effect of other potentially dilutive securities. Excluded from the diluted earnings (loss) per share computation at June 30, 2010 was 6.0 million shares of potentially dilutive securities, as the effect of including these securities would be antidilutive.

(in thousands, except per share data)	Six Months Ended June 30,		Three Months Ended June 30,	
	2011	2010	2011	2010
<b>Basic income (loss) per share computation</b>				
Numerator:				
Net income (loss)	\$14,172	\$(7,227 )	\$17,029	\$(3,192 )
Denominator:				
Common shares (weighted)	44,710	43,789	44,880	43,849
Vested RSUs (weighted)	2,473	3,148	2,484	3,167
Weighted average number of shares outstanding	47,183	46,937	47,364	47,016
Basic income (loss) per common share	\$0.30	\$(0.15 )	\$0.36	\$(0.07 )
<b>Diluted income per share computation</b>				
Numerator:				
Net income (loss)	\$14,172	\$(7,227 )	\$17,029	\$(3,192 )
Denominator:				
Common shares (weighted)	44,710	43,789	44,880	43,849
Vested RSUs (weighted)	2,473	3,148	2,484	3,167
Stock options	173	-	240	-
Common stock warrants	191	-	405	-
Weighted average number of shares outstanding	47,547	46,937	48,009	47,016
Diluted income (loss) per common share	\$0.30	\$(0.15 )	\$0.35	\$(0.07 )
<b>Excluded potentially dilutive securities:</b>				
Common shares issuable (1):				
Nonvested RSUs	-	127	-	127
Common stock options (vested and nonvested)	-	3,713	-	3,713
Common stock warrants	-	2,193	-	2,193
Total excluded dilutive common stock equivalents	-	6,033	-	6,033

(1) Number of shares issuable represents those securities which were either i) nonvested at period end or ii) were vested but antidilutive. The number of shares is based on maximum number of shares issuable on exercise at period end. Such amounts have not been adjusted for the treasury stock method or weighted average outstanding calculations as required if the securities were dilutive.



## NOTE 9 COMMITMENTS AND CONTINGENCIES

### Securities Class Action and Derivative Litigation

A lawsuit captioned *Bang v. Acura Pharmaceuticals, et al*, was filed on September 10, 2010 in the United States District Court for the Northern District of Illinois, Eastern Division (Case 1:10-cv-05757) against us and certain of our current and former officers seeking unspecified damages on behalf of a putative class of persons who purchased our common stock between February 21, 2006 and April 22, 2010. The complaint alleged that certain Company officers made false or misleading statements, or failed to disclose material facts in order to make statements not misleading, relating to our Acurox® with Niacin Tablet product candidate, resulting in violations of Section 10(b) of the Securities Exchange Act of 1934 (the “Exchange Act”), Rule 10b-5 under the Exchange Act and Section 20(a) of the Exchange Act. The complaint further alleges that such false or misleading statements or omissions had the effect of artificially inflating the price of our common stock. On March 14, 2011, an amended complaint was filed in this lawsuit. The amended complaint asserts the same claims as the initial complaint based upon the same alleged false or misleading statements, and has added three of our current directors as defendants. The Court has changed the caption of this case to *In re Acura Pharmaceuticals, Inc. Securities Litigation*. We filed a motion to dismiss this case on May 13, 2011. We believe that the allegations in the complaint are without merit and intend to vigorously defend the litigation.

On October 25, 2010, Kiley Hill, a purported stockholder of the Company filed a shareholder derivative action in the Circuit Court of Cook County, Illinois, Chancery Division captioned *Hill v. Acura Pharmaceuticals et al.* (Case No. 2010-CH-46380), against our directors and certain of our executive officers, generally relating to the same events that are the subject of the class action litigation described above. The complaint purports to be brought on our behalf and names us as a nominal defendant. The complaint seeks unspecified damages from the individual defendants for breaches of fiduciary duty, abuse of control, gross mismanagement, contribution and indemnification, waste of corporate assets and unjust enrichment for actions occurring from at least February 21, 2006 through April 22, 2010. Substantively similar complaints captioned *Hagan v. Acura Pharmaceuticals et al.* (Case No. 2010-CH-46621) and *Newell v. Reddick et al* (Case No. 2010-CH-46873) were filed in the Circuit Court of Cook County, Illinois, Chancery Division, by other purported stockholders of the Company on October 27, 2010 and October 28, 2010, respectively. We have agreed to a temporary stay of these derivative actions.

### Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to us, has been named along with numerous other companies as a defendant in cases filed in three separate state coordinated litigations pending in Pennsylvania, New Jersey and California, respectively captioned *In re: Reglan®/Metoclopramide Mass Tort Litigation*, Philadelphia County Court of Common Pleas, January Term, 2010, No. 01997; *In re: Reglan® Litigation*, Superior Court of New Jersey, Law Division, Atlantic County, Case No. 289, Master Docket No. ATL-L-3865-10; and *Reglan®/Metoclopramide Cases*, Superior Court of California, San Francisco County, Judicial Council Coordination Proceeding No. 4631, Superior Court No.: CJC-10-004631. In this product liability litigation against numerous pharmaceutical product manufacturers and distributors, including us, plaintiffs claim injuries from their use of the Reglan brand of metoclopramide and generic metoclopramide. In the Pennsylvania state court mass tort proceeding, over 200 lawsuits have been filed against us and Halsey Drug Company alleging that plaintiffs developed neurological disorders as a result of their use of the Reglan brand and/or generic metoclopramide. Plaintiffs have filed approximately 150 lawsuits against us, but have served less than 50 individual lawsuits upon us in the New Jersey action. In the California action, we were not served with any complaints until very recently when a single complaint including over 400 plaintiffs was served. In the Spring of 2011, over 70 plaintiffs filed Reglan litigation in the Circuit Court of St. Clair County, Illinois entitled *Agresta v. Walgreens et al.*, in which we, together with numerous generic and brand drug companies, are a named defendant. However, these Illinois state court complaints have not yet been served on us.

In the lawsuits filed to date, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by us. We discontinued manufacture and distribution of generic metoclopramide more than 15 years ago. In addition, we believe the June 23, 2011 decision by the U.S. Supreme Court in *PLIVA v. Mensing* holding that state tort law failure to warn claims against generic drug companies are pre-empted by the 1984 Hatch-Waxman Act Amendments and federal drug regulations will assist us in favorably resolving these cases. We believe these claims are without merit and intend to vigorously defend these actions.

#### Statutory Minimum Withholding Tax Obligations

Under our stock option plans and our 2005 RSU plan, our employees may elect to have shares withheld upon exercise of options and upon the exchange of RSUs in satisfaction of the statutory minimum withholding tax obligations of such employees relating to such option exercises or RSU exchanges. On January 1, 2011, certain of our employees elected to have 0.29 million common shares withheld by the Company upon the exchange of their RSUs in satisfaction of their combined \$1.0 million withholding tax obligations. In addition, during the six months ended June 30, 2011, employees exercising stock options elected to have 0.22 million common shares withheld by the Company in satisfaction of their combined \$0.8 million withholding tax obligations.

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

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

### Forward-Looking Statements

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to, Pfizer's ability to successfully launch and commercialize our Oxecta™ Tablets, the ability of Pfizer and the ability of other pharmaceutical companies, if any, to whom we may license our Aversion® Technology or Impede™ Technology, to obtain necessary regulatory approvals and commercialize products utilizing such technologies and the market acceptance of such products, expectations regarding potential market share for our products, our ability to enter into additional license agreements for our other product candidates, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability to fulfill the U.S. Food and Drug Administration's, or FDA, requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date and the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates, the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, whether the FDA will agree with our analysis of our clinical studies and how it may evaluate the results of these studies or whether further studies of our product candidates will be required to support FDA approval, whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications or for abuse deterrent features, and whether our product candidates will ultimately deter abuse in commercial settings. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in Item 1A of Part II of this Report and in our filings with the Securities and Exchange Commission.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on such forward-looking statements.

### Company Overview

We are a specialty pharmaceutical company engaged in the research, development and commercialization of products intended to introduce limits or impediments to abuse and intentional misuse. Our products and product candidates are based on widely-used commercial products and do not alter the safety and efficacy of the active pharmaceutical ingredients. Our lead product, Oxecta™ Tablets CII, or Oxecta (formerly Acurox®), was approved for marketing by the United States Food and Drug Administration, or FDA, on June 17, 2011. Oxecta is an immediate-release oxycodone hydrochloride, or HCl, tablet utilizing our proprietary Aversion® Technology. Oxecta represents the first immediate-release oxycodone product approved by the FDA in a formulation with features and benefits intended to

minimize abuse. Oxecta will be manufactured and commercialized by Pfizer under our October 2007 license agreement with a subsidiary of Pfizer. We expect Pfizer to commercially launch Oxecta late in the third quarter or early in the fourth quarter of 2011. On June 30, 2011, we received a \$20.0 million milestone payment from Pfizer as a result of the FDA approval of Oxecta.

In addition to Oxecta, we have licensed to Pfizer the rights to develop, manufacture and commercialize three other immediate-release opioid products utilizing our Aversion Technology in the United States, Canada and Mexico, including:

- hydrocodone bitartrate / acetaminophen tablets;
- oxycodone HCl / acetaminophen tablets; and
- an undisclosed opioid analgesic tablet product.

The development of these additional products may follow a program consistent with that of Oxecta.

We believe our Aversion Technology can also be used to develop and commercialize unique formulations of non-opioid pharmaceutical products associated with abuse and intentional misuse. Our initial non-opioid product candidates are a benzodiazepine product for the treatment of anxiety disorders and a stimulant product for the treatment of attention deficit disorder.

We have also developed an over-the-counter, or OTC, immediate-release pseudoephedrine HCl tablet, utilizing our proprietary Impede™ Technology (“Impede PSE”). Pseudoephedrine HCl, or PSE, is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products, including Sudafed®. Our Impede Technology is a proprietary mixture of inactive ingredients designed to limit or impede extraction of pseudoephedrine from tablets for use as a starting material in producing methamphetamine. We are currently scaling up the manufacture of Impede PSE for commercial availability in the fourth quarter of 2011.

