SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20649

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

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** *(Address of Principal Executive Offices)*	**60067** *(Zip Code)*

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 S-T (§232.405 of this charter) during the preceding 12 months (or to such shorter period that the registrant was required to submit and post such files).
Yes þ No ☐

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

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

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

As of October 30, 2014 the registrant had 48,847,982 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
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Item 1. Financial Statements

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

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,251	$ 12,340
Marketable securities (Note 6)	13,313	13,733
Accounts receivable, net of allowances of $5 and $28	132	194
Accrued investment income	92	120
Inventories, net (Note 7)	403	251
Prepaid expenses and other current assets	812	629
Other current deferred assets	140	186
Total current assets	16,143	27,453
Property, plant and equipment, net	957	941
Deferred debt issuance costs	179	231
Other assets	1	5
Intangible asset	2,000	-
Total assets	$ 19,280	$ 28,630
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 116	$ 274
Accrued expenses (Note 8)	1,488	541
Other current liabilities	40	5
Deferred revenue	228	287
Current maturities of long-term debt (Note 9)	1,160	-
Total current liabilities	3,032	1,107
Long-term portion of accrued interest	140	-
Long-term debt, net of debt discount of $311 and $400 (Note 9)	8,529	9,600
Total liabilities	$ 11,701	$ 10,707
Commitments and contingencies (Note 14)		
Common stock: $.01 par value per shares; 100,000 shares authorized, 48,848 and 48,325 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	488	483
Additional paid-in capital	366,691	366,533
Accumulated deficit	(359,625)	(349,112)
Accumulated other comprehensive income (loss)	25	19
Total stockholders' equity	$ 7,579	$ 17,923
Total liabilities and stockholders' equity	$ 19,280	$ 28,630

See accompanying Notes to Consolidated Financial Statements.

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

	Three months Ended September 30,		Nine months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Royalty revenue	$ -	$ 3	$ 4	$ 8
Product sales, net	145	80	218	80
Total revenues, net	145	83	222	88
Operating expenses:				
Cost of sales (excludes inventory write-down)	108	78	188	78
Inventory write-down	-	-	201	361
Research and development	955	1,289	3,674	4,120
Selling, marketing, general and administrative	1,728	1,941	5,903	6,138
Total operating expenses	2,791	3,308	9,966	10,697
Operating loss	(2,646)	(3,225)	(9,744)	(10,609)
Non-operating income (expense):				
Investment income	46	55	143	136
Loss on sales of marketable securities	-	(20)	(5)	(11)
Interest expense (Note 9)	(304)	-	(907)	-
Total other income (expense)	(258)	35	(769)	125
Loss before income taxes	(2,904)	(3,190)	(10,513)	(10,484)
Provision for income taxes	-	-	-	-
Net loss	(2,904)	$ (3,190)	$ (10,513)	$ (10,484)
Other comprehensive income (expense):				
Unrealized gains (losses) on securities	(44)	114	6	35
Total other comprehensive income (expense)	(44)	114	6	35
Comprehensive loss	$ (2,948)	$ (3,076)	$ (10,507)	$ (10,449)
Loss per share:				
Basic	$ (0.06)	$ (0.07)	$ (0.22)	$ (0.22)
Diluted	$ (0.06)	$ (0.07)	$ (0.22)	$ (0.22)
Weighted average shares outstanding:				
Basic	48,922	47,458	48,871	47,297
Diluted	48,922	47,458	48,871	47,297

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, 2014					
	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	$ Amount	Capital	Deficit	Income (Loss)	Total
Balance at December 31, 2013	48,325	$ 483	$ 366,533	$ (349,112)	$ 19	$ 17,923
Net loss	-	-	-	(10,513)	-	(10,513)
Other comprehensive income (loss)	-	-	-	-	6	6
Share-based compensation	-	-	683	-	-	683
Net distribution of common stock pursuant to restricted stock unit award plan	825	8	(7)	-	-	1
Common shares withheld for withholding taxes on distribution of restricted stock units	(315)	(3)	(522)	-	-	(525)
Net issuance of common stock pursuant to cashless exercise of stock options	8	-	-	-	-	-
Common shares withheld for withholding taxes on cashless exercise of stock options	(2)	-	(4)	-	-	(4)
Issuance of common stock for exercise of stock options	7	-	8	-	-	8
Balance at September 30, 2014	48,848	$ 488	$ 366,691	$ (359,625)	$ 25	$ 7,579

