

ACURA PHARMACEUTICALS, INC

Form 10-Q

November 02, 2010

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20649

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 September 30, 2010

or

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

For the transition period from _____ to _____

Commission File Number 1-10113

Acura Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

New York

(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 November 2, 2010 the registrant had 43,894,514 shares of common stock, \$.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

UNAUDITED

(in thousands, except par values)

	September 30, 2010	December 31, 2009
Assets		
Current assets		
Cash and cash equivalents	\$ 25,872	\$ 30,174
Collaboration revenue receivable	55	357
Prepaid insurance	336	193
Prepaid expenses and other current assets	51	33
Total current assets	26,314	30,757
Property, plant and equipment, net	1,077	1,160
Total assets	\$ 27,391	\$ 31,917
Liabilities and Stockholders' Equity		
Current liabilities		
Deferred program fee revenue	\$ 700	\$ 1,555
Accrued expenses	622	452
Total current liabilities	1,322	2,007
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock - \$.01 par value; 100,000 shares authorized; 43,894 and 43,728 shares issued and outstanding at September 30, 2010 and December 31, 2009	439	437
Additional paid-in capital	358,631	352,694
Accumulated deficit	(333,001)	(323,221)
Total stockholders' equity	26,069	29,910
Total liabilities and stockholders' equity	\$ 27,391	\$ 31,917

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2010	2009	2010	2009
Revenue				
Program fee revenue	\$ 855	\$ 2,688	\$ 233	\$ 583
Collaboration revenue	2,097	397	59	225
Total revenue	2,952	3,085	292	808
Operating expense				
Research and development expense	5,714	3,828	1,142	1,494
Marketing, general and administrative expense	7,025	8,680	1,716	3,284
Total operating expense	12,739	12,508	2,858	4,778
Loss from operations	(9,787)	(9,423)	(2,566)	(3,970)
Other income, net	17	131	15	20
Loss before income tax	(9,770)	(9,292)	(2,551)	(3,950)
Income tax expense	10	2,459	2	4
Net loss	\$ (9,780)	\$ (11,751)	\$ (2,553)	\$ (3,954)
Loss per share - basic and diluted	\$ (0.21)	\$ (0.26)	\$ (0.05)	\$ (0.09)
Weighted average shares – basic and diluted	46,992	45,839	47,100	45,992

See accompanying notes to the consolidated financial statements.

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

NINE MONTHS ENDED SEPTEMBER 30, 2010

UNAUDITED
(in thousands, except par values)

	Common Stock \$0.01 Par Value - Shares	Common Stock \$0.01 Par Value - Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2009	43,728	\$ 437	\$ 352,694	\$ (323,221)	\$ 29,910
Net loss	-	-	-	(9,780)	(9,780)
Share-based compensation	-	-	5,547	-	5,547
Exercise of warrants	166	2	390	-	392
Balance at September 30, 2010	43,894	\$ 439	\$ 358,631	\$ (333,001)	\$ 26,069

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30,

UNAUDITED

(in thousands, except supplemental disclosures)

	2010	2009
Cash flows from operating activities		
Net loss	\$ (9,780)	\$ (11,751)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	101	96
Deferred income taxes	-	2,479
Non-cash share-based compensation expense	5,547	6,529
Loss on asset dispositions	14	3
Changes in assets and liabilities		
Collaboration revenue receivable	302	3,304
Prepaid expenses and other current assets	(161)	91
Accounts payable	-	(382)
Accrued expenses	170	(176)
Deferred program fee revenue	(855)	(2,688)
Net cash used in operating activities	(4,662)	(2,495)
Cash flows from investing activities		
Capital expenditures	(32)	(213)
Investment maturities	-	5,039
Net cash (used in) provide by investing activities	(32)	4,826
Cash flows from financing activities—proceeds from warrant exercise	392	-
(Decrease) increase in cash and cash equivalents	(4,302)	2,331
Cash and cash equivalents at beginning of period	30,174	30,398
Cash and cash equivalents at end of period	\$ 25,872	\$ 32,729
Cash paid during the period for income taxes	\$ 15	\$ 102

SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES

Nine Months Ended September 30, 2010

1. We issued 14,000 shares of common stock after a cashless exercise of a warrant to acquire 64,000 shares of stock.

Nine Months Ended September 30, 2009

1. We issued 193,000 shares of common stock after a cashless exercise of warrants to acquire 391,000 shares of stock.
2. We issued 50,000 shares of common stock after a cashless exercise of an employee stock option to acquire 100,000 shares of common stock and after we withheld 50,000 shares from such exercise to pay \$173,000 of minimum statutory withholding payroll taxes.