#### Oxecta

Oxecta is a Schedule II narcotic indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. The safety and efficacy of Oxecta 5mg and 7.5mg tablets was established by demonstrating bioequivalence to commercially available oxycodone immediate-release tablets in the fasted state. Oxecta differs from oxycodone tablets when taken with a high fat meal though these differences are not considered clinically relevant, and Oxecta can be taken without regard to food. The FDA-approved label for Oxecta describes elements unique to our Aversion Technology, which differs from current commercially available oxycodone immediate-release tablets. The label for Oxecta includes the results from a clinical study that evaluated the effects of nasally snorting crushed Oxecta and commercially available oxycodone tablets, and limitations on exposing Oxecta tablets to solvents in order to dissolve them. The clinical study (Study K###-##-####) evaluated 40 non-dependent recreational opioid users, who self-administered the equivalent of 15mg of oxycodone. After accounting for a sequence effect, the study demonstrated:

- 30% of subjects exposed to Oxecta responded that they would not take the drug again compared to 5% of subjects exposed to immediate-release oxycodone;
- subjects taking Oxecta reported a higher incidence of nasopharyngeal and facial adverse events compared to immediate-release oxycodone;
- a decreased ability to completely insufflate two crushed Oxecta tablets within a fixed time period (21 of 40 subjects), while all subjects were able to completely insufflate the entire dose of immediate-release oxycodone; and
- small numeric differences in the median and mean drug liking scores, which were lower in response to Oxecta than immediate-release oxycodone.

Further, the product label guides patients not to crush and dissolve the tablets or pre-soak, lick or otherwise wet the tablets prior to administration. Similarly, caregivers are advised not to crush and dissolve the tablets or otherwise use Oxecta for administration via nasogastric, gastric or other feeding tubes as it may cause an obstruction. Our laboratory studies demonstrated that the Oxecta tablet characteristics may change when Oxecta is exposed to certain solvents, including water. We believe these Aversion Technology features differentiate Oxecta from the immediate-release oxycodone products currently available in the U.S. market.

The misuse and abuse of pharmaceutical products in general, and opioid analgesics in particular, is a significant societal problem. Opioid analgesics, which are used to treat both acute and chronic pain, are the most widely-prescribed and most often abused pharmaceutical products in the United States. It is estimated that 75 million people in the United States suffer from pain, and, according to U.S. government surveys, 35 million people, or more than 10% of the U.S. population, have used prescription opioid analgesics for non-medical purposes at some point in their lifetime. We expect our Aversion Technology opioid products to compete primarily in the market for immediate-release opioid products, or IR Opioid Products. In 2010, IMS Health reported 260 million prescriptions dispensed for opioid analgesic tablets and capsules, of which approximately 244 million were for IR Opioid Products and 16 million were for extended-release opioid tablet and capsule products, or ER Opioid Products. Our market research study conducted in 2005 with 435 opioid-prescribing physicians in the United States revealed that 94% of the physicians experienced at least one suspicious incident in the past month regarding opioid prescribing and 61% believe opioid-seeking patients represent a risk to their practice.

In October 2007, we entered into a License, Development and Commercialization Agreement, or the Pfizer Agreement, with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer, covering the United States, Canada and Mexico. Under the Pfizer Agreement, Pfizer will manufacture and commercialize Oxecta in the United States and develop and commercialize three additional opioid analgesic products utilizing our proprietary Aversion Technology, including hydrocodone / acetaminophen, oxycodone / acetaminophen and an undisclosed opioid analgesic tablet product. As of June 30, 2011, we had received an aggregate of \$78.5 million in payments from Pfizer in the form of a \$30.0 million upfront cash payment, milestone payments, option fees and reimbursement for research and development expenses, including a \$20.0 million milestone fee relating to the receipt of FDA approval of the New Drug Application, or NDA, for Oxecta. In addition, we are eligible to receive milestone payments based on future regulatory events and product sales achievements, reimbursement for certain research and development expenses and tiered royalties of 5%-25% on combined annual net sales of all products commercialized under the Pfizer Agreement.

#### Impede™ PSE

Our Impede PSE product is an immediate-release pseudoephedrine HCl tablet which utilizes our patent pending Impede Technology. Our Impede Technology, a proprietary mixture of inactive ingredients, is designed to limit or impede extraction of PSE from tablets for use as a starting material in producing methamphetamine. We are developing Impede PSE 30mg tablets and have demonstrated that our product: (1) is bioequivalent to Sudafed 30mg Tablets and a 30mg generic store brand, and (2) in independent laboratory tests, effectively prevents the extraction of PSE for conversion into methamphetamine using the three most common extraction methods. We have contracted with a third-party manufacturer for the scale-up and commercial manufacture of Impede PSE. We expect to market Impede PSE directly to national and regional drug store chains and expect this product to be commercially available in the fourth quarter of 2011.

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

PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products. PSE is sold in products as the only active ingredient in both immediate and extended-release products. In addition, PSE is combined with other cold, sinus and allergy ingredients such as pain relievers, cough suppressants and antihistamines. PSE also competes against phenylephrine, an alternate nasal decongestant available in non-prescription products. Our 2010 market research study showed that 93% of the 204 pharmacists surveyed believe that PSE has superior efficacy as a nasal decongestant compared to phenylephrine. Due to the CMEA, many cold, sinus and allergy products replaced PSE with phenylephrine to avoid the security and consumer sales volume restrictions imposed by the CMEA on PSE products.





We expect our Impede Technology products containing PSE to compete in the highly competitive market for cold, sinus and allergy products generally available to consumers without a prescription. In 2009, AC Nielsen reported approximately \$1.0 billion in sales of non-prescription products containing either PSE or phenylephrine as a nasal decongestant, of which approximately 47% contained PSE. Products in this category consist of many different formulations containing different active ingredients such as analgesics, cough suppressants and antihistamines and have strong consumer brand recognition. As a result of the CMEA all non-prescription PSE products to be held securely behind the pharmacy counter, has set monthly consumer purchase volume limits, and has necessitated consumer interaction with pharmacy personnel to purchase PSE-containing products. We intend to capitalize on this consumer-pharmacist interaction at the point of sale by soliciting distribution to the pharmacies of national and regional drug chains and educating and encouraging pharmacists to recommend Impede PSE to their customers. In a 2010 survey of 204 pharmacists, pharmacists indicated they would recommend Impede PSE, if available in the pharmacy, more than competing products. We also may create Impede PSE product awareness through television, radio, and print advertising.

Most PSE-containing products are classified by the FDA for OTC sale, or without a doctor's prescription, and many product formulations do not require the approval of New Drug Application, or NDA, or an Abbreviated New Drug Application, or ANDA, by the FDA for commercial distribution and marketing. Tablet products containing 60 mg or less of PSE are considered by the FDA to be safe and effective for use by the general public without a prescription. We believe 30mg Impede PSE developed utilizing Impede Technology meets or will meet the FDA's requirements for "Over-the-Counter Human Drugs Which are Generally Recognized as Safe and Effective and Not Misbranded" as set forth in the FDA's regulations applicable to OTC Monograph products. As such, we intend to commercialize Impede PSE without submitting a NDA or ANDA to the FDA.

#### Product Labeling for Impede Technology Products

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

#### Product Portfolio Overview

Our product portfolio consists of two products that we expect to be commercialized in 2011. We expect Pfizer to commercially launch Oxecta late in the third quarter or early in the fourth quarter of 2011 and to have commercial quantities of Impede PSE available in the fourth quarter of 2011.

Oxecta represents the first FDA approval for our Aversion Technology opioid products and we believe it demonstrates the FDA's willingness to consider label differentiation compared to currently marketed immediate-release opioid products when the product features are supported by scientifically derived and supported studies. Following Oxecta, we have the following product candidates in development:

- three Aversion Technology opioids products without niacin in development by and licensed to Pfizer;
- one Aversion Technology opioid product with niacin in development by us and licensed to Pfizer;
  - two Aversion Technology non-opioid products wholly owned by us;
  - Impede PSE tablets utilizing our Impede Technology wholly owned by us; and
- combination cold, allergy and sinus products containing PSE utilizing our Impede Technology being evaluated for feasibility.

## Aversion Technology

Our pipeline of IR Opioid Products and non-opioid products utilize our Aversion Technology, which is intended to deliver the known effectiveness of an FDA-approved active pharmaceutical ingredient and a similar side effect profile while incorporating ingredients that are designed to discourage some of the common methods of abuse and intentional misuse, including:

- intravenous injection by forming a viscous gelatinous mixture when tablets and capsules are dissolved in solvents suitable for injection;
  - nasal snorting by inducing disliked nasal discomfort when tablets and capsules are crushed and snorted; and
- intentional swallowing of excess quantities of tablets or capsules when our Aversion Technology optionally includes niacin, which can cause dose-related flushing side effects which may be disliked.

The extent and manner in which these features are described in the FDA-approved label for these pipeline products will be dependent on the results of and acceptance by the FDA of our or our licensees' studies for each of these products. Our lead product Oxecta utilizes the Aversion Technology without niacin. The FDA-approved label for Oxecta includes a description of the effects of snorting Oxecta and prohibitions on dissolving Oxecta.

#### Aversion Technology with Niacin

We expect Aversion Technology products which include niacin to require a more extensive development program. Since niacin is designated as an active ingredient by the FDA, our products must meet the combination drug requirements of the FDA. In the past, the FDA has required us to complete a single Phase 3 safety and efficacy study in place of a smaller bioequivalence study.

We submitted an NDA for Aversion oxycodone HCl with niacin tablets on December 30, 2008 and received a Complete Response Letter, or CRL, from the FDA on June 30, 2009. The FDA questioned: (a) the perceived increased incidence of flushing when Aversion oxycodone HCl with niacin tablets are taken by pain patients at recommended doses, (b) a lack of evidence supporting the effectiveness of niacin to reduce peak drug liking (Emax) when taken at abused (high) doses in the fasted state, and (c) the potential to mitigate the effectiveness of niacin with food or NSAIDs. We and Pfizer continue to evaluate strategies to address the issues raised by the FDA in the CRL to our Aversion oxycodone HCl with niacin tablets NDA submission.

