ACURA PHARMACEUTICALS, INC
Form 10-Q
May 02, 2013

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20649

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2013

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	**11-0853640**
(State or other Jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

616 N. North Court, Suite 120

Palatine, Illinois	**60067**
(Address of Principal Executive Offices)	*(Zip Code)*

847 705 7709

(Registrant's telephone number, including area code)

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

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

Yes þ 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 þ	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 þ

As of April 30, 2013 the registrant had 46,375,485 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

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Part 1. FINANCIAL INFORMATION

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

(Unaudited; in thousands except par value)

	March 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$3,460	$7,476
Marketable securities	19,993	19,946
Accounts receivable, net	18	-
Accrued investment income	71	36
Finished goods inventory, net	379	219
Income taxes refundable	20	43
Prepaid expenses and other current assets	245	271
Other deferred assets	32	-
Total current assets	24,218	27,991
Property, plant and equipment, net	1,018	1,052
Other assets	9	11
Total assets	$25,245	$29,054
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,349	$994
Accrued expenses	777	413
Deferred revenue	37	-
Other current liabilities	12	12
Total current liabilities	2,175	1,419
Other liabilities	5	5
Total liabilities	2,180	1,424
Commitments and contingencies (Note 11)		
Stockholders' Equity:		
Common stock: $.01 par value per shares; 100,000 shares authorized, 46,376 and 45,867 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	464	459
Additional paid-in capital	362,018	362,422

Accumulated deficit	(339,429)	(335,211)
Accumulated other comprehensive income (loss)	12	(40)
Total stockholders' equity	23,065	27,630
Total liabilities and stockholders' equity	$25,245	$29,054

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(Unaudited; in thousands except per share amounts)

	Three Months Ended March 31,	
	2013	2012
Revenues:		
Royalty revenue	$4	$-
Total revenues	4	-
Operating expenses:		
Research and development	2,026	903
Selling, general and administrative	2,222	1,441
Total operating expenses	4,248	2,344
Operating loss	(4,244)	(2,344)
Non-operating income:		
Investment income	10	11
Gain on sales of marketable securities	16	-
Total other income	26	11
Loss before income taxes	(4,218)	(2,333)
Provision for income taxes	-	-
Net loss	$(4,218)	$(2,333)
Other comprehensive income (loss):		
Unrealized gains on securities	52	-
Total other comprehensive income (loss)	52	-
Comprehensive income (loss)	$(4,166)	$(2,333)
Earnings (loss) per share:		
Basic	$(0.09)	$(0.05)
Diluted	$(0.09)	$(0.05)
Weighted average shares outstanding:		
Basic	46,685	47,517
Diluted	46,685	47,517

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited; in thousands)

	Three Months Ended March 31, 2013					
	Common Stock					
	Shares	$ Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at December 31, 2012	45,867	$ 459	$ 362,422	$ (335,211)	$ (40)	$ 27,630
Net loss	-	-	-	(4,218)	-	(4,218)
Other comprehensive income (loss)	-	-	-	-	52	52
Share-based compensation	-	-	315	-	-	315
Net distribution of common stock pursuant to restricted stock unit award plan	826	8	(7)	-	-	1
Common shares withheld for withholding taxes on distribution of restricted stock units	(321)	(3)	(709)	-	-	(712)
Net issuance of common stock pursuant to cashless exercise of stock options	4	-	-	-	-	-
Common shares withheld for withholding taxes on cashless exercise of stock options	(1)	-	(4)	-	-	(4)
Issuance of common stock for exercise of stock options	1	-	1	-	-	1
Balance at March 31, 2013	46,376	$ 464	$ 362,018	$ (339,429)	$ 12	$ 23,065

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Three Months Ended March 31,	
	2013	2012
Cash Flows from Operating Activities:		
Net loss	$(4,218)	$(2,333)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	34	32
Share-based compensation	315	424
Gain on sales of marketable securities	(16)	-
Changes in assets and liabilities		
Accounts receivable, net	(18)	-
Accrued investment income	(35)	36
Finished goods inventory, net	(160)	-
Income taxes refundable	23	-
Prepaid expenses and other current assets	26	58
Other deferred assets	(32)	-
Other assets	2	-
Accounts payable	355	126
Accrued expenses	364	281
Deferred revenue	37	-
Net cash used in operating activities	(3,323)	(1,376)
Cash Flows from Investing Activities:		
Purchases of marketable securities	(7,065)	-
Proceeds from sale of marketable securities	7,086	-
Additions to property, plant and equipment	-	(71)
Net cash provided by (used in) investing activities	21	(71)
Cash Flows from Financing Activities:		
Proceeds from exercise of stock options	1	8
Proceeds from distribution of restricted stock units	1	1
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(716)	(1,041)
Net cash used in financing activities	(714)	(1,032)
Net decrease in cash and cash equivalents	(4,016)	(2,479)
Cash and cash equivalents at beginning of period	7,476	35,685
Cash and cash equivalents at end of period	$3,460	$33,206

Supplemental Disclosures of Cash Flow Information:

Cash paid during the period for:

Interest	$-	$-
Income taxes, net of refunds	$(23)	$-

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

Supplemental Disclosures of Noncash Investing and Financing Activities:

Three Months Ended March 31, 2013

1. 829 thousand shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan and after withholding 3 thousand shares for $7 in exercise costs and withholding 321 thousand shares for $712 in statutory minimum payroll taxes, a net 505 thousand shares of common stock were issued.

2. Options to purchase 7 thousand shares of common stock were exercised utilizing various cashless exercise features of our plan and after withholding 3 thousand shares for $9 in exercise costs and withholding 1 thousand shares for $4 in statutory minimum payroll taxes, we issued 3 thousand shares of common stock.

Three Months Ended March 31, 2012

1. 829 thousand shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan and after withholding 2 thousand shares for $7 in exercise costs and withholding 296 thousand shares for $1,034 in statutory minimum payroll taxes, a net 531 thousand shares of common stock were issued.

2. Options to purchase 10 thousand shares of common stock were exercised utilizing various cashless exercise features of our plan and after withholding 4 thousand shares for $13 in exercise costs and withholding 2 thousand shares for $7 in statutory minimum payroll taxes, we issued 4 thousand shares of common stock.