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2010 AND 2009

NOTE 1 BASIS OF PRESENTATION

Acura Pharmaceuticals, Inc., a New York corporation, and its wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc. (the “Company” or “We”) is a specialty pharmaceutical company engaged in research, development and manufacture of product candidates intended to introduce limits and impediments to abuse by utilizing our proprietary Aversion® Technology, Impede™ Technology and other novel 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 three and nine months ended September 30, 2010 are not necessarily indicative of results expected for the full year ending December 31, 2010. 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, 2009 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission. The 2009 year-end consolidated balance sheet presented in this Report was derived from the Company’s 2009 year-end audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles. Amounts presented in the financial statements are rounded to the nearest thousand 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. The Company has entered into several cancelable CRO arrangements and at September 30, 2010 our obligations under these arrangements was approximately \$0.5 million for services to be incurred as subjects are enrolled and progress through the studies.

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 “King Agreement”) with King Pharmaceuticals Research and Development, Inc. (“King”), we recognize program fee revenue, collaboration revenue and milestone revenue.

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

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

Milestone revenue is contingent upon the achievement of certain pre-defined events in the King Agreement. Milestone payments from King 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 King Agreement and the amounts of the revenue correspond to the milestone payments set forth in the King 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 when payments are made to us by King.

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 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. At both September 30, 2010 and December 31, 2009 all our remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

NOTE 5 ACCRUED EXPENSES

Accrued expenses are summarized as follows:

(in thousands)	Sept 30, 2010	Dec 31, 2009
Payroll, payroll taxes, bonus and benefits	\$ 322	\$ 89
Legal and accountant services	155	160
State franchise taxes	-	21
Property taxes	21	19
Clinical and regulatory services	33	75
Other fees and services	91	88
	\$ 622	\$ 452

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 highly subjective assumptions including the expected volatility of the market price of the Company’s common stock as determined by reviewing its historical public market closing prices, risk-free interest rate and expected dividend yields. The Company 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 (in thousands):

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2010	2009	2010	2009
Research and development				
Stock Options	\$ 1,151	\$ 1,204	\$ 267	\$ 498
RSUs	209	133	70	70
	1,360	1,337	337	568
General and administrative				
Stock Options	3,674	4,687	691	1,853
RSUs	513	505	171	254
	4,187	5,192	862	2,107
Total share-based compensation expense	\$ 5,547	\$ 6,529	\$ 1,199	\$ 2,675

Stock Option Award Plans

At September 30, 2010, the Company has stock options issued and outstanding under three stock option plans. The Company's 1995 and 1998 Stock Option Plans have 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 the 1998 and 2008 stock option plans, only one-fourth of vested non-incentive stock options ("NonISO") may be exercised during each of calendar years 2011, 2012, 2013 and 2014.

Exercise of NonISO stock option shares 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 an 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 NonISO stock options exercised by employees and the closing market price of our common stock at the time of exercise. Such withholding taxes will be paid and charged against additional paid in capital as the NonISO stock options are exercised.

At September 30, 2010, stock options to purchase 3.7 million common shares were outstanding of which 3.4 million and 2.7 million stock options were vested at September 30, 2010 and December 31, 2009, respectively. The aggregate intrinsic value of the stock option awards fully vested and outstanding at September 30, 2010 was \$1.4 million. There were no stock options granted during either of the three month periods ended September 30, 2010 or 2009. During the nine month period ended September 30, 2010 and 2009, stock options to purchase 0.1 million shares and 1.3 million shares of common stock having a weighted average exercise price of \$5.47 and \$6.38 were granted and 0.05 million and 0.02 million stock options expired, respectively. During the nine month period ended September 30, 2009 stock options for 0.1 million shares were exercised at a price of \$1.30 per share.

Assumptions used in the Black-Scholes model to determine fair value for the 2010 and 2009 stock option awards were:

	2010	2009
Dividend yield	0.0%	0.0%
Average risk-free interest rate	3.85%	2.77%
Average volatility	122%	124%
Expected forfeitures	0.0%	0.0%
Expected holding period	10 years	10 years
Weighted average grant date fair value	\$ 5.23	\$ 6.06

As of September 30, 2010 the Company had \$2.0 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.

