SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20649

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 ☑ 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 ☑ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☑	Smaller reporting company ☐

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

As of October 29, 2013 the registrant had 48,322,362 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2013

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
(Unaudited; in thousands except par value)

	September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 2,553	$ 7,476
Marketable securities	16,873	19,946
Accounts receivable, net allowances of $21	55	-
Accrued investment income	129	36
Inventories, net	298	219
Income taxes refundable	-	43
Prepaid expenses and other current assets	807	271
Other current deferred assets	51	-
Total current assets	20,766	27,991
Property, plant and equipment, net	972	1,052
Other assets	24	11
Total assets	$ 21,762	$ 29,054
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 253	$ 994
Accrued expenses	775	413
Deferred revenue	71	-
Other current liabilities	12	12
Total current liabilities	1,111	1,419
Other liabilities	5	5
Total liabilities	1,116	1,424
Commitments and contingencies (Note 13)		
Stockholders' Equity:		
Common stock: $.01 par value per share; 100,000 shares authorized, 48,322 and 45,867 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	483	459
Additional paid-in capital	365,863	362,422
Accumulated deficit	(345,695)	(335,211)
Accumulated other comprehensive income (loss)	(5)	(40)
Total stockholders' equity	20,646	27,630
Total liabilities and stockholders' equity	$ 21,762	$ 29,054

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPRENESIVE INCOME (LOSS)
(Unaudited; in thousands except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
Royalty revenue	$ 3	$ -	$ 8	$ -
Product sales, net	80	-	80	-
Total revenues, net	83	-	88	-
Operating expenses:				
Cost of sales (excluding inventory write-down)	78	-	78	-
Inventory write-down	-	-	361	-
Research and development	1,289	696	4,120	2,518
Selling, marketing, general and administrative	1,941	1,453	6,138	4,164
Total operating expenses	3,308	2,149	10,697	6,682
Operating loss	(3,225)	(2,149)	(10,609)	(6,682)
Non-operating income:				
Investment income	55	9	136	30
Loss on sales of marketable securities	(20)	-	(11)	-
Total other income	35	9	125	30
Loss before income taxes	(3,190)	(2,140)	(10,484)	(6,652)
Provision for income taxes	-	-	-	-
Net loss	$ (3,190)	$ (2,140)	$ (10,484)	$ (6,652)
Other comprehensive income:				
Unrealized gains on securities	114	-	35	-
Total other comprehensive income	114	-	35	-
Comprehensive loss	$ (3,076)	$ (2,140)	$ (10,449)	$ (6,652)
Loss per share:				
Basic	$ (0.07)	$ (0.04)	$ (0.22)	$ (0.14)
Diluted	$ (0.07)	$ (0.04)	$ (0.22)	$ (0.14)
Weighted average shares outstanding:				
Basic	47,458	47,522	47,297	47,520
Diluted	47,458	47,522	47,297	47,520

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited; in thousands)

	Nine Months Ended September 30, 2013					
	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	$ Amount	Capital	Deficit	Income (Loss)	Total
Balance at December 31, 2012	45,867	$ 459	$ 362,422	$ (335,211)	$ (40)	$ 27,630
Net loss	-	-	-	(10,484)	-	(10,484)
Other comprehensive income (loss)	-	-	-	-	35	35
Share-based compensation	-	-	945	-	-	945
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 under “at the market” offerings, net of offering costs of $102	1,940	19	3,207	-	-	3,226
Issuance of common stock for exercise of stock options	7	-	9	-	-	9
Balance at September 30, 2013	48,322	$ 483	$ 365,863	$ (345,695)	$ (5)	$ 20,646

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited; in thousands)