#### Impede Technology

The chemical structure of PSE is very similar to methamphetamine, facilitating a straight-forward chemical conversion to methamphetamine. There are multiple known processes to convert PSE to methamphetamine, all of which are not complex and do not require specialized equipment; however, many do require readily available but uncommon ingredients. The three most popular processes follow two general processing steps: (1) dissolving the PSE tablets in a solvent to isolate the base form of PSE and (2) a chemical reduction of the base PSE into methamphetamine for drying into crystals. Since all the solvents are ultimately dried off, a vast range of solvents are amenable to the process.

Impede Technology utilizes a proprietary mixture of inactive ingredients intended to limit or impede extraction of PSE from the tablets for use as a starting material in producing the illicit drug methamphetamine. Specifically, the Impede Technology forms a viscous, gelatinous mixture when our tablets are dissolved in solvents typically used in the PSE extraction phase of methamphetamine production. The unique mixture of inactive ingredients in Impede is generally recognized as safe by the FDA.

#### Patents and Patent Applications

In April 2007, the United States Patent and Trademark Office, or USPTO, issued to us U.S. Patent No. 7,201,920 titled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms," or the 920 Patent. The 54 allowed claims in the 920 Patent encompass certain pharmaceutical compositions intended to deter the most common methods of prescription opioid analgesic product misuse and abuse. These patented pharmaceutical compositions include the mixture of functional inactive ingredients and specific opioid analgesics such as oxycodone HCl and hydrocodone bitartrate among others.

In January 2009, the USPTO issued to us U.S. Patent No. 7,476,402, or the 402 Patent, with 18 allowed claims. The 402 Patent encompasses certain combinations of kappa and mu opioid receptor agonists and other ingredients intended to deter opioid analgesic product misuse and abuse.

In March 2009, the USPTO issued to us U.S. Patent No. 7,510,726, or the 726 Patent, with 20 allowed claims. The '726 Patent encompasses a wider range of abuse deterrent compositions than our '920 Patent.

Neither of the '920 Patent, '402 Patent or '726 Patent requires niacin to be a constituent of a product for the product to be within the scope of the patent claims.

In May 2011, the USPTO issued a notice of allowance for our non-provision patent application containing 7 claims. The patent, when issued, will encompass a wider range of potentially abused pharmaceutically active ingredients than our 920 and 726 Patents.

In addition to our issued U.S. patents, we have filed multiple U.S. patent applications and international patent applications relating to compositions containing abusable active pharmaceutical ingredients as well as applications covering our Impede Technology. Except for those rights conferred in the Pfizer Agreement, we have retained all intellectual property rights to our Aversion Technology, Impede Technology, and related product candidates.

Reference is made to the Risk Factors contained in Item 1A of Part II of this Report for a discussion, among other things, of patent applications and patents owned by third parties including claims that may encompass our Aversion Technology and Oxecta tablets.

#### Company's Present Financial Condition

At June 30, 2011, we had cash and cash equivalents of \$39.5 million, which includes the \$20.0 million milestone payment from Pfizer triggered by FDA approval of the Oxecta NDA, and working capital of \$38.8 million compared to cash and cash equivalents of \$24.0 million and working capital of \$23.3 million at December 31, 2010. We had income from operations of \$14.5 million for the six months ended June 30, 2011 compared to a loss from operations of \$7.2 million for the six months ended June 30, 2010. We had accumulated deficits of approximately \$321.8 million and \$335.9 million at June 30, 2011 and December 31, 2010, respectively. We estimate that our current cash reserves will be sufficient to fund our operations and the development and commercialization of our Aversion and Impede Technologies and related product candidates through at least the next 12 months.

We have yet to generate any product sales or royalty revenues from product sales. To fund our continued operations, we expect to rely on our current cash resources, additional payments that may be made under the Pfizer Agreement, including our receipt of royalties from Pfizer, which royalty obligations only apply to sales occurring after the one year anniversary of the first commercial sale of Oxecta, and any potential payments related to the achievement of specified milestones for Oxecta and other product candidates under the Pfizer Agreement, and under any future license agreements with other pharmaceutical company partners, of which there can be no assurance of us entering into, and revenues, if any, from our commercialization of our Impede PSE Tablets, for which there can be no assurance. Our cash requirements for operating activities may increase in the future as we continue to conduct pre-clinical studies and clinical trials for our product candidates, maintain, defend, if necessary, expand the scope of our intellectual property, hire additional personnel, scale-up commercial supply of Impede PSE, commercialize Impede PSE, or invest in other areas.

#### Results of Operations for the Six Months Ended June 30, 2011 and 2010

	June 30,		Increase (Decrease)	
	2011	2010	Dollars	%
<b>Revenues</b>				
Program fee revenue	\$ 466	\$ 622	\$ (156 )	(25 ) %
Milestone revenue	20,000	-	20,000	*
Collaboration revenue	-	2,038	(2,038 )	(100 )
<b>Total revenue</b>	<b>20,466</b>	<b>2,660</b>	<b>17,806</b>	<b>669</b>
<b>Operating expenses</b>				
Research and development	2,283	4,572	(2,289 )	(50 )
Marketing, general and administrative	3,655	5,309	(1,654 )	(31 )
<b>Total operating expenses</b>	<b>5,938</b>	<b>9,881</b>	<b>(3,943 )</b>	<b>(40 )</b>
Income (loss) from operations	14,528	(7,221 )	21,749	301
Other (expense) income, net	(15 )	2	17	850
Income (loss) before income tax	14,513	(7,219 )	21,732	301
Income tax expense	341	8	333	4,163

Net income (loss)	\$ 14,172	\$ (7,227 )	\$ 21,399	296	%
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## Revenue

Pfizer paid us a \$30.0 million upfront fee in connection with the closing of the Pfizer Agreement in December 2007. We have assigned an equal portion of Pfizer's \$30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. Program fee revenue recognized in the six months ended June 30, 2011 and 2010 from amortization of this upfront fee was \$0.5 million and \$0.6 million, respectively. On June 17, 2011 the Oxecta NDA was approved and we recognized \$20.0 million milestone revenue while fully recognizing the remaining program fee revenue.

Collaboration revenue recognized in the six months ended June 30, 2010 was \$2.0 million for invoiced reimbursement of our R&D expenses incurred pursuant to the Pfizer Agreement. We invoice Pfizer in arrears on a calendar quarter basis. We did not incur reimbursable R&D expenses during the first six months 2011 and we estimate such R&D expenses in the future for which we will receive reimbursement from Pfizer to be minimal.

## Operating Expense

R&D expense during the six months ended June 30, 2011 and 2010 were for product candidates utilizing our Aversion® and Impede™ Technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, compensation, benefits and other personnel related expenses, and facility costs. Included in the 2011 and 2010 results are non-cash share-based compensation expenses of \$0.4 million and \$1.0 million, respectively. Excluding the share-based compensation expense, there is a \$1.7 million decrease in development expenses primarily attributable to a reduction of our clinical study costs on the Oxecta. Our ongoing development activities include our benzodiazepine tablet product candidate, an extended release opioid product candidate, and the continuation of scale-up for our Impede PSE manufacturing process to quantities required for commercial distribution.

Marketing expenses during the six months ended June 30, 2011 and 2010 primarily consisted of market research studies on our Aversion® and Impede™ Technologies. Our G&A expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll. Included in the 2011 and 2010 results are non-cash share-based compensation expenses of \$1.5 million and \$3.3 million, respectively. Excluding the share-based compensation expense, our marketing, general and administrative expenses increased \$0.2 million.

## Other Income

During the six months ended June 30, 2011 and 2010, our cash was invested in accordance with the investment policy approved by our Board of Directors resulting in minimal interest income earned in 2011 and 2010 due to the prevailing low interest rates.

## Net Income (Loss)

During June 2011, we decreased our valuation allowance on our deferred income tax assets by \$5.0 million. We recorded a benefit from income taxes of \$5.0 million against our current period's income tax provision. The net income for the six months ended June 30, 2011 includes a tax provision for federal alternative minimum taxes. A state tax provision was recorded for the Company's operations apportioned to various state jurisdictions.

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

June 30,	Increase (Decrease)
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	2011	2010	Dollars	%
<b>Revenues</b>				
Program fee revenue	\$ 233	\$ 233	\$ -	- %
Milestone revenue	20,000	-	20,000	*
Collaboration revenue	-	387	(387 )	(100 )
<b>Total revenue</b>	<b>20,233</b>	<b>620</b>	<b>19,613</b>	<b>3,163</b>
<b>Operating expenses</b>				
Research and development	1,142	1,525	(383 )	(25 )
Marketing, general and administrative	1,729	2,281	(552 )	(24 )
<b>Total operating expenses</b>	<b>2,871</b>	<b>3,806</b>	<b>(935 )</b>	<b>(25 )</b>
Income (loss) from operations	17,362	(3,186 )	20,548	645
Other income (expense), net	5	(3 )	8	267
Income (loss) before income tax	17,367	(3,189 )	20,556	645
<b>Income tax expense</b>	<b>338</b>	<b>3</b>	<b>335</b>	<b>11,167</b>
<b>Net income (loss)</b>	<b>\$ 17,029</b>	<b>\$ (3,192 )</b>	<b>\$ 20,221</b>	<b>634 %</b>



## Revenue

Pfizer paid us a \$30.0 million upfront fee in connection with the closing of the Pfizer Agreement in December 2007. We have assigned an equal portion of Pfizer's \$30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. Program fee revenue recognized in each of the three months ended June 30, 2011 and 2010 from amortization of this upfront fee was \$0.2 million. On June 17, 2011 the Oxecta NDA was approved and we recognized \$20.0 million milestone revenue while fully recognizing the remaining program fee revenue.

Collaboration revenue recognized in the three months ended June 30, 2010 was \$0.4 million for invoiced reimbursement of our R&D expenses incurred pursuant to the Pfizer Agreement. We invoice Pfizer in arrears on a calendar quarter basis. We did not incur reimbursable R&D expenses during the second quarter 2011 and we estimate such R&D expenses in the future for which we will receive reimbursement from Pfizer to be minimal.