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. If a change in control occurs (whether prior to or after 2011), an acceleration of unvested shares will occur and all shares underlying the RSU award will be distributed at or about the time of the change in control and any unrecognized share-based compensation expense will be recognized in our consolidated financial statements.

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 an 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.

At September 30, 2010 and December 31, 2009, 3.32 million RSUs were outstanding of which 3.23 million and 3.11 million were fully vested, respectively. The aggregate intrinsic value of the RSU awards fully vested and outstanding at September 30, 2010 was \$8.0 million. There were no RSUs granted during either of the three month periods ended September 30, 2010 or 2009. There were no RSUs granted during the nine month period ended September 30, 2010. During the nine month period ended 2009, awards of 0.33 million RSUs were granted having a fair value of \$2.1 million. As of September 30, 2010, the Company had \$0.5 million of unrecognized share-based compensation expense from RSU activity which will be recognized in our consolidated financial statements over their remaining vesting periods unless a change in control occurs as described above.

NOTE 7 COMMON STOCK WARRANTS

At September 30, 2010, the Company had common stock warrants outstanding exercisable for 2.2 million shares of common stock at an exercise price of \$3.40 per share with an expiration date of August 2014.

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 restricted stock units ("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 September 30, 2010 and 2009 are 6.0 million and 8.0 million, respectively, of potentially dilutive securities, as the effect of including these securities would be antidilutive.

(in thousands, except per share data)	Nine Months Ended September 30,		Three Months Ended September 30,	
	2010	2009	2010	2009
Basic and diluted loss per share computation				
Numerator:				
Net loss	\$ (9,780)	\$ (11,751)	\$ (2,553)	\$ (3,954)
Denominator:				
Common shares (weighted)	43,825	42,841	43,895	42,958
Vested RSUs (weighted)	3,167	2,998	3,205	3,034
Weighted average number of shares outstanding	46,992	45,839	47,100	45,992
Basic and diluted loss per common share	\$ (0.21)	\$ (0.26)	\$ (0.05)	\$ (0.09)
Excluded potentially dilutive securities:				
Common shares issuable (1):				
Nonvested RSUs	88	270	88	270
Common stock options (vested and nonvested)	3,713	4,164	3,713	4,164
Common stock warrants	2,193	3,517	2,193	3,517
Total excluded dilutive common stock equivalents	5,994	7,951	5,994	7,951

(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 and Class Action 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 alleges 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® 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. 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.

Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to the Company, has been named along with numerous other companies as a defendant in two separate state coordinated litigations pending in Pennsylvania and New Jersey, respectively captioned In re: Reglan® /Metoclopramide Mass Tort Litigation, Philadelphia County Court of Common Pleas, January Term, 2010, No. 01997 and In re: Reglan® Litigation, Superior Court of New Jersey, Law Division, Atlantic County, Case No. 289, Master Docket No. ATL-L-3865-10. In this product liability litigation against numerous pharmaceutical product manufacturers and distributors, including the Company, plaintiffs claim injuries from their use of the Reglan® brand of metoclopramide and generic metoclopramide. In the Pennsylvania state court mass tort proceeding, approximately 40 lawsuits have been filed alleging that Plaintiffs developed neurological disorders as a result of their use of the Reglan® brand and/or generic metoclopramide. Plaintiffs have not yet filed any individual lawsuits against the Company in the New Jersey action. In the lawsuits filed to date, Plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by the Company. The Company had discontinued manufacture and distribution of generic metoclopramide more than 15 years ago. The Company believes these claims are without merit and will vigorously defend these actions.

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

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

Forward-Looking Statements

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. The most significant of such factors include, but are not limited to, our ability and the ability of King Pharmaceuticals Research and Development, Inc. ("King") (to whom we have licensed our Aversion® Technology for certain opioid analgesic products in the United States, Canada and Mexico) 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, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability to fulfill the U.S. Food and Drug Administration's ("FDA") requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date and the results of 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, the risk that the FDA may not agree with our analysis of our clinical studies and may evaluate the results of these studies by different methods or conclude that the results of the studies are not statistically significant, clinically meaningful or that there were human errors in the conduct of the studies or the risk that further studies of our product candidates are not positive or otherwise do not 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, whether our product candidates will ultimately deter abuse in commercial settings, and the uncertainties inherent in scientific research, drug development, laboratory and clinical trials and the regulatory approval process.