	Nine Months Ended September 30,	
	2013	2012
Cash Flows from Operating Activities:		
Net loss	$ (10,484)	$ (6,652)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	104	97
Share-based compensation	945	1,272
Provision to reduce inventory to net realizable value	361	-
Loss on sales of marketable securities	11	-
Changes in assets and liabilities		
Accounts receivable, net	(55)	-
Accrued investment income	(93)	-
Inventories	(440)	-
Income taxes refundable	43	(4)
Prepaid expenses and other current assets	(536)	(70)
Other current deferred assets	(51)	-
Other assets	(13)	-
Accounts payable	(741)	175
Accrued expenses	362	(18)
Deferred revenue	71	-
Net cash used in operating activities	(10,516)	(5,200)
Cash Flows from Investing Activities:		
Purchases of marketable securities	(7,611)	-
Proceeds from sale of marketable securities	10,708	-
Additions to property, plant and equipment	(24)	(129)
Net cash provided by (used in) investing activities	3,073	(129)
Cash Flows from Financing Activities:		
Proceeds from exercise of stock options	9	9
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)	(1,046)
Proceeds from “at the market” offering	3,328	-
Offering transaction costs	(102)	-
Net cash provided by (used) in financing activities	2,520	(1,036)
Net decrease in cash and cash equivalents	(4,923)	(6,365)
Cash and cash equivalents at beginning of period	7,476	35,685
Cash and cash equivalents at end of period	$ 2,553	$ 29,320
Supplemental Disclosures of Cash Flow Information:		
Cash paid (refunded) during the period for:		
Interest	$ -	$ -
Income taxes, net of refunds	$ (42)	$ -

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:

Nine Months Ended September 30, 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.

Nine Months Ended September 30, 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; we issued 531 thousand shares of common stock.

2. Options to purchase 17 thousand shares of common stock were exercised utilizing various cashless exercise features of our plan and after withholding 7 thousand shares for $22 in exercise costs and withholding 3 thousand shares for $12 in statutory minimum payroll taxes, we issued 7 thousand shares of common stock.

See accompanying Notes to Consolidated Financial Statements.

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. 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 and nine months ended September 30, 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. At September 30, 2013 we had $0.4 million in prepaid CRO costs. 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 $76 thousand accrued for CRO and clinical trial study expenses at September 30, 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 as well as directly to chain drug stores. 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 to certain customers. Accordingly, the Company has deferred revenue recognition on Nexafed shipments of $71 thousand since the product's launch to these customers until the right of return no longer exists or adequate history and information is available to estimate product returns.

We are a party to a 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"). Commencing in February 2013, we began earning royalties based on net sales of Oxecta by Pfizer. Such royalties are paid to us within 45 days after the end of each calendar quarter. We have recorded royalties of approximately $8 thousand for the nine month period ended September 30, 2013 on Oxecta's net sales of approximately $165 thousand.

Shipping and Handling Costs

The Company records shipping and handling costs in selling expenses. The costs recorded to selling expenses from the shipments of Nexafed during the nine month period ended September 30, 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, or the Pfizer Territories, 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. 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 of 5% of net sales for Oxecta. The applicable royalty rate for Oxecta net sales payable under the Pfizer Agreement increases if net sales exceed certain specified thresholds. 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.

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 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"), and on April 29, 2013 we initiated suit against Ranbaxy Pharmaceuticals, Inc., each 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. If any subsequent 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.

On October 9, 2013, we announced that we had entered into distinct Settlement Agreements with each of Par and Impax, to settle our patent infringement action pending against them in the United States District Court for the District of Delaware. In the suit, we alleged that a generic Oxecta® product for which each of Par and Impax is separately seeking approval to market in the United States pursuant to an ANDA filing with the FDA infringes a U.S. patent owned by us. Par is the first filer of an ANDA for a generic Oxecta® product and is entitled to the 180-day first filer exclusivity under applicable law and FDA regulations.

Under the terms of the Settlement Agreement with Par, Par may launch its generic Oxecta® product in the U.S., through the grant of a non-exclusive, royalty-bearing license from us that would trigger on January 1, 2022. We currently have Orange Book patents that are due to expire between November 2023 and March 2025. In certain limited circumstances, our license to Par would become effective prior to January 1, 2022. Par is required to pay us royalties in the range of 10% to 15% of Par's net profits from the sale of its generic Oxecta® product.