## Operating Expense

R&D expense during the three months ended June 30, 2011 and 2010 were for product candidates utilizing our Aversion® and Impede™ Technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, compensation, benefits and other personnel related expenses, and facility costs. Included in the 2011 and 2010 results are non-cash share-based compensation expenses of \$0.1 million and \$0.5 million, respectively. Excluding the share-based compensation expense, there is a \$0.1 million decrease in development expenses. Our ongoing development activities include our benzodiazepine tablet product candidate, an extended release opioid product candidate, and the commencement of scale-up for our Impede PSE manufacturing process to quantities required for commercial distribution.

Marketing expenses during the three months ended June 30, 2011 and 2010 primarily consisted of market research studies on our Aversion® and Impede™ Technologies. Our G&A expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll. Included in the 2011 and 2010 results are non-cash share-based compensation expenses of \$0.5 million and \$1.5 million, respectively. Excluding the share-based compensation expense, our marketing, general and administrative expenses increased \$0.5 million.

## Other Income

During the three months ended June 30, 2011 and 2010, our cash was invested in accordance with the investment policy approved by our Board of Directors resulting in minimal interest income earned in 2011 and 2010 due to the prevailing low interest rates.

## Net Income (Loss)

During June 2011, we decreased our valuation allowance on our deferred income tax assets by \$5.0 million. We recorded a benefit from income taxes of \$5.0 million against our current period's income tax provision. The net income for the three months ended June 30, 2011 includes a tax provision for federal alternative minimum taxes. A state tax provision was recorded for the Company's operations apportioned to various state jurisdictions.

## Liquidity and Capital Resources

At June 30, 2011, the Company had cash and cash equivalents of \$39.5 million, including the \$20.0 million milestone payment by Pfizer, compared to \$24.0 million at December 31, 2010. The Company had working capital of \$38.8

million at June 30, 2011 compared to \$23.3 million at December 31, 2010. The increase in our cash provided by operations is due to the period's net income resulting from the milestone revenue triggered by FDA approval of the Oxecta NDA, offset by the payment of employee withholding taxes approximating \$1.8 million associated with the exercise of stock options and RSU distributions during the six month period, adjusted for certain non-cash items such as deferred program fee revenue and share-based compensation expenses.

At July 27, 2011, the Company had cash and cash equivalents of approximately \$38.9 million. We estimate that our current cash reserves will be sufficient to fund operations and the development of Aversion and Impede Technologies and related product candidates through at least the next 12 months.

#### Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company's 2010 Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company's critical accounting policies described in the 2010 Annual Report are also applicable to 2011.

#### Item 4. Controls and Procedures

(a) **Disclosure Controls and Procedures.** The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined on Rules 13a – 13(e) and 15(d) – 15(e) under the Exchange Act) as of the end of the period covered by this Report. The Company's disclosure controls and procedures are designed to provide reasonable assurance that information is recorded, processed, summarized and reported accurately and on a timely basis in the Company's periodic reports filed with the SEC. Based upon such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures are effective to provide reasonable assurance. Notwithstanding the foregoing, a control system, no matter how well designed and operated, can provide only reasonable, not absolute assurance that it will detect or uncover failures within the Company to disclose material information otherwise require to be set forth in the Company's periodic reports.

(b) **Changes in Internal Controls over Financial Reporting.** There were no changes in our internal controls over financial reporting during the first fiscal quarter of 2011 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## PART II. OTHER INFORMATION

#### Item 1. Legal Proceedings

The information required by this Item is incorporated by reference to Note 9, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

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

The Risk Factors set forth in Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2010 are hereby superseded and replaced with the following Risk Factors. Shareholders and prospective investors in the Company's common stock should carefully consider the following Risk Factors.

#### Risks Relating to Our Business and Industry

We are largely dependent on the commercial success of Oxecta™ Tablets, or Oxecta (formerly Acurox®), and we have not generated any revenue from sales of Oxecta.

We anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend in large part on the commercial success of our only U.S. Food and Drug Administration, or FDA, approved product, Oxecta, which in turn, will depend on several factors, including:

- the timely and successful launch of Oxecta in the United States by Pfizer, to whom we have licensed Oxecta;
  - Pfizer's obtaining and increasing market demand for, and sales of, Oxecta;
  - obtaining acceptance of Oxecta by physicians and patients;

- obtaining and maintaining adequate levels of coverage and reimbursement for Oxecta from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;
- maintaining compliance with regulatory requirements;
- Pfizer's establishing and maintaining agreements with wholesalers and distributors on commercially reasonable terms;
  - Pfizer's manufacture and supply of adequate supplies of Oxecta to meet commercial demand; and
- maintaining intellectual property protection for Oxecta and obtaining favorable drug listing treatment by the FDA to minimize generic competition.

We expect Pfizer to commercially launch Oxecta late in the third quarter or early in the fourth quarter of 2011. However, we cannot be certain that Pfizer will timely launch Oxecta or devote sufficient resources upon commercialization. Pfizer's marketing of Oxecta may result in low market acceptance and insufficient demand for, and sales of, the product. If Pfizer fails to successfully launch Oxecta and increase sales, we may be unable to generate sufficient revenues to sustain or grow our business and we may never become profitable, and our business, financial condition and results of operations will be materially affected.

If Pfizer is not successful in commercializing Oxecta and other licensed product candidates incorporating the Aversion Technology our revenues and our business will suffer.

Pursuant to our license, development and commercialization agreement with a subsidiary of Pfizer, or the Pfizer Agreement, Pfizer is responsible for manufacturing, marketing, pricing, promoting, selling, and distributing Oxecta and certain of our product candidates in development in the United States, Canada and Mexico, or the Pfizer Territory. If such agreement is terminated in accordance with its terms, including due to a party's failure to perform its obligations or responsibilities under the agreement, then we would need to commercialize the products ourselves for which we currently have no infrastructure, or alternatively enter into a new agreement with another pharmaceutical company, of which no assurance can be given. If we are unable to build the necessary infrastructure to commercialize the products ourselves, which would substantially increase our expenses and capital requirements that we might not be able to fund, or are unable to find a suitable replacement development and commercialization partner, we would be unable to generate any revenues from these products. Even if we are successful at replacing the commercialization capabilities of Pfizer, our revenues and/or royalties for these products could be adversely impacted.

Pfizer's manufacturing facility is currently the sole commercial source of supply for Oxecta and our other product candidates licensed to Pfizer. If Pfizer's manufacturing facility fails to obtain sufficient DEA quotas for the opioid active ingredients contained in such product candidates, fails to source adequate quantities of active and inactive ingredients, fails to comply with regulatory requirements, or otherwise experiences disruptions in commercial supply of our product candidates, product revenue and our royalties could be adversely impacted.

Pfizer has a diversified product line for which Oxecta Tablets and our other product candidates licensed to Pfizer will vie for Pfizer's promotional, marketing, and selling resources. If Pfizer fails to commit sufficient promotional, marketing and selling resources to our products, product revenue and our royalties could be adversely impacted. Additionally, in view of Pfizer's recent acquisition of King Pharmaceuticals in February 2011, there can be no assurance that Pfizer will commit the resources required for the successful commercialization of Oxecta Tablets or the development and commercialization of our licensed product candidates.

The market for our opioid product candidates is highly competitive with many marketed non-abuse deterrent brand and generic products and other abuse deterrent product candidates in development. If Pfizer prices our product candidates inappropriately, fails to position our products properly, targets inappropriate physician specialties, or otherwise does not provide sufficient promotional support, product revenue and our royalties could be adversely impacted.

Pfizer's promotional, marketing and sales activities in connection with Oxecta and our other product candidates licensed to Pfizer are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program. The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. If Pfizer's activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, Pfizer may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its activities with regard to the commercialization of our products, which could harm the commercial success of our products and materially affect our business, financial condition and results of operations.

We have a history of operating losses and may not achieve profitability sufficient to generate a positive return on shareholders' investment.

We had a net loss of \$12.7 million for the year ended December 31, 2010, a net loss of \$15.8 million for the year ended December 31, 2009 and net income of \$14.5 million for the year ended December 31, 2008. Our future profitability will depend on several factors, including:

- our receipt of milestone payments and royalties relating to our FDA approved Oxecta Tablets, for which we only receive royalties on sales occurring after the one year anniversary of the first commercial sale of Oxecta Tablets, and other products developed and commercialized under the Pfizer Agreement;
- the receipt of FDA approval and the successful commercialization by Pfizer and other future licensees (if any) of products utilizing our Aversion® Technology and our ability to commercialize our Impede® Technology without infringing the patents and other intellectual property rights of third parties; and
- our successful launch and marketing of Impede™ pseudoephedrine product ("Impede™ PSE") and other products utilizing our Impede Technology, and market acceptance, increased demand for and sales of Impede PSE.

We cannot assure you that our Oxecta or Impede PSE products will be successfully commercialized or our Aversion Technology products in development will be approved for commercialization by the FDA.

We recognized revenues of \$3.3 million and \$3.8 million in the years ended December 31, 2010 and 2009, respectively, from payments received under the Pfizer Agreement. However, we have not yet generated any revenues from Aversion Technology or Impede Technology product sales. Even if we or Pfizer succeed in commercializing one or more of our Aversion Technology products or if we are successful in commercializing our Impede Technology products, we expect to continue using cash reserves for the foreseeable future. Our expenses may increase in the foreseeable future as a result of continued research and development of additional product candidates, maintaining and expanding the scope of our intellectual property, commercializing our Impede PSE product, and hiring of additional research and development staff.

We will need to generate revenues from direct product sales or indirectly from royalties on sales to achieve and maintain profitability. If we cannot successfully commercialize Impede PSE or successfully develop, obtain regulatory approval and commercialize our products licensed to Pfizer under the Pfizer Agreement or other products under similar license agreements that we may enter into with other pharmaceutical companies in the future, of which no assurance can be given, we will not be able to generate such royalty revenues or achieve future profitability. Our failure to achieve or maintain profitability would have a material adverse impact on the market price of our common stock.