Other important factors that may also affect future results include, but are not limited to: our ability to attract and retain skilled personnel; our ability to secure and protect our patents, trademarks and other proprietary rights; litigation or regulatory action that could require us to pay significant damages or change the way we conduct our business; our

ability to compete successfully against current and future competitors; our dependence on third-party suppliers of raw materials; our ability to secure U.S. Drug Enforcement Administration quotas and source the active ingredients for our products in development; difficulties or delays in conducting clinical trials for our product candidates or in the commercial manufacture and supply of our products; and other risks and uncertainties detailed in this Report and in our 2009 Annual Report on Form 10-K filed with the Securities and Exchange Commission. When used on this website, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions identify forward-looking statements.

Company Overview

We are a specialty pharmaceutical company engaged in research, development and manufacture of product candidates intended to introduce limits or impediments to abuse utilizing our proprietary Aversion® and Impede™ Technologies. Our Aversion® Technology opioid analgesic product candidates are intended to effectively relieve pain while simultaneously introducing limits or impediments to common methods of opioid product misuse and abuse, including the:

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

Acurox® (oxycodone HCl) Tablets (without niacin)

We and King Pharmaceuticals R&D (“King”) are jointly developing opioid analgesic product candidates both with and without niacin utilizing our patented Aversion® Technology. In developing Acurox® Tablets (without niacin) we and King have completed two Phase 1 pharmacokinetic (PK) studies demonstrating: (a) Acurox® Tablets are bioequivalent to the anticipated reference listed drug under fasted conditions, and (b) Acurox® Tablets have greater total oxycodone plasma levels with a lower peak drug concentration under fed compared to fasted conditions. We expect these PK studies will provide the basis for establishing safety and analgesic efficacy of Acurox® Tablets for inclusion in a 505(b)(2) NDA submission to the FDA by King. We have also completed laboratory tests characterizing the impediments to abusing Acurox® Tablets by intravenous administration. In addition, King has completed a Phase 2 clinical like/dislike study of crushed Acurox® Tablets administered intranasally in recreational opioid abusers. On September 27, 2010, King and Acura met with the FDA to discuss the contents of an Acurox® Tablets NDA submission acceptable to FDA for filing. As a result of this pre-NDA meeting, we currently expect King to submit an NDA for Acurox® Tablets to the FDA in the first quarter of 2011.

A primary market research survey of 401 opioid prescribing physicians suggests that regardless of whether Acurox® Tablets contain niacin or do not contain niacin, Acurox® has the potential for garnering a substantial share of immediate release opioid analgesics prescriptions, although there can be no assurance in this regard. This finding was confirmed in a separate primary market research study of 435 physicians which concluded the particular combination of ingredients [i.e. with or without niacin] does not appear to have a substantial effect on the estimated brand market share potential.

Acurox® with Niacin (oxycodone HCl/niacin) Tablets

We and King are analyzing the results from study AP-ADF-114 (Study 114), an abuse liability study comparing the like/dislike scores of excess oral doses of Acurox® with Niacin Tablets to excess oral doses of oxycodone HCl tablets alone without niacin. Study 114 was not included in the original NDA filing for Acurox® with Niacin Tablets for which we received an FDA Complete Response Letter (“CRL”) in June 2009. We intend to complete our Study 114 analyses and associated Clinical Study Report and respond to the FDA’s CRL for Acurox® with Niacin Tablets.

All of our opioid product candidates utilizing Aversion® Technology (with or without niacin) are encompassed by two issued U.S. patents, which in combination with our anticipated product labeling and drug product listing strategies are anticipated to provide our opioid products licensed to King with protection from generic competition through the expiration of our patents in 2025.

Impede™ PSE Tablets

We have developed a pseudoephedrine hydrochloride (PSE) tablet product candidate utilizing our Impede™ Technology. Impede™ Technology utilizes a proprietary mixture of functional 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. The unique mixture of inactive ingredients in the Impede™ PSE product candidate are generally recognized as safe.