See accompanying Notes to Consolidated Financial Statements.

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ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2013 AND 2012

NOTE 1 – DESCRIPTION OF BUSINESS AND PRESENTATION

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the "Company", "We", or "Our") is a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed two proprietary technologies. Our Aversion® Technology is a mixture of inactive ingredients incorporated into pharmaceutical tablets and capsules intended to address some common methods of product tampering associated with opioid abuse. Pfizer Inc.'s Oxecta® (oxycodone HCl) tablets, CII is the first approved and marketed product utilizing Aversion and is commercialized under a license agreement we have with a subsidiary of Pfizer, or the Pfizer Agreement. We have also developed our Impede® Technology which is a combination of inactive ingredients that are intended to prevent the extraction of pseudoephedrine from tablets and disrupt the direct conversion of pseudoephedrine from tablets into methamphetamine. In late December 2012, we launched in the United States Nexafed® (pseudoephedrine HC1) tablets formulated with our Impede Technology.

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 months ended March 31, 2013 are not necessarily indicative of results expected for the full year ending December 31, 2013. 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, 2012 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission. The 2012 year-end consolidated balance sheet presented in this Report was derived from the Company's 2012 year-end audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles.

NOTE 2 - RESEARCH AND DEVELOPMENT ACTIVITIES

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. We had $46 thousand accrued CRO and clinical trial study expenses at March 31, 2013. We had no accrued costs at December 31, 2012.

NOTE 3 - REVENUE RECOGNITION

Revenue is generally realized or realizable and earned when there is persuasive evidence an arrangement exists, delivery has occurred or services rendered, the price is fixed and determinable, and collection is reasonably assured. The Company records revenue from its Nexafed product sales when the price is fixed and determinable at the date of sale, title and risk of ownership have been transferred to the customer, and returns can be reasonably estimated.

Nexafed was launched in mid-December 2012. The Company sells Nexafed in the United States to wholesale pharmaceutical distributors and directly to one chain drug store. Nexafed is sold subject to the right of return for a period of up to twelve months after the product expiration. Nexafed currently has a shelf life of twenty-four months from the date of manufacture. Given the limited sales history of Nexafed, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company has deferred recognition of revenue on $37 thousand of product shipments of Nexafed since its launch until the right of return no longer exists or adequate history and information is available to estimate product returns.

In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer Inc. (the “Pfizer Agreement”), we began to earn royalties starting in February 2013. These royalties are based on net sales of Oxecta by Pfizer and are paid to Acura within 45 days after the end of each calendar quarter. The Company has recorded royalties of approximately $4 thousand for the first period ended March 31, 2013 on net sales of approximately $77 thousand.

Shipping and Handling Costs

The Company records shipping and handling costs in selling expenses. The amounts recorded from the shipments of Nexafed in the first quarter of 2013 were not material.

NOTE 4 - LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

On October 30, 2007, we and King Pharmaceuticals Research and Development, Inc., now a wholly-owned subsidiary of Pfizer, entered into the Pfizer Agreement to develop and commercialize in the United States, Canada and Mexico certain opioid analgesic products utilizing our proprietary Aversion Technology. Oxecta was approved on June 17, 2011 and sales of Oxecta by Pfizer commenced February 2012. On September 24, 2012, we entered into a letter agreement with Pfizer which amended the Pfizer Agreement and provided for the termination of Pfizer’s license to our Aversion® Technology used in the three development-stage products licensed to Pfizer and for the transfer of these products back to us. These development-stage products were hydrocodone bitartrate/acetaminophen tablets, oxycodone HCl/acetaminophen tablets and an undisclosed opioid.

Pursuant to the Pfizer Agreement, we and Pfizer formed a joint steering committee to oversee development and commercialization strategies for Oxecta. Pfizer is responsible, at its own expense, for all regulatory, manufacturing and commercialization activities for Oxecta in all Pfizer Territories. Subject to the Pfizer Agreement, Pfizer will have final decision making authority with respect to all regulatory and commercialization activities for Oxecta.

We can receive a one-time $50 million sales milestone payment upon the first attainment of $750 million in net sales of Oxecta across all Pfizer Territories. In addition, for Oxecta sales occurring on and following February 2, 2013 (the one year anniversary of the first commercial sale of Oxecta), Pfizer will pay us a royalty at one of six rates ranging from 5% to 25% based on the level of annual net sales for Oxecta across all Pfizer Territories, with the highest applicable royalty rate applied to such annual sales.

Pfizer's royalty payment obligations for Oxecta expire on a country-by-country basis upon the later of (i) the expiration of the last valid patent claim covering Oxecta in such country, or (ii) 15 years from the first commercial sale of Oxecta in such country. No minimum annual fees are payable by either party under the Pfizer Agreement. If Pfizer, after consultation with us, enters into a license agreement with a third party to avoid or settle such third party's allegations or claims regarding freedom to operate against Oxecta, Pfizer may deduct 50% of any royalties or other license payments it pays to such third party under such license, provided that the royalties payable to us are no less than 80% of the royalties otherwise due to us under the Pfizer Agreement.

The Pfizer Agreement expires upon the expiration of Pfizer's royalty payment and other payment obligations under the Pfizer Agreement. Pfizer may terminate the Pfizer Agreement in its entirety at any time by written notice to us. We may terminate the Pfizer Agreement in its entirety if Pfizer commences any interference or opposition proceeding challenging the validity or enforceability of any of our patent rights licensed to Pfizer under the Pfizer Agreement. Either party has the right to terminate the Pfizer Agreement on a country-by-country basis if the other party is in material breach of its obligations under the Pfizer Agreement relating to such country, and to terminate the Agreement in its entirety in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws, in each case subject to applicable cure periods.

In the event of termination, no payments are due except those royalties and milestones that have accrued prior to termination under the Pfizer Agreement and all licenses under the Pfizer Agreement are terminated. For all Acura terminations and termination by Pfizer where we are not in breach, the Pfizer Agreement provides for the transition of development and marketing of the licensed products from Pfizer to us, including the conveyance by Pfizer to us of the trademarks and all regulatory filings and approvals solely used in connection with the commercialization of such licensed products and, in certain cases, for Pfizer's supply of such licensed products for a transitional period at Pfizer's cost plus a mark-up.