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,	
	2014	2013
Cash Flows from Operating Activities:		
Net loss	$ (10,513)	$ (10,484)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	90	104
Provision to reduce inventory to net realizable value	201	361
Share-based compensation	716	945
Amortization of debt discount and deferred debt issue costs	140	-
Amortization of bond premium in marketable securities	201	-
Loss (gain) on sales of marketable securities	5	11
Loss on disposal of property and equipment	1	-
Changes in assets and liabilities		
Accounts receivable, net	62	(55)
Accrued investment income	28	(93)
Inventories	(353)	(440)
Income taxes refundable	-	43
Prepaid expenses and other current assets	(183)	(536)
Other current deferred assets	46	(51)
Other long-term assets	4	(13)
Accounts payable	(158)	(741)
Accrued expenses	1,087	362
Deferred revenue	(59)	71
Net cash used in operating activities	(8,685)	(10,516)
Cash Flows from Investing Activities:		
Purchases of marketable securities	(2,203)	(7,611)
Proceeds from sale and maturities of marketable securities	2,424	10,708
Additions to property, plant and equipment	(105)	(24)
Acquisition of product rights	(2,000)	-
Net cash (used in) provided by investing activities	(1,884)	3,073
Cash Flows from Financing Activities:		
Proceeds from exercise of stock options	8	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	(529)	(716)
Proceeds from “at-the-market” offering	-	3,328
Offering transaction costs	-	(102)
Net cash (used in) provided by financing activities	(520)	2,520
Net decreases in cash and cash equivalents	(11,089)	(4,923)
Cash and cash equivalents at beginning of year	12,340	7,476
Cash and cash equivalents at end of year	$ 1,251	$ 2,553
Supplemental Disclosures of Cash Flow Information:		
Cash paid (refunded) during the year for:		
Interest	$ 557	$ -
Income taxes, net of refunds	$ -	$ (42)

See accompanying Notes to Consolidated Financial Statements.

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

Supplemental disclosures of noncash investing and financing activities (amounts presented are rounded to the nearest thousand):

Nine months Ended September 30, 2014

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 4 thousand shares for $7 in exercise costs and withholding 315 thousand shares for $525 in statutory minimum payroll taxes; we issued 510 thousand shares of common stock.
2. Options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features of the stock option plan and after withholding 16 thousand shares for $32 in exercise costs and withholding 2 thousand shares for $4 in statutory minimum payroll taxes, we issued 6 thousand shares of common stock.

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 $0.7 million in statutory minimum payroll taxes; we issued 505 thousand shares of common stock.
2. Options to purchase 7 thousand shares of common stock were exercised utilizing various cashless exercise features of the stock option 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.

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2014 AND SEPTEMBER 30, 2013

NOTE 1 - DESCRIPTION OF BUSINESS

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 oxycodone HCl tablets, CII formulated with Aversion® Technology, or Aversion® Oxycodone, is the first approved product utilizing Aversion®. Aversion Oxycodone was marketed by Pfizer Inc. under the brand name Oxecta® pursuant to our license agreement with Pfizer. Such license agreement was terminated effective April 9, 2014 and we have re-acquired all rights to Aversion Oxycodone. We have also developed our Impede® Technology which is a combination of inactive ingredients that prevent the extraction of pseudoephedrine from tablets and disrupt the direct conversion of pseudoephedrine from tablets into methamphetamine. In mid-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, 2014 are not necessarily indicative of results expected for the full year ending December 31, 2014. 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, 2013 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission. The 2013 year-end consolidated balance sheet presented in this Report was derived from the Company's 2013 year-end audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles.

NOTE 2 – ACCOUNTING PRONOUNCEMENTS

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2017.