We must rely on current cash reserves, technology licensing fees and third party financing to fund operations.

Pending the receipt of milestone payments and royalties, if any, under the Pfizer Agreement or under similar license agreements that we may enter into with other pharmaceutical companies in the future, of which no assurance can be given, we must rely on our current cash reserves, revenues from sales of Impede PSE, if any, and third-party financing to fund operations and product development activities. No assurance can be given that current cash reserves or revenues from Impede PSE product sales will be sufficient to fund the continued operations and development of our product candidates until such time as we generate additional revenue from the Pfizer Agreement or any similar future license agreements. Moreover, no assurance can be given that we will be successful in raising additional financing or, if funding is obtained, that such funding will be sufficient to fund operations until product candidates utilizing our Aversion and Impede Technologies may be commercialized.



Our and our licensees' ability to market and promote Oxecta and other Aversion Technology products by describing the abuse deterrent features of such products will be determined by the FDA approved label for such products.

The commercial success of our Aversion Technology products will depend upon our and our licensees' ability to obtain FDA approved labeling describing such products' abuse deterrent features or benefits. Our or our licensees' failure to achieve FDA approval of product labeling containing such information will prevent or substantially limit our and our licensees' advertising and promotion of such abuse deterrent features in order to differentiate Aversion Technology products from other immediate release opioid products containing the same active ingredients, and would have a material adverse impact on our business and results of operations. The FDA has publicly stated that explicit indications or claims of abuse deterrence will not be permitted unless such indications or claims are supported by double blind controlled clinical studies demonstrating an actual reduction in product abuse by patients or drug abusers. Because the cost, time and practicality of designing and implementing clinical studies adequate to support explicit claims of abuse deterrence are prohibitive, we are not pursuing and have not conducted the clinical trials necessary to include an explicit product label claim of abuse deterrence. Instead, we will rely on certain clinical and laboratory studies to support product labeling describing the relative difficulty of abusing or misusing our products and such products' abuse deterrent features. However, the extent to which such information is included in the FDA approved product label is the subject of our and our licensees' discussions with, and agreement by, the FDA as part of the New Drug Application, or NDA, review process for each of our product candidates. The outcome of those discussions with the FDA will determine whether we or our licensees will be able to market our products with labeling that sufficiently differentiates them from other products that have comparable therapeutic profiles. While the FDA approved label for Oxecta includes the results from a clinical study which evaluated the effects of nasally snorting crushed Oxecta and commercially available oxycodone tablets and limitations on wetting or dissolving Oxecta, it does not, however, include the results of our laboratory studies intended to evaluate Oxecta's potential to limit extraction of oxycodone HCl from dissolved Oxecta Tablets and resist conversion into an injectable, or IV solution. The absence of the results of these extraction and syringe studies in the FDA approved label for Oxecta may substantially limit Pfizer's ability to differentiate Oxecta from other immediate release oxycodone products, which would have a material adverse effect on market acceptance of Oxecta and on our business and results of operations.

Notwithstanding the FDA approved labeling for Oxecta, there can be no assurance that our Aversion Technology products in development will receive FDA approved labeling that describes the abuse deterrent features of such products. If the FDA does not approve labeling containing such information, we or our licensees will not be able to promote such products based on their abuse deterrent features, may not be able to differentiate such products from other immediate release opioid products containing the same active ingredients, and may not be able to charge a premium above the price of such other products which could materially adversely affect our business and results of operations.

Because the FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse deterrent characteristics of our product, as in the case of Oxecta, the FDA may object to our or our licensee's marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of Oxecta from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution, which could harm the commercial success of our product and materially affect our business, financial condition and results of operations.

Our product candidates are unproven and may not be approved by the FDA.

We are committing a majority of our resources to the development of product candidates utilizing our Aversion and Impede Technologies. Notwithstanding the receipt of FDA approval of Oxecta Tablets, there can be no assurance that the FDA will approve any other product candidate utilizing Aversion Technology for commercial distribution. Further there can be no assurance that other product candidates that may be developed using Aversion

Technology or Impede Technology will achieve the targeted end points in the required clinical studies or perform as intended in other pre-clinical and clinical studies or lead to an NDA submission or filing acceptance. Our failure to successfully develop and achieve final FDA approval of our product candidates in development utilizing Aversion Technology will have a material adverse effect on our financial condition.

If the FDA disagrees with our determination that certain of our products meet the over-the-counter, or OTC, requirements, once those products are commercialized, they may be removed from the market; the FDA or the U.S. Federal Trade Commission, or FTC, may object to our advertisement and promotion of the extraction characteristics and benefits of our Impede products.

Drugs that have been deemed safe and effective by the FDA for use by the general public without a prescription are classified as OTC drug products. Certain OTC drug products may be commercialized without premarket review by the FDA if the standards set forth in the applicable regulatory monograph are met. An OTC monograph provides the marketing conditions for the applicable OTC drug product, including active ingredients, labeling, and other general requirements such as compliance with current Good Manufacturing Practices, or cGMP, and establishment registration. Any product which fails to conform to each of the general conditions and a monograph is subject to regulatory action. Further, although the FDA regulates OTC drug product labeling, the FTC regulates the advertising and marketing of OTC drug products. We believe that Impede PSE is classified for OTC sale under an FDA OTC monograph which will allow us to commercialize them without submitting an NDA or Abbreviated New Drug Application, or ANDA, to the FDA. We have also determined that, provided we adhere to the FDA's requirements for OTC monograph products, including product labeling, we can advertise and promote the extraction characteristics and benefits of Impede PSE which are supported by our research studies. No assurance can be given, however, that the FDA will agree that Impede PSE may be sold under the FDA's OTC monograph product regulations or that the FDA or FTC will not object to our advertisement and promotion of Impede PSE's extraction characteristics and benefits. If the FDA determines that Impede PSE does not conform to the OTC monograph or if we fail to meet the general conditions, once commercialized, the product may be removed from the market and we may face various actions including, but not limited to, restrictions on the marketing or distribution of such products, warning letters, fines, product seizure, or injunctions or the imposition of civil or criminal penalties. Any of these actions may materially and adversely affect our financial condition and operations. If the FDA requires that we submit a NDA or ANDA to obtain marketing approval for Impede PSE, this would result in substantial additional costs, delay or suspend the commercialization of Impede PSE and require FDA approval prior to sale, of which no assurance can be provided. In such case, the label for Impede PSE would be subject to FDA review and approval and there can be no assurance that we will be able to market Impede PSE with labeling sufficient to differentiate it from products that have comparable therapeutic profiles. If we are unable to advertise and promote the extraction characteristics of Impede PSE, we may be unable to compete with national brands and pharmacy chain store brands.

Our Aversion and Impede Technology products may not be successful in limiting or impeding abuse or misuse upon commercialization.

We are committing a majority of our resources to the development of products utilizing our Aversion and Impede Technologies. Notwithstanding the receipt of FDA approval of Oxecta Tablets and the results of our numerous clinical and laboratory studies for Oxecta and our Aversion and Impede Technology products in development, there can be no assurance that upon commercialization, Oxecta or any other product utilizing our Aversion or Impede Technologies will perform as tested and limit or impede the actual abuse or misuse of such products. Moreover, there can be no assurance that the post-approval epidemiological study required by the FDA as a condition of approval of Oxecta will show a reduction in the consequences of abuse and misuse by patients for whom Oxecta is prescribed. The failure of Oxecta or other products utilizing our Aversion and Impede Technologies to limit or impede actual abuse or misuse in practice will have a material adverse impact on market acceptance for such products and on our financial condition and results of operations.

Relying on third party clinical research organizations, or CROs, may result in delays in our pre-clinical, clinical or laboratory testing. If pre-clinical, clinical or laboratory testing for our product candidates are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines.

To obtain FDA approval to commercially sell and distribute in the United States any of our prescription product candidates, we or our licensees must submit to the FDA an NDA demonstrating, among other things, that the product candidate is safe and effective for its intended use. As we do not possess the resources or employ all the personnel necessary to conduct such testing, we rely on CROs for the majority of this testing with our product candidates. As a result, we have less control over our development program than if we performed the testing entirely on our own. Third parties may not perform their responsibilities on our anticipated schedule. Delays in our development programs could significantly increase our product development costs and delay product commercialization.

The commencement of clinical trials with our product candidates may be delayed for several reasons, including but not limited to delays in demonstrating sufficient pre-clinical safety required to obtain regulatory approval to commence a clinical trial, reaching agreements on acceptable terms with prospective CROs, clinical trial sites and licensees, manufacturing and quality assurance release of a sufficient supply of a product candidate for use in our clinical trials and/or obtaining institutional review board approval to conduct a clinical trial at a prospective clinical site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or regulatory authorities due to several factors, including ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials, a determination by us or regulatory authorities that continuing a trial presents an unreasonable health risk to participants, failure to conduct clinical trials in accordance with regulatory requirements, lower than anticipated recruitment or retention rate of patients in clinical trials, inspection of the clinical trial operations or trial sites by regulatory authorities, the imposition of a clinical hold by FDA, lack of adequate funding to continue clinical trials, and/or negative or unanticipated results of clinical trials.

Clinical trials required by the FDA for commercial approval may not demonstrate safety or efficacy of our product candidates. Success in pre-clinical testing and early clinical trials does not assure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. Even if the results of our pivotal phase III clinical trials are positive, we and our licensees may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we or our licensees can submit NDAs or obtain regulatory approval for our product candidates.

Clinical trials are expensive and at times difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, if participating subjects or patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we, our licensees or the FDA believes that participating patients are being exposed to unacceptable health risks, we or our licensees may suspend the clinical trials. Failure can occur at any stage of the trials, and we or our licensees could encounter problems causing the abandonment of clinical trials or the need to conduct additional clinical studies, relating to a product candidate.

Even if our clinical trials and laboratory testing are completed as planned, their results may not support commercially viable product label claims. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their intended use. Such failure may cause us or our licensees to abandon a product candidate and may delay the development of other product candidates.