Paragraph IV ANDA Litigation

On or about September 17, 2012, we believe the FDA internally changed the status of Oxecta to be considered a Reference Listed Drug, or RLD. An RLD is the standard to which all generic versions must be shown to be bioequivalent and a drug company seeking approval to market a generic equivalent must refer to the RLD. By designating Oxecta as an RLD, the FDA was allowed to accept ANDAs referencing Oxecta.

On September 20, 2012, we announced that we had received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from a generic sponsor seeking FDA approval to market a generic version of Oxecta. Since such date, we have received similar Paragraph IV Notices from four other generic pharmaceutical companies. The Paragraph IV Notices refer to our U.S. Patent Numbers 7,201,920, 7,510,726 and 7,981,439, which cover our Aversion Technology and Oxecta and are listed in the FDA Orange Book. The Paragraph IV Notices state that each generic sponsor believes that such patents are invalid, unenforceable or not infringed. Pfizer, Acura's licensee for Oxecta, has advised us that they will not exercise their first right under the Pfizer Agreement to control the enforcement of the ANDA litigation against the generic sponsors. As a result, on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. – Florida ("Watson"), Par Pharmaceutical, Inc. ("Par"), Impax Laboratories, Inc. ("Impax"), and Sandoz Inc. ("Sandoz") in the United States District Court for the District of Delaware alleging infringement of our U.S. Patent No. 7,510,726. The commencement of such litigation prohibits the FDA from granting approval of the filed ANDAs until the earliest of 30 months from the date Acura received notice of the first Paragraph IV certification, or the conclusion of litigation. The litigation is in its early stages. A fifth Paragraph IV Notice was received on April 3, 2013, and we are considering our options with respect to this Notice. If an infringement suit is initiated in Delaware, it is likely that the suit would be consolidated with the current action.

On January 2, 2013, the court granted our motion to dismiss the suit against Watson on the grounds that Watson had amended its ANDA from a Paragraph IV certification to Paragraph III, which indicated its intent not to market its product in advance of our patents expiring.

During the course of the litigation, Acura has executed a covenant not to sue Par on Acura's 7,201,920 and 7,981,439 patents based on the products described in its ANDAs.

On April 2, 2013, the USPTO issued U.S. Patent No. 8,409,616 with claims directed at our Aversion Technology. This patent was listed in FDA's Orange Book on April 22, 2013 which will require all of the Paragraph IV ANDA filers to decide whether to amend their Paragraph IV certifications to include this newly issued patent. If any ANDA filer decides to amend its certification to allege that this new patent is invalid and/or that its ANDA product will not infringe any claim of this patent, we will have the option of bringing an infringement suit against that filer asserting the '616 patent.

Litigation is inherently uncertain and we cannot predict the outcome of these infringement actions. If any of these generic companies prevails in its respective lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of Oxecta prior to the expiration of our patents in 2025. Additionally, it is possible that other generic manufacturers may also seek to launch a generic version of Oxecta and challenge our patents. Any determination in these infringement actions that our patents covering our Aversion Technology and Oxecta are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents, could materially adversely affect the Company's operations and financial condition.

NOTE 5 - 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 March 31, 2013 and December 31, 2012, 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 ("NOL") 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. Our NOL carryforwards will expire in varying amounts between 2013 and 2031 if not used, and those expirations will cause fluctuations in our valuation allowances.

NOTE 6 - INVESTMENTS IN MARKETABLE SECURITIES

Investments in marketable securities consisted of the following:

	March 31, 2013 (in millions)	December 31, 2012 (in millions)
Marketable securities:		
Corporate bonds — maturing within 1 year	$ 1.6	$ 1.2
Corporate bonds — maturing after 1 through 4.25 years	9.7	6.3
Pooled investment fund	2.0	8.0
Exchange-traded funds	6.7	4.4
Total marketable securities	$ 20.0	$ 19.9

The Company's marketable securities are classified as available-for-sale and are recorded at fair value based on quoted market prices or net asset value using the specific identification method. The purchase cost of corporate bonds may include a purchase price premium or discount which will be amortized or accreted against earned interest income to the maturity date of the bond. Our investments are classified as current in the Company's Consolidated Balance Sheet as they may be sold within one year in response to changes in market prices or interest rates, to realign our investment concentrations or to meet our working capital needs.

The following tables provide a summary of the fair value and unrealized gains (losses) related to the Company's available-for-sale securities (in millions):

	March 31, 2013 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$11.3	$ -	$ -	$11.3
Pooled investment fund	2.0	-	-	2.0
Exchange-traded funds	6.7	-	-	6.7
Total - Current	$20.0	$ -	$ -	$20.0

	December 31, 2012 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$7.6	$ -	$ (0.1)	$7.5
Pooled investment fund	8.0	-	-	8.0
Exchange-traded funds	4.4	-	-	4.4
Total - Current	$20.0	$ -	$ (0.1)	$19.9

Fair Value Measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants. Fair values determined based on Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined based on Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. Fair values determined based on Level 3 inputs utilize unobservable inputs and include valuations of assets or liabilities for which there is little, if any, market activity. A financial asset or liability's classification within the above hierarchy is determined based on the lowest level input that is significant to the fair value measurement. We had no liabilities at March 31, 2013 meeting fair value measurement.

Our assets measured at fair value or disclosed at fair value on a recurring basis as at March 31, 2013 and December 31, 2012 consisted of the following (in millions):

	March 31, 2013 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	11.3	11.3	-	-
Pooled investment fund	2.0	-	2.0	-
Exchange-traded funds	6.7	6.7	-	-
Total	$20.0	$18.0	$2.0	$ -

	December 31, 2012 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	7.5	7.5	-	-
Pooled investment fund	8.0	-	8.0	-
Exchange-traded funds	4.4	4.4	-	-
Total	$19.9	$11.9	$8.0	$ -

Accumulated Other Comprehensive Income (Loss)

Unrealized gains or losses on marketable securities are recorded in accumulated other comprehensive income (loss). Accumulated other comprehensive income (loss) at March 31, 2013 and December 31, 2012 consisted of cumulative

unrealized gains of $12 thousand and unrealized losses of $40 thousand on marketable securities, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) includes all changes in equity during a period except those that resulted from investments by or distributions to the Company's stockholders. Other comprehensive income (loss) refers to revenues, expenses, gains and losses that, under GAAP, are included in comprehensive income (loss), but excluded from net income (loss) as these amounts are recorded directly as an adjustment to stockholders' equity. Acura's other comprehensive income (loss) is composed of unrealized gains (losses) on certain holdings of marketable securities, net of any realized gains (losses) included in net income (loss).