NOTE 3 - 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, to develop and commercialize in the United States, Canada and Mexico certain opioid analgesic products utilizing our Aversion Technology. Aversion Oxycodone was approved by the U.S. Food and Drug Administration, or FDA, on June 17, 2011 and sales of Aversion Oxycodone, under Pfizer's brand name Oxecta, commenced in February 2012. For sales of Aversion Oxycodone occurring on and following February 2, 2013 (the one year anniversary of first commercial sale), Pfizer paid us a royalty of 5% of net sales of Aversion Oxycodone. On September 24, 2012, we entered into a letter agreement with Pfizer which provided for the termination of Pfizer's license to our Aversion Technology used in three development-stage products licensed to Pfizer and for the return of these products to us.

On April 9, 2014, we entered into a second letter agreement with Pfizer providing for the termination of the Pfizer Agreement and the return of Aversion Oxycodone to us effective April 9, 2014. The letter agreement further provides that (i) Pfizer will cease the development, marketing and sale of any product using our technologies effective April 9, 2014, (ii) Pfizer will retain its Oxecta® trademark, (iii) Pfizer will transfer to us of all studies, data, regulatory filings (including the NDA) and all other information relating to Aversion Oxycodone pursuant to a transition process described in the letter agreement, (iv) we will remit to Pfizer a one-time termination payment of $2.0 million, and (v) each party waives all claims against the other relating to the Pfizer Agreement. Pfizer's royalty payment obligations relating to Aversion Oxycodone ceased effective April 9, 2014 and all royalty payments due to us have been received. Our termination payment of $2.0 million has been recorded on our financial statements as an intangible asset and will be amortized over the remaining useful life of the patent. The intangible asset will be periodically assessed on its recorded value for impairment. We plan to enter into a license agreement with another pharmaceutical company for the manufacture and sale of Aversion Oxycodone in the United States and possibly other territories, of which no assurance can be given.

Paragraph IV ANDA Litigation

On or about September 17, 2012, we believe the FDA internally changed the status of Aversion Oxycodone 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 Aversion Oxycodone as an RLD, the FDA was allowed to accept ANDAs referencing Aversion Oxycodone.

On September 20, 2012, we announced that we had received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from a generic sponsor of an ANDA for a generic drug listing Aversion Oxycodone as the reference listed drug. Since such date, we have received similar Paragraph IV Notices from three other generic pharmaceutical companies that have filed ANDAs listing Aversion Oxycodone as the reference drug. 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 Aversion Oxycodone. The Paragraph IV Notices state that each generic sponsor believes that such patents are invalid, unenforceable or not infringed. On October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. – Florida (Watson), Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc., and on April 29, 2013, we initiated suit against Ranbaxy, Inc., each in the United States District Court for the District of Delaware alleging infringement of our U.S. Patent No. 7,510,726 listed in the FDA's Orange Book. The commencement of such litigation prohibits the FDA from granting approval of the filed ANDAs until the earliest of 30 months from the date the FDA accepted the application for filing, or the conclusion of litigation. In January 2013, we dismissed our suit against Watson on the grounds that Watson had amended its ANDA from a Paragraph IV Certification to a Paragraph III Certification, which indicated its intent not to market its generic Aversion Oxycodone product in advance of our patent 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 Aversion Oxycodone 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 Aversion Oxycodone 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 Aversion Oxycodone 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 Aversion Oxycodone product.

Under the Settlement Agreement with Impax, Impax may launch its generic Aversion Oxycodone 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 Aversion Oxycodone 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 Aversion Oxycodone 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.

On May 8, 2014, we announced that we had entered into a Settlement Agreement with Ranbaxy Inc. to settle our patent infringement action pending in the United States District Court for the District of Delaware. In the suit, we alleged that a generic of our Aversion Oxycodone product for which Ranbaxy is seeking approval to market in the United States pursuant to an ANDA filed with the FDA infringes U.S. patents owned by us. The Settlement Agreement provides that Ranbaxy's current generic of our Aversion Oxycodone product that is the subject of its ANDA filing does not infringe our Orange Book listed patents with the FDA. We have not provided Ranbaxy a license to our patents and we may re-commence patent infringement litigation against Ranbaxy if Ranbaxy changes the formulation of its current generic Aversion Oxycodone product.