We have no commercial manufacturing capacity and rely on third-party contract manufacturers to produce commercial quantities of our products.

We do not have the facilities, equipment or personnel to manufacture commercial quantities of our products and therefore must rely on our licensees or other qualified third-party contract manufactures with appropriate facilities and equipment to contract manufacture commercial quantities of products utilizing our Aversion and Impede Technologies. These licensees and third- party contract manufacturers are also subject to current good manufacturing practice, or cGMP regulations, which impose extensive procedural and documentation requirements. Any performance failure on the part of our licensees or contract manufacturers could delay commercialization of any approved products, depriving us of potential product revenue.

Our drug products, including Impede PSE, require precise, high quality manufacturing. Failure by our contract manufacturers to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could materially adversely affect our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMP and other applicable

government regulations; however, beyond contractual remedies that may be available to us, we do not have control over third-party manufacturers' compliance with these regulations and standards.

If for some reason our contract manufacturers cannot perform as agreed, we may be required to replace them. Although we believe there are a number of potential replacements, we may incur added costs and delays in identifying and qualifying any such replacements. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drug candidates.

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

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

We or our licensees may encounter delays or rejections during any stage of the regulatory review and approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the product candidates to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of an NDA the FDA may refuse to file the application, deny approval of the application, require additional testing or data and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. For instance, the FDA's approval of Oxecta is conditioned on Pfizer conducting a post-approval epidemiological study to assess the actual abuse levels and consequences of Oxecta in the market. The Prescription Drug User Fee Act, or PDUFA, sets time standards for the FDA's review of NDA's. The FDA's timelines described in the PDUFA guidance are flexible and subject to change based on workload and other potential review issues and may delay the FDA's review of an NDA. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we or our licensees desire and could affect the marketability of our products.

Even if we comply with all the FDA regulatory requirements, we or our licensees may never obtain regulatory approval for any of our product candidates in development. For example, our Aversion Technology products in development intended to provide impediments to over-ingesting the product may include niacin. We have previously submitted an NDA to the FDA for an Aversion Technology product containing niacin which was not approved by the FDA. To obtain approval of an Aversion Technology product with niacin, we will be required to address all the issues raised by the FDA as deficient in our NDA, of which no assurance can be given. If we or our licensees fail to obtain regulatory approval for any of our product candidates in development, we will have fewer commercialized products and correspondingly lower revenues. Even if regulatory approval of our products in development is received, such approval may involve limitations on the indicated uses or promotional claims we or our licensees may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles but without abuse deterrent features (see risk factor above entitled "Our and our licensees ability to market and promote Oxecta and other Aversion Technology products by describing the abuse deterrent features of such products will be determined by the FDA approved label for such products"). Such events would have a material adverse effect on our operations and financial condition. We may market certain of our product without the prior application to and approval by the FDA. The FDA may subsequently require us to withdraw such products and submit NDA's for approval prior to re-marketing.

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





We must maintain FDA approval to manufacture clinical supplies of our product candidates at our facility; failure to maintain compliance with FDA requirements may prevent or delay the manufacture of our product candidates and costs of manufacture may be higher than expected.

We have installed the equipment necessary to manufacture clinical trial supplies of our Aversion and Impede Technology product candidates in tablet formulations at our Culver, Indiana facility. To be used in clinical trials, all of our product candidates must be manufactured in conformity with cGMP regulations. All such product candidates must be manufactured, packaged, and labeled and stored in accordance with cGMPs. Modifications, enhancements or changes in manufacturing sites of marketed products are, in many circumstances, subject to FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain. Our Culver, Indiana facility, and those of any third-party manufacturers that we or our licensees may use, are periodically subject to inspection by the FDA and other governmental agencies, and operations at these facilities could be interrupted or halted if the FDA deems such inspections are unsatisfactory. Failure to comply with FDA or other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production or distribution, suspension of FDA review of our product candidates, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution.

We develop our products, and manufacture clinical supplies, at a single location. Any disruption at this facility could adversely affect our business and results of operations.

We rely on our Culver, Indiana facility for developing our product candidates and the manufacture of clinical supplies of our product candidates. If the Culver, Indiana facility were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to repair or replace. If our Culver facility were affected by a disaster, we would be forced to rely entirely on CROs and third-party contract manufacturers for an indefinite period of time. Although we believe we possess adequate insurance for damage to our property and for the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. Moreover, any disruptions or delays at our Culver, Indiana facility could impair our ability to develop our product candidates utilizing the Aversion or Impede Technologies, which could adversely affect our business and results of operations.

Our operations are subject to environmental, health and safety, and other laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

Our business, properties and product candidates are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage and disposal of hazardous substances, waste and other regulated materials. Because we own and operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or may be altered in the future, could adversely affect our financial condition and results of operations.

Our failure to successfully establish new license agreements with pharmaceutical companies for the development and commercialization of our other products in development may adversely impair our ability to develop, market and sell such products.

The Pfizer Agreement grants Pfizer an exclusive license to develop and commercialize Oxecta and certain other opioid analgesic products in the Pfizer Territory. We believe that opportunities exist to enter into agreements similar

to the Pfizer Agreement with other partners for the commercialization of these same opioid products outside the Pfizer Territory and for the development and commercialization of additional Aversion Technology and Impede Technology product candidates for other abused and misused drugs, such as tranquilizers, stimulants, sedatives and nasal decongestants in the United States and worldwide. However, there can be no assurance that we will be successful in entering into such license agreements in the future. If we are unable to enter into such agreements, our ability to develop and commercialize our product candidates, and our financial condition and results of operations, would be adversely affected.

If our licensees do not satisfy their obligations, we will be unable to develop our licensed product candidates.

As part of our Pfizer Agreement or other future similar license agreements, we do not and will not have day-to-day control over the activities of our licensees with respect to any product candidate. If a licensee fails to fulfill its obligations under an agreement with us, we may be unable to assume the development of the product candidate covered by that agreement or to enter into alternative arrangements with another third party. In addition, we may encounter delays in the commercialization of the product candidate that is the subject of a license agreement. Accordingly, our ability to receive any revenue from the product candidates covered by such agreements will be dependent on the efforts of our licensee. We could be involved in disputes with a licensee, which could lead to delays in or termination of, our development and commercialization programs and result in time consuming and expensive litigation or arbitration. In addition, any such dispute could diminish our licensee's commitment to us and reduce the resources they devote to developing and commercializing our products. If any licensee terminates or breaches its agreement, or otherwise fails to complete its obligations in a timely manner, our chances of successfully developing or commercializing our product candidates would be materially adversely effected. Additionally, due to the nature of the market for our product candidates, it may be necessary for us to license all or a significant portion of our product candidates to a single company thereby eliminating our opportunity to commercialize other product candidates with other licensees.

If we fail to maintain our license agreement with Pfizer, we may have to reduce or delay our product candidate development.

Our plan for developing, manufacturing and commercializing Oxecta Tablets and certain other opioid analgesic product candidates utilizing our Aversion Technology currently requires us to maintain our license agreement with Pfizer. In addition to other customary termination provisions, the Pfizer Agreement provides that Pfizer may terminate the Pfizer Agreement at any time upon written notice to us. If Pfizer elects to terminate the Pfizer Agreement, or if we are otherwise unable to maintain our existing relationship with Pfizer, we may have to limit the size or scope of, or delay or abandon the development of, our Aversion oxycodone HCl with niacin tablets and other Aversion Technology opioid analgesic product candidates or undertake and fund development of these product candidates ourselves. If we were required to fund the commercialization efforts with respect to Oxecta Tablets and the development and commercialization efforts to our other Aversion Technology opioid analgesic product candidates on our own, we may need to obtain additional financing, which may not be available on acceptable terms, or at all.

The market may not be receptive to products incorporating our Aversion or Impede Technologies.

The commercial success of our products will depend on acceptance by health care providers and others that such products are clinically useful, cost-effective and safe. There can be no assurance given that our products utilizing the Aversion or Impede Technologies would be accepted by health care providers and others. Factors that may materially affect market acceptance of our product candidates include but are not limited to:

- the relative advantages and disadvantages of our products compared to competitive products;
- the relative timing to commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products;
- the perception of health care providers of their role in helping to prevent abuse and their willingness to prescribe abuse-deterrent products to do so;
  - the willingness of third party payers to reimburse for our prescription products;
  - the willingness of pharmacy chains to stock our Impede Technology products; and
  - the willingness of consumers to pay for our products.

Our product candidates, if successfully developed and commercially launched, will compete with both currently marketed and new products launched in the future by other companies. Health care providers may not accept or utilize any of our products. Physicians and other prescribers may not be inclined to prescribe our prescription products unless our products demonstrate commercially viable advantages over other products currently marketed for the same indications. Pharmacy chains may not be willing to stock our Impede Technology products and pharmacists may not recommend such products to consumers. Further, consumers may not be willing to purchase our products. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

If we are not successful in commercializing Impede PSE and other Impede Technology products our revenues and business will suffer.

We intend to market and sell Impede PSE to regional and national drug store chains. Impede PSE will compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in marketing their competing products. Category leading brands are often supported by regional and national advertising and promotional efforts. Impede PSE will compete with national brands as well as pharmacy chain store brands that are offered at a lower price. There can be no assurance that we will succeed in commercializing Impede PSE, or that even if commercialized, that the pricing of Impede PSE will allow us to

generate significant revenues or profit. Regulations have been enacted in several state or local jurisdictions requiring a doctor's prescription to obtain pseudoephedrine products. An expansion of such restrictions to other jurisdictions or even nationally will adversely impact our ability to market Impede PSE as an OTC product and generate revenue from Impede PSE product sales.

If we, our licensees or others identify serious adverse events or deaths relating to any of our products once on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues.

We or our licensees are required to report to relevant regulatory authorities all serious adverse events or deaths involving our product candidates or approved products. If we, our licensees, or others identify such events, regulatory authorities may withdraw their approvals of such products; we or our licensees may be required to reformulate our products; we or our licensees may have to recall the affected products from the market and may not be able to reintroduce them onto the market; our reputation in the marketplace may suffer; and we may become the target of lawsuits, including class actions suits. Any of these events could harm or prevent sales of the affected products and could materially adversely affect our business and financial condition.