NOTE 7 – INVENTORIES

Inventories consist of finished goods held for sale and distribution on our Nexafed® product. Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value). The Company writes down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results. We had inventory valued at $0.4 million and $0.2 million at March 31, 2013 and December 31, 2012, respectively. The cost of sales on $37 thousand of product shipments of Nexafed since its launch is excluded from the value of the March 31, 2013 inventory and is reported in the Balance Sheet account as a deferred asset until the right of return no longer exists or adequate history and information is available to estimate product returns on the product shipments. Purchases of active pharmaceutical ingredients and raw materials required for our development and clinical trial manufacture of product candidates utilizing our Aversion® or Impede® Technologies are expensed as incurred.

NOTE 8 - ACCRUED EXPENSES

Accrued expenses consisted of the following (in thousands):

	March 31, 2013	December 31, 2012
Payroll, payroll taxes, bonus and benefits	$ 103	$ 55
Professional services	336	216
Franchise taxes	8	5
Property taxes	23	20
Contract manufacturing services	83	21
Clinical and regulatory services	46	21
Other fees and services	178	75
Total	$ 777	$ 413

NOTE 9 - SHARE-BASED COMPENSATION

We have three share-based compensation plans covering stock options and Restricted Stock Units (“RSU”) for our employees and directors.

We measure our compensation cost related to share-based payment transactions based on fair value of the equity or liability instrument issued. For purposes of estimating the fair value of each stock option unit on the date of grant, we

utilize the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of our common stock (as determined by reviewing our historical public market closing prices). Our accounting for share-based compensation for RSUs is based on the fair-value method. The fair value of the RSUs is the market price of our common stock on the date of grant, less its exercise cost.

Our share-based compensation expense recognized in the Company's results of operations for the period is shown below (in thousands):

	Three Months Ended March 31,	
	2013	2012
Research and development		
Stock options	$81	$91
General and administrative		
Stock options	234	333
Total	$315	$424

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Stock Option Award Plans

At March 31, 2013, 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. Absent a change in control, the balance of the vested non-incentive stock options ("NonISO") granted under the 1998 and 2008 stock option plans may be exercised in equal amounts during each of calendar years 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 three months ended March 31, 2013, 7 thousand NonISOs were exercised by our employees. Our employees elected to have 4 thousand shares withheld in satisfaction of $13 thousand for both the exercise costs and the withholding tax obligations resulting in the net issuance of 3 thousand common shares to them. During the three months ended March 31, 2012, 16 thousand NonISOs were exercised by our employees. Our employees elected to have 6 thousand shares withheld in satisfaction of $20 thousand for both the exercise costs and the withholding tax obligations which resulted in the net issuance of 10 thousand common shares to them.

As of March 31, 2013 the Company had $1.3 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 of the option grants over the next 1.7 years. 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 three months ended March 31, 2013 and 2012 is shown below:

	Three Months Ended March 31,			
	2013		2012	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, beginning	3,296	$ 5.50	3,556	$ 6.41
Granted	75	2.32	105	3.48
Exercised	(8)	1.30	(16)	1.30
Forfeited or expired	(15)	2.32	(204)	9.33
Outstanding, ending	3,348	$ 5.46	3,441	$ 6.17
Options exercisable	2,866	$ 5.89	2,878	$ 6.70

Assumptions used in the Black-Scholes model to determine fair value for the stock option awards granted during the period are show below:

	Three Months Ended March 31,			
	2013		2012	
Dividend yield	0.0	%	0.0	%
Average risk-free interest rate	1.86	%	1.97	%
Average volatility	114	%	114	%
Expected forfeitures	0.0	%	0.0	%
Expected holding period	10 years		10 years	
Weighted average grant date fair value	$2.17		$3.25	

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. An 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. To date, 75% of RSU awards under the 2005 RSU Plan have been distributed. Absent a change of control, the balance of the RSU awards will be distributed on January 1, 2014. Distribution of RSU shares to employees may require the Company to make minimum statutory 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 each of January 1, 2013, 2012 and 2011, 0.83 million RSUs were distributed to our employees and directors. Our employees' elections to withhold 0.32 million shares in satisfaction of $0.71 million withholding tax obligations resulted in the net issuance of 0.50 million shares in January 2013. Our employees' elections to withhold 0.30 million shares in satisfaction of $1.0 million withholding tax obligations resulted in the net issuance of 0.53 million shares in January 2012. Our employees' elections to withhold 0.29 million shares in satisfaction of $1.0 million withholding tax obligations resulted in the net issuance of 0.54 million shares in January 2011.

A summary of the RSU Plan as of March 31, 2013 and 2012 and for the three months then ended consisted of the following (in thousands):

	Three Months Ended March 31,			
	2013		2012	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	1,658	1,658	2,487	2,487
Granted	-	-	-	-
Distributed	(829)	(829)	(829)	(829)
Vested	-	-	-	-
Forfeited or expired	-	-	-	-
Outstanding, ending	829	829	1,658	1,658

NOTE 9 - COMMON STOCK WARRANTS

The Company has outstanding common stock purchase warrants at March 31, 2013 exercisable for 1.9 million shares of common stock, all of which contain a cashless exercise feature. These warrants have an exercise price of $3.40 per share and expiration date of August 2014.

NOTE 10 - EARNINGS PER SHARE (“EPS”)

Basic EPS is computed by dividing net income or loss by the weighted average common shares outstanding during a period, including shares weighted related to vested RSUs. Diluted EPS is based on the treasury stock method and computed based on the same number of shares used in the basic share calculation and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and stock warrants, assuming the exercise of all in-the-money stock options and warrants. Common stock equivalents are excluded from the computation where their inclusion would be anti-dilutive. No such adjustments were made for either 2013 or 2012 as the Company reported a net loss for the three month periods and including the effects of common stock equivalents in the diluted EPS calculation would have been antidilutive.