Under the Settlement Agreement with Impax, Impax may launch its generic Oxecta® product in the U.S., through the grant of a non-exclusive, royalty-free license from us that would trigger 180 days following the first sale of a generic Oxecta® product in the U.S. by an entity that is entitled to the 180 day first-filer exclusivity under applicable law and FDA regulations (or if no entity is entitled to such 180 day exclusivity period, the date on which a generic Oxecta® product is first sold in the U.S. or November 27, 2021, whichever date occurs first). In certain circumstances, our license to Impax would become effective prior to such time.

The Settlement Agreements provide for a full settlement of all claims that were asserted in each of the Par and Impax suits, subject to the Court's acceptance of the stipulations of dismissal. As required by law, the Settlement Agreements with Par and Impax have been submitted to the U.S. Federal Trade Commission ("FTC") and U.S. Department of Justice ("DOJ"). There can be no assurance that the FTC and/or the DOJ will not raise objections to, or request modifications to, the Settlement Agreements; that such modifications will be acceptable to the parties; or that the Settlement will continue to be effective.

The Settlement Agreements with Par and Impax do not affect the status of our separate Oxecta patent litigations against Sandoz Inc. and Ranbaxy Inc. pending in the United States District Court for the District of Delaware.

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. Ranbaxy has certified Paragraph IV against the '616 patent asserting that the '616 patent is either invalid or unenforceable or that their generic product will not infringe the claims of the patent.

Litigation is inherently uncertain and we cannot predict the outcome of these infringement actions. If Sandoz and/or Ranbaxy 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 September 30, 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:

	September 30, 2013 (in millions)	December 31, 2012 (in millions)
Marketable securities:		
Corporate bonds — maturing within 1 year	$ 3.6	$ 1.2
Corporate bonds — maturing after 1 through 4 years	7.4	6.3
Pooled investment fund	2.0	8.0
Exchange-traded funds	3.9	4.4
Total marketable securities	$ 16.9	$ 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):

	September 30, 2013 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 11.0	$ -	$ -	$ 11.0
Pooled investment fund	2.0	-	-	2.0
Exchange-traded funds	3.9	-	-	3.9
Total - Current	$ 16.9	$ -	$ -	$ 16.9

	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 September 30, 2013 meeting fair value measurement.

Our assets measured at fair value or disclosed at fair value on a recurring basis as at September 30, 2013 and December 31, 2012 consisted of the following (in millions):

	September 30, 2013 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	11.0	11.0	-	-
Pooled investment fund	2.0	-	2.0	-
Exchange-traded funds	3.9	3.9	-	-
Total	$ 16.9	$ 14.9	$ 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) on marketable securities consisted of cumulative unrealized gains of $46 thousand at September 30, 2013 and $40 thousand of cumulative unrealized losses at December 31, 2012.

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. Our gross inventory is valued at $0.7 million and $0.2 million at September 30, 2013 and December 31, 2012, respectively. We have established an inventory reserve of $0.4 million which results in a net reported inventory value of $0.3 million at September 30, 2013. We did not have an inventory reserve at December 31, 2012. The related cost of sales on the $71 thousand deferred revenue from Nexafed shipments since the product's launch is excluded from the value of the September 30, 2013 inventory and is reported in our Balance Sheet in the other current deferred assets account until the right of return no longer exists or adequate history and information is available to estimate product returns on the product shipments. Our 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):

	September 30, 2013	December 31, 2012
Payroll, payroll taxes, bonus and benefits	$ 96	$ 55
Professional services	449	216
Franchise taxes	15	5
Property taxes	17	20
Contract manufacturing services	-	21
Clinical and regulatory services	76	21
Other fees and services	122	75
Total	$ 775	$ 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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Stock options				
Research and development	$ 81	$ 91	$ 243	$ 273
General and administrative	234	333	702	999
Total	$ 315	$ 424	$ 945	$ 1,272

Stock Option Award Plans

At September 30, 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 nine months ended September 30, 2013, 14 thousand NonISOs were exercised by our employees. Our employees elected to have 4 thousand shares withheld in satisfaction of $14 thousand for both the exercise costs and the withholding tax obligations resulting in the net issuance of 10 thousand common shares to them. During the nine months ended September 30, 2012, 24 thousand NonISOs were exercised by our employees. Our employees elected to have 10 thousand shares withheld in satisfaction of $34 thousand for both the exercise costs and the withholding tax obligations which resulted in the net issuance of 14 thousand common shares to them.