We sponsored an independent pharmaceutical laboratory test of our Impede™ PSE tablets compared to Sudafed®* brand PSE tablets in an attempt to extract PSE from 100 x 30 mg tablets for conversion to methamphetamine using what we believe to be the three most commonly used conversion processes. The results of these tests demonstrated that while PSE was readily extracted from Sudafed® tablets, Impede™ PSE effectively impeded the extraction of the PSE for conversion into methamphetamine. The results of these tests are summarized in the table below:

% Pseudoephedrine HCl extracted
from 100 x 30mg tablets

Product Tested	Method 1	Method 2	Method 3
Impede™ PSE Tablets	0%	0%	0%
Sudafed® Tablets	96%	89%	79%

*Sudafed® is a registered trademark of Johnson and Johnson Corporation

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 our 30 mg PSE tablet product 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 Code of Federal Regulations at 21CFR330.1 which will allow us to commercialize our Impede™ PSE Tablets without submitting a new drug application (NDA) to the FDA. We are currently evaluating commercialization strategies for our Impede™ PSE Tablets.

Additional Product Candidates

We are developing a benzodiazepine tablet product candidate utilizing our Aversion® Technology. The primary active ingredient in this product candidate is intended for the treatment of anxiety disorders. Benzodiazepine products are classified as Schedule IV controlled substances by the U.S. Drug Enforcement Administration ("DEA").

King Agreement

We have entered into a license agreement (the "King Agreement") with King to develop and commercialize in the United States, Canada and Mexico (the "King Territory") Acurox® Tablets, Acuracet® Tablets, Vycavert® Tablets and a fourth undisclosed opioid analgesic product candidate utilizing our proprietary Aversion® Technology. King has an option to license in the King Territory certain future opioid analgesic products developed utilizing our Aversion® Technology.

We are responsible, using commercially reasonable efforts, for all Acurox® with Niacin Tablet development activities through FDA approval of a 505(b)(2) NDA, for which certain expenses are reimbursed to us by King. After NDA approval, for which no assurances can be given, King will be responsible for manufacturing and commercializing Acurox® with Niacin Tablets in the U.S. With respect to all other products licensed by King pursuant to the King Agreement in all King Territories, including Acurox® Tablets (without niacin), King will be responsible, at its own expense, for development, regulatory, manufacturing and commercialization activities.

As of September 30, 2010 we have received aggregate payments of \$58.3 million from King, consisting of a \$30.0 million non-refundable upfront cash payment, \$17.3 million in reimbursed R&D expenses relating to Acurox® Tablets, \$6.0 million in fees relating to King's exercise of its option to license each of an undisclosed opioid analgesic tablet product and Vycavert® Tablets, and a \$5.0 million milestone fee for successful achievement of the primary endpoints for our pivotal Phase III clinical study for Acurox® with Niacin Tablets. The King Agreement provides for King to pay us: (a) a \$3.0 million option exercise fee for each future opioid product candidate King licenses, (b) up to \$23 million in regulatory milestone payments for each King licensed product candidate, including Acurox® Tablets, in specific countries in the King Territory, and (c) a one-time \$50 million sales milestone payment upon the first attainment of an aggregate of \$750 million in net sales of all of our licensed products combined in all King Territories. In addition, for sales occurring following the one year anniversary of the first commercial sale of the first licensed product sold, King will pay us a royalty at one of six rates ranging from 5% to 25% based on the level of combined annual net sales for all products licensed by us to King in all King Territories, with the highest applicable royalty rate applied to such combined annual sales. No minimum annual fees are payable by either party under the King Agreement.

Under the terms of the King Agreement, King may terminate the Agreement (i) in its entirety at any time by written notice to Acura and (ii) with respect to an individual product by providing 12 month advance notice to Acura.

The foregoing description of the King Agreement contains forward-looking statements about Acurox® Tablets, Acurox® with Niacin Tablets, and other product candidates pursuant to the King Agreement. As with any pharmaceutical products under development or proposed to be developed, substantial risks and uncertainties exist in development, regulatory review and commercialization process. There can be no assurance that any product developed, in whole or in part, pursuant to the King Agreement will receive regulatory approval or prove to be commercially successful. Accordingly, investors in the Company should recognize that there is no assurance that the Company will receive the milestone payments or royalty revenues described in the King Agreement or even if such milestones are achieved, that the related products will be successfully commercialized and that any royalty revenues payable to us by King will materialize.