A reconciliation of the numerators and denominators of basic and diluted EPS for the period are as following:

	Three Months Ended March 31,	
	2013	2012
EPS – basic and diluted		
Numerator: net loss	$(4,218)	$(2,333)
Denominator:		
Common shares	45,856	45,859
Vested RSUs	829	1,658
Basic and diluted weighted average shares outstanding	46,685	47,517
EPS – basic and diluted	$(0.09)	$(0.05)
Excluded dilutive securities:		
Common stock issuable:		
Stock options	3,348	3,441
Common stock warrants	1,856	1,856
Total excluded potentially dilutive shares	5,204	5,297

NOTE 11 - COMMITMENTS AND CONTINGENCIES

Facility Lease

The Company leases administrative office space in Palatine, Illinois under a lease expiring March 31, 2014 for approximately $25 thousand annually.

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 the spring of 2011 when a single complaint including over 400 plaintiffs was served. To date, Acura has not been served with any metoclopramide lawsuits in jurisdictions other than Philadelphia, New Jersey and California state courts.

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 ("Mensing* decision") 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 have consistently maintained the position that these claims are without merit and intend to vigorously defend these actions.

In New Jersey, Generic Defendants, including Acura, filed dispositive motions based on the *Mensing* decision, which the Court granted with a limited exception. In June 2012, the New Jersey trial court dismissed Acura with prejudice.

In Philadelphia, and California, Generic Defendants, including Acura, also filed dispositive motions based on the *Mensing* decision.

On November 18, 2011, the Philadelphia trial court denied Generic Defendants' dispositive motion. In December 2011, the Generic Defendants appealed this ruling. On April 13, 2012, all trial court proceedings were stayed pending decisions by the Pennsylvania appellate courts. On November 28, 2012, the Pennsylvania Superior Court heard the appellate oral argument. A decision on this appeal should be issued later in 2013 and a further appeal to the Pennsylvania Supreme Court likely will follow. This appeal process eventually could result in dismissal of all of the Philadelphia cases against all generic defendants including Acura, although there can be no assurance in this regard. Legal fees related to this matter are currently covered by our insurance carrier.

In California, the trial court issued an April 17, 2012 ruling (confirmed in a May 25, 2012 Order) denying Generic Defendants' dispositive preemption motions. The Generics Defendants' appeals from this order were denied by the California appellate courts. Therefore, plaintiffs are now permitted to proceed with their lawsuits including state law claims based on (1) failing to communicate warnings to physicians through "Dear Doctor" letters; (2) failure to update labeling to adopt brand labeling changes; and (3) failure to withdraw generic products from the market. Despite its refusal to grant the demurrer or motion to strike, the California trial court acknowledged the preemptive effect of *Mensing* so that any claim "that would render the generic defendants in violation of federal law if they are found responsible under a state law cause of action, would not be permissible." Nonetheless, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by us. Therefore, we expect the number of plaintiffs with possible claims to be reduced voluntarily or by motion practice. Action will be taken in an effort to dismiss Acura from these cases, although there can be no assurance in this regard. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to this matter as of March 31, 2013 and we are presently unable to determine if any potential loss would be covered by our insurance carrier. Legal fees related to this matter are currently covered by our insurance carrier.

Financial Advisor Agreement

In connection with our August 2007 Unit Offering, we are obligated to pay a fee to our then financial advisor upon each exercise of the warrants issued in the Unit Offering, in proportion to the number of warrants exercised. The amount of the fee assuming 100% exercise of the remaining 1.9 million warrants is $0.38 million. We have not reflected this obligation as a liability in our consolidated financial statements as the payment is contingent upon the timing and exercise of the warrants by each of the warrant holders. Such fee, if any, will be paid to the financial advisor and be offset against the equity proceeds as the warrants are exercised.

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, our and our licensee's ability to successfully launch and commercialize our products and technologies including Oxecta® Tablets and Nexafed® Tablets, the price discounting that may be offered by Pfizer for Oxecta®, our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, the willingness of wholesalers and pharmacies to stock Nexafed® Tablets, expectations regarding potential market share for our products and the timing of first sales, our ability to enter into additional license agreements for our other product candidates, our exposure to product liability and other lawsuits in connection with the commercialization of our products, the increased cost of insurance and the availability of product liability insurance coverage, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability of our patents to protect our products from generic competition, our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation, and the ability to fulfill the 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, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development to meet over-the-counter, or OTC, Monograph standards as applicable, 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 and laboratory 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 and will be able to promote the features of our abuse discouraging technologies, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede technology will disrupt the processing of pseudoephedrine into methamphetamine. 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 expressions 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 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 technologies and products intended to address medication abuse and misuse. We have discovered and developed two proprietary technologies. Our Aversion® Technology is a mixture of inactive ingredients incorporated into pharmaceutical tablets and capsules intended to address some common methods of product tampering associated with opioid abuse. Pfizer Inc.'s Oxecta® (oxycodone HCl) tablets, CII is the first approved and marketed product utilizing Aversion and is commercialized under a license agreement we have with a subsidiary of Pfizer, or the Pfizer Agreement. We have also developed our Impede® Technology which is a combination of inactive ingredients that are intended to prevent the extraction of pseudoephedrine from tablets and disrupt the direct conversion of pseudoephedrine from tablets into methamphetamine.

We have 7 additional opioid products utilizing Aversion in various stages of development. Pursuant to a September 24, 2012 letter agreement with Pfizer, all rights to these development-stage opioid products have reverted back to us. Our product containing hydrocodone bitartrate and acetaminophen utilizing the Aversion technology, or hydrocodone/acetaminophen, is the most advanced opioid product in development and the primary focus of our opioid development efforts. Hydrocodone/acetaminophen is the most widely prescribed and often abused opioid product in the United States. Pfizer previously completed a clinical study demonstrating the hydrocodone/acetaminophen product is bioequivalent to its reference listed drug, however we believe the Pfizer product may have contained up to 12% more hydrocodone bitartrate than expected. We have estimated that the Pfizer study would have achieved the bioequivalence standard after adjusting the results for such additional amount of hydrocodone bitartrate. We filed an Investigational New Drug Application, or IND, with the Food and Drug Administration, or FDA, on December 20, 2012, which became effective in late January 2013 and allows us to commence clinical trials. We expect that the development program for our hydrocodone/acetaminophen product and our other Aversion opioid products in development will be consistent with that of Oxecta. We anticipate submitting a 505(b)(2) NDA with the FDA for our hydrocodone/acetaminophen product in the first half of 2014.