As of September 30, 2013 the Company had $0.7 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 14 months. Under the provisions of 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 nine months ended September 30, 2013 and 2012 is shown below:

	Nine Months Ended September 30,			
	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	(14)	1.30	(24)	1.30
Forfeited or expired	(75)	5.02	(703)	8.44
Outstanding, ending	3,282	$ 5.46	2,934	$ 5.86
Options exercisable	3,021	$ 5.70	2,640	$ 6.11

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

	Nine Months Ended September 30,	
	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 employees 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 January 1st of 2013, 2012 and 2011, 0.83 million RSUs were distributed to our employees and directors. Our employees made 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 made 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.

A summary of the RSU Plan as of September 30, 2013 and 2012 and for the nine months then ended consisted of the following (in thousands):

	Nine Months Ended September 30,			
	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 10 – EQUITY FINANCING

Our universal shelf registration statement on Form S-3 was declared effective by the Securities and Exchange Commission ("SEC") on March 15, 2013. On April 18, 2013, we filed a prospectus supplement with the SEC pursuant to which we may sell shares of our common stock from time to time in "at the market" offerings and certain other transactions, having sales proceeds of up to $13 million. During the three months ended June 30, 2013, we sold approximately 114 thousand shares of our common stock under a Sales Agreement with MLV & Co., our sales agent, through an "at the market" offering, for gross proceeds of approximately $0.25 million. Transaction costs were approximately $8 thousand. During the three months ended September 30, 2013, we sold approximately 1.83 million shares of our common stock for gross proceeds of approximately $3.1 million and transaction costs of approximately $0.1 million. The net proceeds of these transactions for the nine months ending September 30, 2013 were approximately $3.2 million and will be used for general corporate purposes, which may include working capital, capital expenditures, research, development and marketing expenditures and clinical trial expenditures.

NOTE 11 - COMMON STOCK WARRANTS

The Company has outstanding common stock purchase warrants at September 30, 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 12 - 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. These 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 and nine month periods, and including the effects of these 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 is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
EPS – basic and diluted				
Numerator: net loss	$ (3,190)	$ (2,140)	$ (10,484)	$ (6,652)
Denominator:				
Common shares	46,629	45,864	46,468	45,862
Vested RSUs	829	1,658	829	1,658
Basic and diluted weighted average shares outstanding	47,458	47,522	47,297	47,520
EPS – basic and diluted	$ (0.07)	$ (0.04)	$ (0.22)	$ (0.14)
Excluded securities:				
Common shares issuable:				
Stock options	3,282	2,934	3,282	2,934
Common stock warrants	1,856	1,856	1,856	1,856
Total excluded common shares	5,138	4,790	5,138	4,790