On October 12, 2010 Pfizer, Inc. announced a tender offer to acquire all of the outstanding shares of King Pharmaceuticals, Inc. Pfizer and King are targeting a late fourth quarter 2010 or first quarter 2011 closing assuming execution of the tender process and receipt of the appropriate regulatory clearances. Depending on the structure of the Pfizer/King transaction, Pfizer will assume King's obligations under the King Agreement (if King does not survive as a subsidiary of Pfizer) or King will remain the responsible party under the King Agreement (if King survives as a subsidiary of Pfizer).

Patents and Patent Applications

In April 2007, the United States Patent and Trademark Office (“USPTO”), issued to us a patent titled “Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms” (the “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 specific opioid analgesics such as oxycodone HCl and hydrocodone bitartrate among others.

In January 2009, the USPTO issued to us a patent (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 a patent (the “726 Patent”) with 20 allowed claims. The 726 Patent encompasses a wider range of abuse deterrent compositions than our 920 Patent.

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

Company's Present Financial Condition

At November 2, 2010, we had cash and cash equivalents of approximately \$25.5 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.

We have yet to generate any revenues or royalty revenues from product sales. We expect to rely on our current cash resources and additional payments that may be made under the King Agreement and under similar license agreements with other pharmaceutical company partners, of which there can be no assurance, in funding our continued operations. Our cash requirements for operating activities may increase in the future as we continue to conduct pre-clinical studies and clinical trials for our product candidates, maintain, defend, if necessary and expand the scope of our intellectual property, incur litigation costs, hire additional personnel, or invest in other areas.

Results of Operations for the Nine Months Ended September 30, 2010 and 2009

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(\$ in thousands):	September 30,		Increase (Decrease)	
	2010	2009	Dollars	%
Revenue				
Program fee revenue	\$ 855	\$ 2,688	\$ (1,883)	(68)%
Collaboration revenue	2,097	397	1,700	428
Total revenue	2,952	3,085	(133)	(4)
Operating expense				
Research and development expense	5,714	3,828	1,886	49
Marketing, general and administrative expense	7,025	8,680	(1,655)	(19)
Total operating expense	12,739	12,508	231	2
Loss from operations	(9,787)	(9,423)	364	4
Other income, net	17	131	(114)	(87)
Loss before income tax	(9,770)	(9,292)	(478)	5
Income tax expense	10	2,459	(2,449)	(100)
Net loss	\$ (9,780)	\$ (11,751)	\$ (1,971)	(17)%

Revenue

King paid us a \$30.0 million upfront fee in connection with the closing of the King Agreement in December 2007. Revenue recognized in the nine months ended September 30, 2010 and 2009 from amortization of this upfront fee was \$0.9 million and \$2.7 million, respectively. We have assigned a portion of the program fee revenue to each of three product candidates identified under the King Agreement and expect to recognize the remainder of the program fee revenue ratably over our estimate of the development period for each of these product candidates identified in the King Agreement. We currently estimate the development period will extend through June 2011.

Collaboration revenue recognized in the nine months ended September 30, 2010 and 2009 was \$2.1 million and \$0.4 million, respectively, for invoiced reimbursement of our Acurox® Tablet and Acurox® with Niacin Tablet development expenses incurred pursuant to the King Agreement. We invoice King in arrears on a calendar quarter basis for our reimbursable development expenses under the King Agreement. We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of our underlying R&D expenses.

Operating Expense

R&D expense during the nine months ended September 30, 2010 and 2009 were for product candidates utilizing our Aversion® and Impede™ Technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2010 and 2009 results are non-cash share-based compensation expenses of \$1.4 million and \$1.3 million, respectively. Excluding the share-based compensation expense, there is a \$1.9 million increase in development expenses primarily attributable to conducting Study 114 for Acurox® with Niacin Tablets, our ongoing development activities for our benzodiazepine tablet product candidate, the initiation of development of an extended release opioid product candidate and our continuing R&D with a product candidate using our novel Impede™ Technology.

Marketing expenses during the nine months ended September 30, 2010 and 2009 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 2010 and 2009 results are non-cash share-based compensation expenses of \$4.2 million and \$5.2 million, respectively. Excluding the share-based compensation expense, our marketing, general and administrative expenses overall decreased \$0.7 million.

Other Income

During the nine months ended September 30, 2010 and 2009, our cash was invested in accordance with the investment policy approved by our Board of Directors resulting in minimal interest income earned in 2010 and \$0.1 million in 2009 due to the prevailing low interest rates.