We launched Nexafed commercially in mid-December 2012 into the $1 billion United States over the counter market, or OTC, for cold and allergy products containing a decongestant through drug wholesalers to retail pharmacies. Nexafed was demonstrated in a clinical study to meet the FDA Guideline standards for bioequivalence to the reference drug Sudafed® marketed by Johnson & Johnson Corporation. We anticipate developing line extensions for our Nexafed franchise to capitalize on the many different combination offerings in the OTC cold/allergy market. We also have been conducting research on the next generation of our Impede Technology to further improve our Nexafed franchise.

We also have discovered an early-stage technology which, in proof of concept laboratory tests, demonstrates the ability to limit the release of the active ingredient from tablets when multiple tablets are consumed simultaneously.

Aversion Technology Overview

Aversion Technology is a unique composition of inactive pharmaceutical ingredients utilized with an opioid or other drug susceptible of abuse to provide abuse deterrent functionality. We have four issued U.S. patents covering all of our Aversion Technology opioid products, which patents expire between 2023 and 2025. Our Aversion Technology products are intended to provide the same therapeutic benefits of the active drug ingredient as currently marketed products containing the same active pharmaceutical ingredient, while simultaneously discouraging the following common methods of pharmaceutical product misuse and abuse:

· Drug abusers may dissolve pharmaceutical tablets or capsules in water, alcohol, or other common solvents, filter the dissolved solution into a syringe, and inject the resulting fluid intravenously to obtain euphoric effects. Aversion Technology tablets dissolved in generally available solvents, including water or alcohol, into a volume and form suitable for intravenous injection, converts the tablet into a viscous gel mixture. We believe this gel will limit or impede drug abusers from extracting and injecting the active ingredients from our tablets.

· Drug abusers may crush pharmaceutical tablets or capsules and intranasally snort the resulting powder to absorb active ingredient through the nasal passages to obtain euphoric effects. The combination of Aversion Technology inactive ingredients is intended to induce nasal passage discomfort if the tablets are snorted. We believe products which utilize Aversion Technology may be disliked and will discourage prospective nasal drug abusers from snorting crushed tablets or capsules.

The extent and manner in which any of the features described below will be described in the FDA approved label for our pipeline products will be dependent on the results of and the acceptance by the FDA of our and our licensees' studies for each product.

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. Oxecta utilizes our Aversion Technology. Pfizer received FDA approval for its 505(b)(2) NDA for Oxecta on June 17, 2011 and introduced the product into the market in February 2012. To our knowledge, Pfizer has not initiated marketing of Oxecta to physicians pending receipt of comments from the FDA on their promotion materials which were submitted to the FDA in July 2012. Pfizer received FDA's comments on their proposed Oxecta promotional materials in April 2013 and is formulating their plans for Oxecta. As such, Pfizer attained no meaningful sales of Oxecta in 2012 or in the quarter ended March 31, 2013.

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 water and other solvents and administration through feeding tubes. The clinical study evaluated 40 non-dependent recreational opioid users, who self-administered the equivalent of 15mg of oxycodone. After accounting for a first 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.

Although we believe these abuse deterrent characteristics differentiate Oxecta from immediate-release oxycodone products currently on the market, consistent with FDA guidance which requires epidemiology studies to support a claim of abuse deterrence, the clinical significance of the difference in drug liking and difference in response to taking the drug again in this study has not been established. There is no evidence that Oxecta has a reduced liability compared to immediate release oxycodone. Pfizer has agreed to a post-approval commitment with the FDA to perform an epidemiology study to assess the actual impact on abuse of Oxecta tablets.

Further, the Oxecta 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.

Pfizer License, Development and Commercialization Agreement

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. As of March 31, 2013, 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 NDA for Oxecta. In addition, we are eligible to receive milestone payments based on future regulatory events and product sales achievements, and tiered royalties of 5% - 25% on annual net sales of Oxecta.

Aversion Technology Opioid Products in Development

We have multiple opioid products utilizing our Aversion Technology in various stages of development, including the following:

Aversion Technology Tablets	Comparable Brand Name[1]	Status
Hydrocodone bitartrate/acetaminophen	Vicodin®, Lortab®, Norco®	IND submitted to the FDA on December 20, 2012. NDA submission targeted for the first half of 2014.
Hydromorphone HCl	Dilaudid®	Proof of Concept[2]
Methadone HCl	Methadose	Proof of Concept[2]
Morphine Sulfate	MSIR®	Proof of Concept[2]
Oxycodone HCl/acetaminophen	Percocet®	Proof of Concept[2]
Oxymorphone HCl	Opana®	Proof of Concept[2]
Tramadol HCl	Ultram®	Proof of Concept[2]

[1] Comparable Brand Name refers to currently marketed prescription products in the United States containing the same active analgesic ingredient(s) as in the corresponding Aversion Technology product.

[2] Proof of Concept is attained upon demonstration of product stability and bioavailability parameters. All proof of concept formulations contain niacin and will require reformulation.

Development of Hydrocodone/Acetaminophen

Our hydrocodone/acetaminophen product was previously under development by Pfizer who, before returning the product to us: (1) successfully removed niacin from the formulation, (2) conducted bioequivalence testing and (3) held a pre-IND meeting with the FDA. We expect our clinical development program for our hydrocodone/acetaminophen product to consist of:

- A pharmacokinetic study in about 36 fasted subjects to establish bioequivalence of product made by a new contract manufacturer to the FDA's reference listed drug and determine the food effect on our drug;
- A pharmacokinetic study in about 24 subjects to establish safety compared to the reference listed drugs tramadol/acetaminophen (for acetaminophen) and hydrocodone bitartrate/ibuprofen (for hydrocodone);
- A pharmacokinetic study in about 24 subjects demonstrating dose proportionality of our formulation;
- A nasal abuse liability liking study in about 40 recreational drug users against a reference drug;
- Laboratory studies demonstrating extraction, syringing and particle size characteristics of our product; and
- An assessment of the routes of abuse of hydrocodone products.