NOTE 13 - 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

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. An adverse decision by the Pennsylvania Superior Court was issued in July 2013. Further appeal proceedings are pending. 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 entered 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, subject to further developments, plaintiffs may be permitted to proceed with these lawsuits including state law claims based on (1) failing to communicate warnings to physicians through "Dear Doctor" letters; and (2) failure to update labeling to adopt brand labeling changes. California trial court also has 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 September 30, 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, that the U.S. District Court does not approve the stipulations of dismissal relating to our patent infringement ligation with Par and Impax, that the FTC or DOJ challenge the enforceability of the Settlement Agreements with Par and Impax, or that private plaintiffs challenge the Settlement Agreements with Par and Impax, whether or not additional third parties may seek to market generic versions of Oxecta® and the results of any litigation that we have filed or may file to defend and/or assert our patents against such companies, the possible occurrence of one of the specific events that would result in Par or Impax marketing a generic Oxecta® earlier than we anticipate, the possible approval by the FDA of Sandoz' or Ranbaxy's generic Oxecta product prior to the expiry of our patents covering Oxecta, 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 and beliefs with respect to future events and are based on assumptions and subject to significant 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. Forward-looking statements speak only as of the date of this Report, and Acura undertakes no obligation to update or revise these 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. On August 26, 2013, we announced the top-line results from Study AP-ADF-301 ("Study 301"), a phase II clinical study in 40 recreational drug abusers assessing the liability of snorting our hydrocodone/acetaminophen product. Study 301s primary endpoint indicated that Aversion hydrocodone/acetaminophen had slightly lower numeric mean maximum drug liking compared to an equivalent dose of a generic hydrocodone/acetaminophen tablet, however these results were not statistically significant. The Study 301 secondary endpoints demonstrated statistical significance in mean minimum drug liking, including the Overall Drug Liking score and the Take Drug Again assessment. We intend to further evaluate the data from Study 301 and plan to meet with the FDA to discuss the Study 301 results. The projected timeline for submission of the NDA for Aversion hydrocodone/acetaminophen is expected to be delayed. The revised timeline for submission of the NDA for Aversion hydrocodone/acetaminophen will be determined following our meeting with the FDA. We have a meeting scheduled with the FDA to discuss the results of Study 301 on December 5, 2013.

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 nasal 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 have developed a second generation prototype formulation of our Impede Technology, or Impede 2.0, to further improve our Nexafed franchise. Studies sponsored by us at an independent laboratory using an optimized, high yield direct conversion test method that is designed to replicate the direct conversion, or one-pot, process commonly used by clandestine methamphetamine laboratories yielded no measurable amount of methamphetamine compared to an approximate 38% yield with our older Impede Technology. Subsequent one-pot testing with the new formulations demonstrated variability in the one-pot conversion method making it unsuitable to enter into the marketplace. We continue to perform research into improvements for our IMPEDE technology.

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. Pending receipt of the FDA's advice on Pfizer's proposed Oxecta promotional materials, which were submitted to the FDA in July 2012, Pfizer did not market Oxecta to physicians. As such, Pfizer attained no meaningful sales of Oxecta in 2012 or during the nine months ended September 30, 2013. In April 2013 Pfizer received FDA's advice on its Oxecta promotional materials and commenced a non-branded marketing campaign to raise awareness of the problem of opioid abuse in the 3rd quarter of 2013. We have been informed by Pfizer that it will expand commercialization of Oxecta to health care providers in the fourth quarter of 2013. These activities will be directed to a national cross section of healthcare professionals who treat pain, but will not include the use of field representatives.

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 September 30, 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, Pfizer remits to us a royalty of 5% on net sales of Oxecta, based on current annual net sales levels.

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 timeline to be updated following December 5, 2013 meeting with FDA.
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 Aversion Hydrocodone/Acetaminophen

Our hydrocodone/acetaminophen product was previously under development by Pfizer who, before returning the product to us: (1) 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, or Study AP-ADF-301;
- Laboratory studies demonstrating extraction, syringing and particle size characteristics of our product; and
- An assessment of the routes of abuse of hydrocodone products.

On August 26, 2013, we announced top-line results from Study AP-ADF-301 (Study 301), a phase II clinical study in 40 recreational drug abusers assessing the abuse liability of snorting of our crushed hydrocodone/acetaminophen product. Study 301's primary endpoint indicated Aversion hydrocodone/acetaminophen had slightly lower numeric mean maximum drug liking (Emax: 72.1) compared to an equivalent dose of a generic hydrocodone/acetaminophen tablet: Emax: 75.6) currently on the market, however these results were not statistically significant (p=0.22). The secondary endpoints demonstrated the effects of the Aversion ingredients on drug snorting. Aversion hydrocodone/acetaminophen's mean minimum liking (Emin: 40.2) was less than the comparator (Emin: 50.4) (the difference being statistically significant at p=0.0003). The mean minimum drug liking for Aversion H&A and the placebo control were 40.2 and 48.8, respectively (the difference being statistically significant at p=0.0042). A score below 50 indicates a subject disliked the drug they were taking at some point during the treatment (a score of 50 means neither like or dislike), and a score greater than 50 indicates they liked the drug they were taking.