In the event that we or our licensees are successful in bringing any products to market, our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers.

The ability of our licensees to successfully commercialize our products may depend in part on the availability of reimbursement for our prescription products from government health administration authorities, private health insurers, and other third-party payers and administrators, including Medicaid and Medicare. We cannot predict the availability of reimbursement for newly-approved products utilizing our Aversion Technology. Third-party payers and administrators, including state Medicaid programs and Medicare, are challenging the prices charged for pharmaceutical products. Government and other third-party payers increasingly are limiting both coverage and the level of reimbursement for new drugs. Third-party insurance coverage may not be available to patients for any of our products candidates. The continuing efforts of government and third-party payers to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payers do not provide adequate coverage and reimbursement for any product utilizing our Aversion Technology, health care providers may not prescribe them or patients may ask their health care providers to prescribe competing products with more favorable reimbursement. In some foreign markets, pricing and profitability of pharmaceutical products are subject to government control. In the United States, we expect there may be federal and state proposals for similar controls. In addition, we expect that increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or our licensees charge for any of our products in the future. Further, cost control initiatives could impair our ability or the ability of our licensees to commercialize our products and our ability to earn revenues from commercialization.

In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could impact our or our licensees' ability to sell our products profitably. In particular, in 2010, the Patient Protection Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the Healthcare Reform Law of greatest importance to the pharmaceutical industry are the following:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, beginning in 2011;
  - An increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- A new Medicare Part D coverage gap discount program, under which manufacturers must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in

2011;

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- Extension of manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010; and
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research.

At this time, it remains uncertain what the full impact of these provisions will be on the pharmaceutical industry generally or our business in particular.

Consolidation in the healthcare industry could lead to demands for price concessions or for the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations.

Because healthcare costs have risen significantly, numerous initiatives and reforms by legislatures, regulators and third-party payers to curb these cost increases have resulted in a trend in the healthcare industry to consolidate product suppliers and purchasers. As the healthcare industry consolidates, competition among suppliers to provide products to purchasers has become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, and large single accounts continue to use their market power to influence product pricing and purchasing decisions. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to influence the worldwide healthcare industry, resulting in further business consolidations, which may exert further downward pressure on the prices of our anticipated products. This downward pricing pressure may adversely impact our business, financial condition or results of operations.

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

Our success depends on our ability to obtain and maintain patent protection for products developed utilizing our technologies, in the United States and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual questions. Notwithstanding our receipt of U.S. Patent No. 7,201,920 and U.S. Patent No. 7,510,726 from the U.S. Patent and Trademark Office, or USPTO, encompassing our opioid products utilizing our Aversion Technology and a recent notice of allowance from the USPTO for a non-provisional patent application encompassing certain non-opioid products utilizing our Aversion Technology, there is no assurance that any of our patent claims in our other pending non-provisional and provisional patent applications relating to our technologies will issue or if issued, that any of our existing and future patent claims will be held valid and enforceable against third-party infringement or that our products will not infringe any third-party patent or intellectual property. Moreover, any patent claims relating to our technologies may not be sufficiently broad to protect our products. In addition, issued patent claims may be challenged, potentially invalidated or potentially circumvented. Our patent claims may not afford us protection against competitors with similar technology or permit the commercialization of our products without infringing third-party patents or other intellectual property rights.

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

Our success also depends on maintaining the confidentiality of our trade secrets and know-how. We seek to protect such information by entering into confidentiality agreements with employees, potential licensees, raw material

suppliers, contract research organizations, contract manufacturers, consultants and other parties. These agreements may be breached by such parties. We may not be able to obtain an adequate, or perhaps, any remedy to such a breach. In addition, our trade secrets may otherwise become known or be independently developed by our competitors. Our inability to protect our intellectual property or to commercialize our products without infringing third-party patents or other intellectual property rights would have a material adverse affect on our operations and financial condition.



We also rely on or intend to rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. For instance, Johnson & Johnson was recently granted an extension of time to file an opposition to our trademark application for Impede PSE. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks, or we may not have adequate resources to enforce our trademarks.

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

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

- litigation or other proceedings we or our licensee(s) may initiate against third parties to enforce our patent rights or other intellectual property rights;
- litigation or other proceedings we or our licensee(s) may initiate against third parties seeking to invalidate the patents held by such third parties or to obtain a judgment that our products do not infringe such third parties' patents;
- litigation or other proceedings third parties may initiate against us or our licensee(s) to seek to invalidate our patents or to obtain a judgment that third party products do not infringe our patents;
- if our competitors file patent applications that claim technology also claimed by us, we may be forced to participate in interference or opposition proceedings to determine the priority of invention and whether we are entitled to patent rights on such invention; and
- if third parties initiate litigation claiming that our products infringe their patent or other intellectual property rights, we will need to defend against such proceedings.

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

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could harm our business. In certain circumstances, our licensee Pfizer has the first right to control the enforcement of certain of our patents against third party infringers. Pfizer may not put adequate resources or effort into such enforcement actions or otherwise fail to restrain infringing products. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of

not issuing.

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

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We are aware of certain United States and international pending patent applications owned by third parties with claims potentially encompassing Oxecta and our Aversion products in development. While we do not expect the claims contained in such pending patent applications will issue in their present form, there can be no assurance that such patent applications will not issue as patents with claims encompassing one or more of our products. If such patent applications result in valid and enforceable issued patents, containing claims in their current form or otherwise encompassing our products we or our licensees may be required to obtain a license to such patents, should one be available, or alternatively, alter our products so as to avoid infringing such third-party patents. If we or our licensees are unable to obtain a license on commercially reasonable terms, or at all, we or our licensees could be restricted or prevented from commercializing our products. Additionally, any alterations to our products or our technologies could be time consuming and costly and may not result in technologies or products that are non-infringing or commercially viable.

We are aware of an issued United States patent owned by a third party having claims encompassing the use of one of our Aversion inactive ingredients in a controlled release pharmaceutical preparation. We are also aware of an issued United States patent owned by a third party having claims encompassing a pharmaceutical preparation containing viscosity producing ingredients that can be drawn into a syringe when dissolved in 10mL's or less of aqueous solution. While we believe that our Aversion products do not infringe these patents, or that such patents are otherwise invalid, there can be no assurance that we or Pfizer will not be sued for infringing these patent, and if sued, there can be no assurance that we or Pfizer will prevail in any such litigation. If we or Pfizer are found to infringe either or both of these patents, we or Pfizer may seek a license to use the patented technology. If we are unable to obtain such a license, of which no assurance can be given, we or Pfizer may be restricted or prevented from commercializing our Aversion products.

We are aware of certain issued United States patents owned by a third party having claims encompassing a process used to manufacture oxycodone HCl of high purity and pharmaceutical products resulting therefrom. As required by the FDA, Oxecta contains a similar high purity oxycodone HCl manufactured by a supplier that is not the owner or licensee of such patents. The owner of these patents has filed patent infringement actions relating to these patents against companies that have filed abbreviated new drug applications with the FDA for extended-release versions of oxycodone HCl. To our knowledge, the patent owner has not initiated any patent infringement actions against the sellers of immediate-release oxycodone HCl products or their suppliers of oxycodone HCl, however, we cannot be certain that these immediate-release products actually utilize a high purity oxycodone. We cannot provide assurance that Pfizer or its oxycodone HCl supplier will not be sued for infringing these patents. In the event of an infringement action, Pfizer and their oxycodone HCl supplier would have to either: (a) demonstrate that the manufacture of the oxycodone HCl used in Oxecta does not infringe the patent claims, (b) demonstrate the patents are invalid or unenforceable, or (c) enter into a license with the patent owner. If Pfizer or their oxycodone HCl supplier is unable demonstrate the foregoing, or obtain a license to these patents, Pfizer may be required or choose to withdraw Oxecta from the market.

We cannot assure you that our technologies, products and/or actions in developing our products will not infringe third-party patents. Our failure to avoid infringing third-party patents and intellectual property rights in the development and commercialization of our products would have a material adverse affect on our operations and financial condition.

We may be exposed to product liability claims and may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by patients, or health care providers or others that sell or consume our products. These claims may be made even with respect to those products

that possess regulatory approval for commercial sale. We are currently covered by clinical trial product liability insurance on a claims-made basis and expect to expand such coverage to cover our commercialization of Impede PSE prior to the sale of such product. This coverage may not be adequate to cover any product liability claims. Product liability coverage is expensive. In the future, we may not be able to obtain coverage for Impede PSE or, if obtained, maintain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims. Any claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations. Reference is made to the discussion in Note 9 of Item 1, Part I of this Report under the caption “Reglan®/Metoclopramide Litigation” for a discussion of pending product liability litigation filed against the Company in each of Pennsylvania, New Jersey and California.

The pharmaceutical industry is characterized by frequent litigation. Those companies with significant financial resources will be better able to bring and defend any such litigation. No assurance can be given that we would not become involved in future litigation, in addition to the ongoing Reglan/Metoclopramide mass tort litigation. Such litigation may have material adverse consequences to our financial condition and results of operations.

We face significant competition which may result in others developing or commercializing products before or more successfully than we do.

Our products and technologies will, if marketed, compete to varying degrees against both brand and generic products offering similar therapeutic benefits and being developed and marketed by small and large pharmaceutical (for prescription products) and consumer packaged goods (for OTC products) companies. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in research, development and commercialization of their competitive technologies and products. Prescription generic products and OTC store brand products will offer cost savings to third party payers and/or consumers that will create pricing pressure on our products. Also, these competitors may have a substantial sales volume advantage over our products which may result in our costs of manufacturing being higher than our competitors' costs. If our products are unable to capture and maintain market share, we or our licensees may not achieve significant product revenues and our financial condition and results of operations will be materially adversely affected.