We commenced enrollment in study AP-ADF-301, a nasal abuse liability liking study in recreational drug users, in February 2013. The last subject in AP-ADF-301 completed dosing in March 2013. We are awaiting comments from the FDA regarding our statistical analysis plan for this study before analyzing the results.

We have initiated technical transfer for our Aversion hydrocodone/acetaminophen product to the proposed commercial manufacturer to commence scale-up activities.

Based on the development program outlined above, we anticipate preparing and submitting a 505(b)(2) NDA for our hydrocodone/acetaminophen product in the first half of 2014.

We continue to evaluate possible partnering of our Aversion development products with alternative strategic partners.

Impede Technology Overview

Our Impede Technology, a proprietary mixture of inactive ingredients, is intended to prevent the extraction of pseudoephedrine, or PSE, from tablets and disrupt the direct conversion of PSE from tablets into methamphetamine. The chemical structure of PSE is very similar to methamphetamine, facilitating a straight-forward chemical conversion to methamphetamine. OTC PSE products are sometimes purchased and used for this conversion. 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. Two of the three most popular processes follow two general processing steps: (1) dissolving the PSE tablets in a solvent to isolate purified PSE and (2) a chemical reduction of the PSE into methamphetamine for drying into crystals. The third method, or the "one-pot" method, involves the direct chemical reduction of the PSE to methamphetamine in the presence of the tablet's inactive ingredients. All the solvents used are ultimately dried off or otherwise removed so a vast range of solvents are amenable to the process.

Studies sponsored by us at an independent laboratory and confirmed by a law enforcement agency, demonstrated our Impede Technology prevents the extraction of PSE from tablets for conversion into methamphetamine using what we believe are the two most common extraction methods, each requiring extraction of PSE as an initial step. Laboratory tests conducted on our behalf by an independent CRO using the "one-pot" method demonstrated that our Impede Technology disrupted the direct conversion of PSE from the tablets into methamphetamine. The study compared the amount of pure methamphetamine hydrochloride produced from Nexafed and Johnson & Johnson's Sudafed® tablets. Using one hundred 30 mg tablets of both products in multiple one-pot tests with a variety of commonly used solvents, the study demonstrated an average of 38% of the maximum 2.7 grams of pure methamphetamine hydrochloride was recovered from Nexafed. Comparatively, approximately twice as much pure methamphetamine hydrochloride was recovered from Sudafed® tablets. Both products yielded a substantial amount of additional solids such that the purity of the total powder provided contained approximately 65% methamphetamine hydrochloride.

Nexafed®

Our Nexafed product is an immediate-release pseudoephedrine HCl, tablet which utilizes our patent pending Impede Technology. PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products We have demonstrated that our Nexafed 30mg tablets is bioequivalent to Johnson & Johnson's Sudafed® 30mg Tablets when a single 2 tablets dose is administered. Commencing in 2006, the Combat Methamphetamine Epidemic Act, or CMEA, required 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 pharmacies and educating and encouraging pharmacists to recommend Nexafed to their customers.

We launched Nexafed commercially in mid-December 2012 into the United States OTC market for cold and allergy products and have shipped Nexafed to several regional and national drug wholesalers for redistribution to pharmacies, including the three largest U.S. drug wholesalers: McKesson, Cardinal Health and AmerisourceBergen. In March 2013, we completed our first shipment of Nexafed directly to the warehouse of a regional drug chain who, we understand, would further stock all of their pharmacies with Nexafed. We have also gained support from three additional pharmacy chain customers, including one operating food/pharmacy combination stores that ranks in the top 10 in the U.S. based on retail pharmacy outlets. Generally, these chain customers purchase their pseudoephedrine products through their pharmacy departments – as opposed to a centralized OTC purchasing operation. The support for Nexafed from these chain customers varies from providing Nexafed educational materials to their pharmacists and allowing each pharmacy to make their own purchasing decision, to the stocking of Nexafed as their only 30mg pseudoephedrine product. We continue to work to expand the wholesale and retail distribution network for Nexafed.

We are using telemarketing, direct mail, and online and journal advertising to educate pharmacists about Nexafed and encourage pharmacists to recommend Nexafed to their customers. We may use consumer advertising in the future. We have shipped approximately $31 thousand in Nexafed product during the first quarter 2013.

We are marketing our 30mg Nexafed product under FDA's regulations applicable to OTC Monograph products. Nexafed tablets are offered in 24-count blister packaged cartons and priced comparable to other branded PSE 30mg tablets.

Company's Present Financial Condition

At April 29, 2013 we had cash, cash equivalents and marketable securities of approximately $21.5 million. We estimate that our current cash reserves will be sufficient to fund operations through at least the next 12 months.

During the three months ended March 31, 2013 we did not recognized any of the $31 thousand product sales derived from the shipment of Nexafed. Given the limited sales history of Nexafed, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on the product shipments of Nexafed until the right of return no longer exists or adequate history and information is available to estimate product returns. Our royalty revenue from Pfizer's sale of Oxecta Tablets began in February 2013.

To fund our continued operations, we expect to rely on our current cash resources, additional payments that may be made under Pfizer Agreement and under future license agreements with other pharmaceutical company partners, of which there can be no assurance of obtaining, and revenues from our commercialization of our Nexafed Tablets. Our cash requirements for operating activities may increase in the future as we continue to conduct pre-clinical studies and clinical trials for our product candidates, maintain, defend, and expand the scope of our intellectual property, including the prosecution of the Paragraph IV Proceedings, hire additional personnel, commercialize our Nexafed Tablets, or invest in other areas.