The mean minimum liking results correlated closely the Overall Drug Liking score (ODL) and Take Drug Again assessment (TDA). ODL assessed the subject like or dislike for the drug experience 12 hours after taking the dose. The ODL for Aversion hydrocodone/acetaminophen (52.7) was lower than the generic comparator (71.0) (the difference being statistically significant at p=0.0001) with a score of 50 indicating a neither a like or dislike. TDA assessed a subject's willingness to take the drug again assessed 12 hours after taking the dose. The TDA for Aversion hydrocodone/acetaminophen (45.1) was lower than the generic comparator (71.0) (the difference being statistically significant at p=0.0001) with the Aversion hydrocodone/acetaminophen score below 50 indicating an unwillingness to take the drug again.

There were no serious adverse events reported for Aversion hydrocodone/acetaminophen. There was no sequence effect identified in the study but a carryover effect between the 5 study crossover periods was identified for the Emax measure but not the Emin measure. This effect is being further evaluated.

We intend to further evaluate the data from this study and have scheduled to meet with the FDA on December 5, 2013 to discuss these results. Given the absence of statistical significance in Study 301s primary endpoint relating to maximum drug liking, the timeline for submission of a NDA for Aversion hydrocodone/acetaminophen product is expected to be delayed. The revised projected timeline for submission of the NDA will be determined following our meeting with the FDA. Although we do not expect the need to conduct additional nasal abuse like/dislike studies for Aversion hydrocodone/acetaminophen product, this will not be confirmed until our meeting with the FDA to discuss the Study 301 results.

We have completed scale-up activities for our Aversion hydrocodone/acetaminophen product at the proposed commercial manufacturer and have manufactured our registration batches for use in subsequent clinical trials.

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.

We are conducting research on Impede 2.0, our next generation Impede Technology, to further improve our Nexafed franchise. Studies sponsored by us at an independent laboratory using an optimized, high yield direct conversion test method that is designed to replicate the direct conversion, or one-pot, process commonly used by clandestine methamphetamine laboratories yielded no measurable amount of methamphetamine compared to an approximate 38% yield with our older Impede Technology. Subsequent one-pot testing with the new formulation demonstrated variability in the one-pot conversion method making it unsuitable to enter into the marketplace. We continue to perform research into improvements for our IMPEDE technology.

Separately, we now intend to advance the research and development of our first line extension of NEXAFED, a combination product with additional active ingredients, using our IMPEDE 1.0 technology.

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 other pharmacy chain customers. 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 estimate Nexafed is currently stocked in approximately 2,900 US pharmacies or about 4.5% of the 65,000 pharmacy outlets. About 50% of these pharmacies are repeat customers. We continue to work to expand the wholesale and retail distribution network for Nexafed and intend to re-approach some chain customers already stocking Nexafed with programs designed to improve penetration in those chains. On November 1, 2013, we received a purchase order for Nexafed from Rite Aid. Based on the size of this order, we believe Rite Aid may make Nexafed available for distribution in a substantial majority of its 4,600 pharmacies.

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 and are currently readapting our advertising program to differentiate Nexafed from a meth-resistant competitive product that launched in August 2013. We may use consumer advertising in the future. We have shipped approximately $92 thousand and $150 thousand in Nexafed product during the quarter and nine months ended September 30, 2013, respectively.

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 October 30, 2013 we had cash, cash equivalents and marketable securities of approximately $18.7 million. We estimate that our current cash reserves will be sufficient to fund operations through at least the next 12 months.

During the nine months ended September 30, 2013 we recognized $80 thousand of product sales on our gross shipments of Nexafed totaling $150 thousand. Certain of our customers have accepted a pricing allowance in exchange for forfeiting the right to return Nexafed and therefore we are recognizing revenue upon product shipment to them. Additionally we are recognizing revenue from certain of our other customers based on a pharmacy's Nexafed reorder activity with their own drug wholesaler supplier. For all other customers, given the limited sales history of Nexafed, the Company currently cannot reliably estimate expected returns of the product from these customers at the time of shipment. Accordingly, the Company is deferring recognition of revenue on these 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 and we are accruing royalties based on the estimate of net product sales of Oxecta Tablets provided by Pfizer to us.