We believe potential competitors may be developing opioid abuse deterrent technologies and products. Such potential competitors include, but may not be limited to, Pain Therapeutics, in collaboration with Pfizer, Purdue Pharma, Atlantic Pharmaceuticals, Egalet a/s, KemPharm and Collegium Pharmaceuticals, Inc. These companies appear to be focusing their development efforts on extended-release, or ER, opioid products, except for Atlantic Pharmaceuticals, while the majority of our Aversion Technology opioid analgesic product candidates under development are immediate-release, or IR, opioid products. Pfizer, our partner in developing and commercializing Aversion Technology immediate-release opioid products, is also developing and/or marketing ER opioid products, other analgesic products and non-analgesic products, all of which will compete for development and commercialization resources with our products, which may delay development or adversely impact the sales of our products.

Our Impede Technology products containing pseudoephedrine, or PSE, will compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Some of our competitors will have multiple consumer product offerings both within and outside the cold, allergy and sinus category providing them with substantial leverage in dealing with a highly consolidated pharmacy distribution network. The competing products may have well established brand names and may be supported by national or regional advertising. Impede PSE will compete directly with Johnson & Johnson's Sudafed® brand as well as generic formulations manufactured by Perrigo Company and others.

We are concentrating a substantial majority of our efforts and resources on developing product candidates utilizing our Aversion and Impede Technologies. The commercial success of products utilizing such technologies will depend, in large part, on the intensity of competition, FDA approved product labeling for our products compared to competitive products, and the relative timing and sequence for commercial launch of new products by other companies developing, marketing, selling and distributing products that compete with the products utilizing our Aversion and Impede Technologies. Alternative technologies and non-opioid products are being developed to improve or replace the use of opioid analgesics. In the event that such alternatives to opioid analgesics are widely adopted, then the market for products utilizing our Aversion and Impede Technologies may be substantially decreased thus reducing our ability to generate future profits.



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

We are dependent on our management and scientific team, including Robert Jones, our President and Chief Executive Officer, and Albert W. Brzeczko, Ph.D., our Vice President of Technical Affairs. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. While we have employment agreements with certain employees, all of our employees are at-will employees who may terminate their employment at any time. We do not have key personnel insurance on any of our officers or employees. The loss of any of our key personnel, or the inability to attract and retain such personnel, may significantly delay or prevent the achievement of our product and technology development and business objectives and could materially adversely affect our business, financial condition and results of operations.

Our products are subject in regulation by the U.S. Drug Enforcement Administration, or DEA, and such regulation may affect the development and sale of our products.

The DEA regulates certain finished drug products and active pharmaceutical ingredients, including certain opioid active pharmaceutical ingredients and pseudoephedrine HCl that are contained in our products. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of regulation. Furthermore, the amount of active ingredients we can obtain for our clinical trials is limited by the DEA and our quota may not be sufficient to complete clinical trials. There is a risk that DEA regulations may interfere with the supply of the products used in our clinical trials.

In addition, we and our contract manufacturers are subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be a rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain FDA approval and adverse scheduling could have a material adverse effect on the attractiveness of such product. We or our licensees must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

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

Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of Net Operating Loss, or NOL, carryforwards and other tax attributes. We have determined that an ownership change (as defined by Section 382 of the Internal Revenue Code) did occur as a result of restructuring that occurred in 2004. Neither the amount of our NOL carryforwards nor the amount of limitation of such carryforwards

claimed by us have been audited or otherwise validated by the Internal Revenue Service, which could challenge the amount we have calculated. The recognition and measurement of our tax benefit includes estimates and judgment by our management, which includes subjectivity. Changes in estimates may create volatility in our tax rate in future periods based on new information about particular tax positions that may cause management to change its estimates.



## Risks Relating to Our Common Stock

Our quarterly results of operations will fluctuate, and these fluctuations could cause our stock price to decline.

Our quarterly and annual operating results are likely to fluctuate in the future. These fluctuations could cause our stock price to decline. The nature of our business involves variable factors, such as the timing of launch and market acceptance of Oxecta Tablets and the timing of the research, development and regulatory submissions of our products in development that could cause our operating results to fluctuate. The forecasting of the timing and amount of sales of our products is difficult due to market uncertainty and the uncertainty inherent in seeking FDA and other necessary approvals for our product candidates. As a result, in some future quarters or years our clinical, financial or operating results may not meet the expectations of securities analysts and investors which could result in a decline in the price of our stock.

Volatility in stock prices of other companies may contribute to volatility in our stock price.

The market price of our common stock, like the market price for securities of pharmaceutical and biotechnology companies, has historically been highly volatile. The stock market from time to time experiences significant price and volume fluctuations unrelated to the operating performance of particular companies. Factors, such as fluctuations in our operating results, future sales of our common stock, announcements of the timing and amount of product sales, of our products, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements, laboratory or clinical trial results, government regulation, FDA determinations on the approval of a product candidate NDA submission, developments in patent or other proprietary rights, public concern as to the safety of drugs developed by us or others, changes in reimbursement policies, comments made by securities analysts and general market conditions may have a substantial effect on the market price of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation and shareholder derivative litigation has often been instituted. A securities class action suit or shareholder derivative suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources and result in a material adverse affect on our financial condition and results of operations. Reference is made to the discussion in Note 9 of Item 1, Part I of this Report under the caption "Securities Class Action and Derivative Litigation" for a discussion of a pending Securities class action litigation filed against us in the United States District Court for the Northern District of Illinois, Eastern Division, and three shareholder derivative suits filed in the Circuit Court of Cook County, Illinois, Chancery Division.

Our stock price has been volatile and there may not be an active, liquid trading market for our common stock.

Our stock price has experienced significant price and volume fluctuations and may continue to experience volatility in the future. Factors that may have a material impact on the price of our common stock, in addition to the other issues described herein, include the commercial success of Oxecta and Impede PSE, results of or delays in our pre-clinical and clinical studies, any delays in, or failure to receive FDA approval of our product candidates, the success of our license agreement with Pfizer, announcements of technological innovations or new commercial products by us or others, developments in patents and other proprietary rights by us or others, future sales of our common stock by existing stockholders, regulatory developments or changes in regulatory guidance, the departure of our officers, directors or key employees, and period-to-period fluctuations in our financial results. Also, you may not be able to sell your shares at the best market price if trading in our stock is not active or if the volume is low. There is no assurance that an active trading market for our common stock will be maintained on the NASDAQ Capital Market.

The National Association of Securities Dealers, Inc., or NASD, and the Securities and Exchange Commission, or SEC, have adopted rules relating to the listing of publicly traded stock. If we were unable to continue to comply with such rules, we could be delisted from trading on the NASDAQ Capital Market and thereafter trading in our common

stock, if any, would be conducted through the Over-the-Counter Bulletin Board of the NASD. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock from the NASDAQ Capital Market could also result in lower prices per share of our common stock than would otherwise prevail.

We do not have a history of paying dividends on our common stock.

Historically we have not declared and paid any cash dividends on our common stock. We intend to retain all of our earnings for the foreseeable future to finance the operation and expansion of our business. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases.

GCE Holdings LLC can control all matters requiring approval by shareholders.

GCE Holdings LLC beneficially owns approximately 72% of our outstanding common stock as of June 30, 2011 (calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended). As a result, GCE Holdings LLC, in view of its ownership percentage of our common stock, will be able to control all matters requiring approval by our shareholders, including the approval or rejection of mergers, sales or licenses of all or substantially all of our assets, or other business combination transactions. The interests of GCE Holdings LLC may not always coincide with the interests of our other shareholders and as such we may take action in advance of its interests to the detriment of our other shareholders. Accordingly, you may not be able to influence any action we take or consider taking, even if it requires a shareholder vote.

We are currently a “Controlled Company” within the meaning of the NASDAQ Capital Market Listing Requirements and, as a result, are exempt from certain corporate governance requirements.

Because GCE Holdings LLC controls more than 50% of the voting power of our common stock, we are currently considered to be a “controlled company” for purposes of a NASDAQ Capital Market listing requirements. As such, we are permitted, and have elected, to opt out of the NASDAQ Capital Market listing requirements that would otherwise require our board of directors to have a majority of independent directors, our board nominations to be selected, or recommended for the board’s selection either by a nominating committee comprised entirely of independent directors or by a majority of independent directors, and our compensation committee to be comprised entirely of independent directors. Accordingly, you may not have the same protections afforded to stockholders of companies that are subject to all of the NASDAQ Capital Market corporate governance requirements.

Any future sale of a substantial number of shares included in our current registration statement could depress the trading price of our stock, lower our value and make it more difficult for us to raise capital.

In accordance with the terms of the Securities Purchase Agreement dated August 20, 2007 between us and the investors named therein, we filed a registration statement with and declared effective by the Securities and Exchange Commission, or SEC, to register the shares included in our Units issued pursuant to the Securities Purchase Agreement, including shares underlying warrants included in the Units. In addition, pursuant to the exercise of previously granted piggyback registration rights, each of GCE Holdings, LLC, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP and Essex Woodlands Health Ventures V, L.P. have exercised their piggyback registration rights to include an aggregate of 26,584,016 shares in such registration statement. As a result, 34,243,273 shares (representing approximately 65% of our shares outstanding on a fully-diluted basis – including all derivative securities, whether or not currently exercisable) are available for resale by selling stockholders under the registration statement. If some or all of the shares included in such registration statement are sold by our affiliates and others it may have the effect of depressing the trading price of our common stock. In addition, such sales could lower our value and make it more difficult for us to raise capital if needed in the future.

#### Item 6. Exhibits

The exhibits required by this Item are listed below.

- 10.1 Amendment to Executive Employment Agreement dated as of April 28, 2011 between Acura Pharmaceuticals, Inc. and Robert B. Jones.
- 10.2 Second Amendment to Executive Employment Agreement dated as of July 7, 2011 between Acura Pharmaceuticals, Inc. and Robert B. Jones.

- 31.1 Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
- 31.2 Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
- 32.1 Certification of Periodic Report by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase
- 101.LAB XBRL Taxonomy Extension Label Linkbase
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase
- 101.DEF XBRL Taxonomy Extension Definition Linkbase

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.

July 28, 2011

ACURA PHARMACEUTICALS, INC.

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

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