Results of Operations for the Three Months Ended March 31, 2013 and 2012

	March 31			
	2013	2012	Change	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$4	$-	$4	-
Total revenue	4	-	4	-
Operating expenses:				
Research and development	2,026	903	1,123	124
Selling, general and administrative	2,222	1,441	781	54

Total operating expenses	(4,248)	(2,344)	1,904	81
Operating loss	(4,244)	(2,344)	(1,900)	81
Non-operating income:				
Investment income	10	11	(1)	(9)
Gain on sales of marketable securities	16	-	16	-
Total other income	26	11	15	136
Loss before income taxes	(4,218)	(2,333)	1,885	81
Provision for income taxes	-	-	-	-
Net loss	$(4,218)	$(2,333)	$1,885	81

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Revenues

Product Sales

We launched Nexafed commercially in mid-December 2012. Given the limited sales history of Nexafed, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company has deferred recognition of revenue and the related cost of sales on product shipments of Nexafed since its launch until the right of return no longer exists or adequate history and information is available to estimate product returns. As of March 31, 2013, we had $37 thousand in deferred revenue on our balance sheet related to Nexafed shipments made since its commercial launch. We had no product sales for the three months ended March 31, 2012.

Royalty Revenue

In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer Inc., we began to earn royalties on Oxecta net sales starting in February 2013. Pfizer will pay us a royalty at one of six rates ranging from 5% to 25% based on the level of annual net sales for Oxecta across all Pfizer Territories, with the highest applicable royalty rate applied to such annual sales. These royalties are based on net sales of Oxecta reported to us by Pfizer being paid to us within 45 days after the end of each calendar quarter. We recorded royalties of approximately $4 thousand for the quarter ended March 31, 2013 on net sales of approximately $77 thousand.

Operating Expenses

R&D expense during the three months ended March 31, 2013 were primarily for our Aversion development expenses and for the three months ended 2012 were for product candidates utilizing either our Aversion or our 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 each of the 2013 and 2012 results are non-cash share-based compensation expenses of $0.1 million. Excluding the share-based compensation expense, our development expenses increased approximately $1.1 million between reporting periods primarily on our Aversion development expenses on our hydrocodone/acetaminophen product candidate.

Selling and marketing expenses during the three months ended March 31, 2013 and 2012 primarily consisted of advertising and marketing activities on Nexafed which was launched in December 2012. Selling and marketing expenses during the three months ended March 31, 2012 primarily consisted of market research studies on our

Aversion and Impede® Technologies. Our Nexafed advertising and marketing activities will continue in 2013. Our G&A expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in the 2013 and 2012 results are non-cash share-based compensation expenses of $0.2 million and $0.3 million, respectively. Excluding the share-based compensation expense our selling, general and administrative expenses increased approximately $0.9 million, primarily for the advertising and marketing activities on Nexafed and legal services on our paragraph IV litigation, between reporting periods.

Non-operating Income (Expense)

During the three months ended March 31, 2013 and 2012, other non-operating income consisted principally of investment income derived from our cash reserves being invested in accordance with a Board of Director approved investment policy.

Net Income (Loss)

The net loss for the three months ended March 31, 2013 and 2012 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Liquidity and Capital Resources

At March 31, 2013, the Company had cash, cash equivalents and marketable securities of $23.4 million compared to $27.4 million at December 31, 2012. The Company had working capital of $22.0 million at March 31, 2013 compared to $27.6 million at December 31, 2012. The decrease in our cash position is primarily due to the period’s net loss and the payment of employees’ withholding taxes approximating $0.7 million associated with their option exercises and RSU exchanges during such period, adjusted for the non-cash share-based compensation expenses.

At April 29, 2013, the Company had cash, cash equivalents and marketable securities of approximately $21.5 million. We estimate that our current cash reserves will be sufficient to fund operations through at least the next 12 months.

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company's 2012 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 2012 Annual Report are also applicable to 2013.

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 2013 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 4, "License, Development, and Commercialization Agreement – Paragraph IV ANDA Litigation", and Note 9, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

Item 1A. Risk Factors

In addition to the risk factors contained in our Form 10-K for the year ended December 31, 2012, you should carefully consider the risk factor described below.

We may seek to engage in strategic transactions that could have result in negative consequences, and we may not realize the benefits of such transactions or attempts to engage in such transactions.

From time to time, we may seek to engage in strategic transactions with third parties, such as acquisitions of companies or divisions of companies, asset purchases, or in-licensing product candidates or technologies that we believe will complement or expand our existing business. We may also consider a variety of other business arrangements, including strategic partnerships, business combinations and other investments. Any such transaction may require us to incur non-recurring and other charges, increase our near and long-term expenditures, pose significant integration challenges, require additional expertise, result in dilution to our existing stockholders and disrupt our management and business, which could adversely affect our operations and financial results. Moreover, we face significant competition in seeking appropriate strategic partners and transactions, and the negotiation process for any strategic transaction can be time-consuming and complex. In addition, we may not be successful in our efforts to engage in certain strategic transactions. Any failures or delays in entering into strategic transactions anticipated by analysts or the investment community could result in a decline in our stock price.

The following risk factors below amend and replace the risk factors having the same descriptive caption contained in our Form 10-K for the year ended December 31, 2012. The changes to such original risk factors are marked.

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 USPTO encompassing our opioid products utilizing our Aversion Technology, and U.S. Patent No. 7,981,439 and U.S. Patent No. 8,409,616 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. 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, including the Paragraph IV Proceedings described below;
- 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, *including interference proceedings with the USPTO*, 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, including the Paragraph IV Proceedings, 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, including the Paragraph IV Proceedings, 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, including the Paragraph IV Proceedings, 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, including the Paragraph IV Proceedings, 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.

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 product candidates. 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. *We are also aware of an issued United States Patent owned by a third party having claims encompassing the use of certain of our Aversion inactive ingredients in an immediate-release oxycodone HCl tablet formulation. Such third party has informally advised us that it believes Oxecta may infringe its patent.* 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 patents, 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 to demonstrate the foregoing, or obtain a license to these patients, Pfizer may be required or choose to withdraw Oxecta from the market.

We are aware of a certain issued United States patent owned by a third party having claims similar to our second generation Impede Technology directed to ingredient amounts that are generally less than the amounts used in our technology. While we believe our technology does not infringe this patent, we cannot provide assurance that we will not be sued under such patent or if sued, that we will prevail in any such suit.

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.

Item 6. Exhibits

The exhibits required by this Item are listed below.

10.1	Strategic Transaction Bonus Grant Agreement dated February 28, 2013 between the Company and Robert B. Jones.
10.2	Strategic Transaction Bonus Grant Agreement dated February 28, 2013 between the Company and Peter A. Clemens.
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.

April 30, 2013 ACURA PHARMACEUTICALS, INC.

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

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

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