To fund our continued operations, we expect to rely on our current cash resources, net proceeds from our "at-the-market" offering of our common stock pursuant to our Sales Agreement with MLV & Co., 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 litigation of the Paragraph IV Proceedings, hire additional personnel, commercialize our Nexafed Tablets, or invest in other areas.

Three Months Ended September 30, 2013 Compared to Three Months Ended September 30, 2012

	September 30			
	2013	2012	Increase (decrease)	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$ 3	$ -	$ 3	100 %
Product sales, net	80	-	80	100
Total revenues, net	83	-	83	100
Expenses:				
Cost of sales	78	-	78	100
Research and development	1,289	696	593	85
Selling, marketing, general and administrative	1,941	1,453	488	34
Total operating expenses	3,308	2,149	1,159	54
Operating loss	(3,225)	(2,149)	1,076	50
Non-operating income:				
Investment income	55	9	46	nm
Loss on sales of marketable securities	(20)	-	20	100
Total other income	35	9	26	nm
Loss before income taxes	(3,190)	(2,140)	1,050	49
Provision for income taxes	-	-	-	-
Net loss	$ (3,190)	$ (2,140)	$ 1,050	49 %

nm = not meaningful

Revenues

Product Sales

We launched Nexafed commercially in mid-December 2012. Given the limited sales history of Nexafed, the Company could not reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company 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. During the 3rd Quarter 2013 we recognized revenue of $80 thousand for shipments to customers where the right of return no longer existed either because a pricing allowance was accepted in exchange for forfeiting the right of return or because information became available on pharmacy's reorder activity with their drug wholesaler. We will continue to analyze information to assess the recognition of our revenue but also expect to continue the deferral of some revenue in the foreseeable future. As of September 30, 2013, we had $71 thousand in deferred revenue on our balance sheet related to Nexafed shipments which occurred since its commercial launch. We had no product sales for the three months ended September 30, 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 $3 thousand for the quarter ended September 30, 2013 on Pfizer's net sales of Oxecta of approximately $60 thousand.

Cost of Sales

Cost of sales includes third party acquisition costs, third party warehousing and product distribution charges and inventory reserve charges for the Nexafed product line.

Operating Expenses

Research and development ("R&D") expense during the three months ended September 30, 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 R&D expenses increased approximately $0.6 million between reporting periods primarily from our Aversion development expenses on our hydrocodone/acetaminophen product candidate.

Selling and marketing expenses during the three months ended September 30, 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 September 30, 2012 primarily consisted of market research studies on our Aversion and Impede® Technologies. Our Nexafed advertising and marketing activities will continue in 2013. Our general and administrative 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, marketing general and administrative expenses increased approximately $0.6 million between reporting periods, primarily for the legal services on our paragraph IV litigation of $0.4 million and patent and trademark services of $0.2 million.

Non-operating Income

During the three months ended September 30, 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.

Income Taxes

The net loss for the three months ended September 30, 2013 and 2012 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Nine Months Ended September 30, 2013 Compared to Nine Months Ended 2012

	September 30			
	2013	2012	Increase (decrease)	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$ 8	$ -	$ 8	100 %
Product sales, net	80	-	80	100
Total revenues, net	88	-	88	100
Operating expenses:				
Cost of sales	78	-	78	100
Inventory write-down	361	-	361	100
Research and development	4,120	2,518	1,602	64
Selling, general and administrative	6,138	4,164	1,974	47
Total operating expenses	10,697	6,682	4,015	60
Operating loss	(10,609)	(6,682)	3,927	59
Non-operating income:				
Investment income	136	30	106	nm
Loss on sales of marketable securities	(11)	-	11	100
Total other income	125	30	95	nm
Loss before income taxes	(10,484)	(6,652)	3,832	58
Provision for income taxes	-	-	-	-
Net loss	$ (10,484)	$ (6,652)	$ 3,832	58 %