Net Loss

The Company records its tax provision using a 40% effective tax rate. The net loss for the nine months ended September 30, 2010 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization. A state tax provision was recorded for the Company's subsidiary operations apportioned to one state jurisdiction. The Company's net loss for the nine months ended September 30, 2009 included income tax expense of \$2.5 million recorded when we adjusted our deferred income tax asset valuation reserve. We determined it was more likely than not that the Company's net operating loss carryforwards may not be utilized.

Results of Operations for the Three Months Ended September 30, 2010 and 2009

(\$ in thousands):	September 30,		Increase (Decrease)	
	2010	2009	Dollars	%
Revenue				
Program fee revenue	\$ 233	\$ 583	\$ (350)	(60)%
Collaboration revenue	59	225	(166)	(74)
Total revenue	292	808	(516)	(64)
Operating expense				
Research and development expense	1,142	1,494	(352)	(24)
Marketing, general and administrative expense	1,716	3,284	(1,568)	(48)
Total operating expense	2,858	4,778	(1,920)	(40)
Loss from operations	(2,566)	(3,970)	(1,404)	(35)
Other income , net	15	20	(5)	(25)
Loss before income tax	(2,551)	(3,950)	(1,399)	(35)
Income tax expense	2	4	(2)	(50)
Net loss	\$ (2,553)	\$ (3,954)	\$ (1,401)	(35)%

Revenue

King paid us a \$30.0 million upfront fee in connection with the closing of the King Agreement in December 2007. Revenue recognized in the three months ended September 30, 2010 and 2009 from amortization of this upfront fee was \$0.2 million and \$0.6 million, respectively. We have assigned a portion of the program fee revenue to each of three product candidates identified under the King Agreement and expect to recognize the remainder of the program fee revenue ratably over our estimate of the development period for each of these product candidates identified in the King Agreement. We currently estimate the development period will extend through June 2011.

Collaboration revenue recognized in the three months ended September 30, 2010 and 2009 was \$0.1 million and \$0.2 million, respectively, for invoiced reimbursement of our Acurox® Tablet and Acurox® with Niacin Tablet development expenses incurred pursuant to the King Agreement. We invoice King in arrears on a calendar quarter basis for our reimbursable development expenses under the King Agreement. We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying R&D expenses.

Operating Expense

R&D expense during the three months ended September 30, 2010 and 2009 were for product candidates utilizing our Aversion® and Impede™ Technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2010 and 2009 results are non-cash share-based compensation expenses of \$0.3 million and \$0.6 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, the initiation of development of an extended release opioid product candidate and our continuing research efforts with a product candidate using our novel Impede™ Technology.

Marketing expenses during the three months ended September 30, 2010 and 2009 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 2010 and 2009 results are non-cash share-based compensation expenses of \$0.9 million and \$2.1 million, respectively. Excluding the share-based compensation expense, our marketing, general and administrative expenses overall decreased \$0.3 million.

Other Income

During the three months ended September 30, 2010 and 2009, our cash was invested in accordance with the investment policy approved by our Board of Directors resulting in minimal interest income earned in 2010 and 2009 due to the prevailing low interest rates.

Net Loss

The Company records its tax provision using a 40% effective tax rate. The net loss for the three months ended September 30, 2010 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization. A state tax provision was recorded for the Company's subsidiary operations apportioned to one state jurisdiction.

Liquidity and Capital Resources

At September 30, 2010, the Company had unrestricted cash and cash equivalents of \$25.9 million compared to \$30.2 million at December 31, 2009. The Company had working capital of \$25.0 million at September 30, 2010 compared to \$28.8 million at December 31, 2009. The decrease in our cash position is primarily due to the period's net loss adjusted for certain non-cash items such as deferred program fee revenue and share-based compensation expenses offset by the collection of our collaboration revenue receivable and from the cash exercise of outstanding warrants.

At November 2, 2010, the Company had cash and cash equivalents of approximately \$25.5 million. The Company estimates that such cash reserves will be sufficient to fund the development of product candidates and related operating expenses at least through the next 12 months.

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company's 2009 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 2009 Annual Report are also applicable to 2010.

Item 4. Controls and Procedures

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

(b) Changes in Internal Controls over Financial Reporting. There were no changes in our internal controls over financial reporting during the third fiscal quarter of 2010 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 6. Exhibits

The exhibits required by this Item are listed below.

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

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

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

SIGNATURES

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

November 2, 2010

ACURA PHARMACEUTICALS, INC.

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

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