nm = not meaningful

Revenues

Product Sales

We launched Nexafed commercially in mid-December 2012. Given the limited sales history of Nexafed, the Company could not reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company 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. During the 3rd Quarter 2013 we recognized revenue of $80 thousand for shipments to customers where the right of return no longer existed either because a pricing allowance was accepted in exchange for forfeiting the right of return or because information became available on pharmacy's reorder activity with their drug wholesaler. We will continue to analyze information to assess the recognition of our revenue but also expect to continue the deferral of some revenue in the foreseeable future. As of September 30, 2013, we had $71 thousand in deferred revenue on our balance sheet related to Nexafed shipments which occurred since its commercial launch. We had no product sales for the three months ended September 30, 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 $8 thousand for the nine months ended September 30, 2013 on Pfizer's net sales of Oxecta of approximately $165 thousand.

Cost of Sales

Cost of sales includes third party acquisition costs, third party warehousing and product distribution charges and inventory reserve charges for the Nexafed product line. During the second quarter of this year, we established an inventory reserve of $0.4 million.

Operating Expenses

R&D expense during the nine months ended September 30, 2013 were primarily for our Aversion development expenses and for the nine 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 $0.2 million and $0.3 million, respectively. Excluding the share-based compensation expense, our R&D expenses increased approximately $1.7 million between reporting periods primarily from our Aversion development expenses on our hydrocodone/acetaminophen product candidate.

Selling and marketing expenses during the nine months ended September 30, 2013 primarily consisted of advertising and marketing activities on Nexafed which was launched in December 2012. Selling and marketing expenses during the nine months ended September 30, 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 $0.7 million and $1.0 million, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses increased approximately $2.3 million between reporting periods, primarily for the advertising and marketing activities on Nexafed of $0.5 million, legal services on our paragraph IV litigation of $1.3 million, patent and trademark services of $0.2 million and general corporate legal matters of $0.3 million

Non-operating Income

During the nine months ended September 30, 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.

Income Taxes

The net loss for the nine months ended September 30, 2013 and 2012 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Liquidity and Capital Resources

At September 30, 2013, the Company had cash, cash equivalents and marketable securities of $19.4 million compared to $27.4 million at December 31, 2012. The Company had working capital of $19.7 million at September 30, 2013 compared to $26.6 million at December 31, 2012. The decrease in our cash position is primarily due to our period's net operating loss which is adjusted for non-cash share-based compensation expenses. Our net loss includes our advertising and marketing activities on Nexafed of $1.1 million and our legal expenses incurred in our paragraph IV ANDA litigation of $1.3 million. The decrease in our cash position includes our payment of employees' withholding taxes of $0.7 million associated with their option exercises and RSU exchanges during such period, offset by $3.2 million in net proceeds raised from our ATM offering activities.

At October 30, 2013, the Company had cash, cash equivalents and marketable securities of approximately $18.7 million. We estimate that our current cash reserves will be sufficient to fund operations through at least the next 12 months.

Financing Activities

We had financing activities for the quarter ended September 30, 2013 that provided approximately $3.1 million in cash. During the quarter, we sold approximately1.83 million shares of our common stock through a registered "at the market" offering program. See Note 10 to the Company's consolidated financial statements contained in this Report for a discussion of the "at the market" offering program.

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 third 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 13, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

Item 6. Exhibits

The exhibits required by this Item are listed below.

31.1	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
31.2	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
32.1	Certification of Periodic Report by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.

October 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

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Robert B. Jones, the President & Chief Executive Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d – 15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with general accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrants most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

October 30, 2013

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

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Peter A. Clemens, the Chief Financial Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrants most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

October 30, 2013

/s/ Peter A. Clemens
Peter A. Clemens
Chief Financial Officer

CERTIFICATIONS OF THE CHIEF EXEUTIVE OFFICER AND THE CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Acura Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert B. Jones, the Chief Executive Officer of the Company, and Peter A. Clemens, Chief Financial Officer certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

October 30, 2013

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

/s/ Peter A. Clemens
Peter A. Clemens
Chief Financial Officer