On May 21, 2014, we announced that we had entered into a Settlement Agreement with Sandoz Inc. to settle our patent infringement action pending against Sandoz in the United States District Court for the District of Delaware. In the suit, we alleged that a generic of our AVERSION® oxycodone product for which Sandoz is seeking approval to market in the United States pursuant to an ANDA filed with the FDA infringes a U.S. patent owned by us. Under the Settlement Agreement, Sandoz may launch its generic to the AVERSION® oxycodone product in the U.S., through the grant of a non-exclusive license from us that would trigger 180 days following the first sale of a generic to the AVERSION® oxycodone 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 to the AVERSION® oxycodone product is first sold in the U.S). In certain circumstances, our license to Sandoz would become effective prior to such time. Sandoz is not obligated to pay us a royalty if its current formulation of its generic to the AVERSION® oxycodone product is approved by the FDA. In the event Sandoz changes or modifies the structure of its generic AVERSION® oxycodone product, or materially changes or modifies the amounts or type of any excipient used in the Sandoz formulation disclosed in its ANDA filing with the FDA as of July 30, 2013, Sandoz is required to pay us a royalty based upon the Net Profits (as defined in the Settlement Agreement) derived from the net sales of such changed or modified Sandoz generic AVERSION® oxycodone product in the United States.

Litigation is inherently uncertain and we cannot predict the outcome of these infringement actions. It is possible that other generic manufacturers may also seek to launch a generic version of Aversion Oxycodone and challenge our patents. Any determination in such infringement actions that our patents covering our Aversion Technology and Aversion Oxycodone are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents could have a material adverse effect on our operations and financial condition.

By designating Aversion Oxycodone as an RLD, we believe the FDA has acknowledged that Aversion Oxycodone contains unique properties and/or a unique label that is different from other FDA approved immediate-release oxycodone HCl tablets that do not contain abuse resistant characteristics. As required by the Food and Drug Administration Safety and Innovation Act of July 2012, the FDA published for comment draft guidance on the development of abuse-deterrent drug products in January 2013. We believe the ANDA applicants that refer to Aversion Oxycodone as an RLD will have to have substantially equivalent, if not identical, abuse deterrent characteristics to be considered by the FDA as therapeutically equivalent to Aversion Oxycodone. There can be no assurance, however, that FDA will rely on such guidance for ANDA applicants.

NOTE 4 - 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. We record revenue from our 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. We sell Nexafed in the United States to wholesale pharmaceutical distributors 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, we currently cannot reliably estimate expected returns of the product at the time of shipment to certain customers. Accordingly, at September 30, 2014 we had deferred the recognition of revenue on $0.23 million of Nexafed shipments to these customers until the right of return no longer exists or adequate history and information becomes available to estimate product returns.

Commencing in February 2013, we began earning royalties based on net sales of Aversion Oxycodone by Pfizer. We have earned royalties of approximately $4 thousand for the nine months ended September 30, 2014. The Pfizer Agreement was terminated effective April 9, 2014 and Pfizer's royalty payment obligations ceased as of such date. All royalties owed to us have been received.

Shipping and Handling Costs

We record shipping and handling costs in selling expenses. The amounts recorded to selling expenses from the shipments of Nexafed during each of the three month periods ended September 30, 2014 and 2013 were not material.

NOTE 5 - RESEARCH AND DEVELOPMENT ACTIVITIES

Research and Development ("R&D") expenses include internal R&D activities, external Contract Research Organization ("CRO") services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. We make payments to the CRO's based on agreed upon terms and may include payments in advance of a study starting date. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Accrued CRO expenses 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 $0.2 million in accrued CRO expenses and clinical trial study and regulatory expenses at September 30, 2014. We did not have any of these accrued expenses at December 31, 2013. At December 31, 2013, we had $0.36 million of prepaid CRO costs and clinical trial study and regulatory expenses. We did not have any of these prepaid expenses at September 30, 2014.

NOTE 6 - INVESTMENTS IN MARKETABLE SECURITIES

Investments in marketable securities consisted of the following:

	September 30, 2014 (in millions)	December 31, 2013 (in millions)
Marketable securities:		
Corporate bonds — maturing within 1 year	$ 3.5	$ 3.1
Corporate bonds — maturing after 1 through 3 years	4.8	5.9
Corporate bonds — maturing after 3 through 4 years	-	0.9
Exchange-traded funds	5.0	3.8
Total marketable securities	$ 13.3	$ 13.7

Our marketable securities are classified as available-for-sale and are recorded at fair value based on quoted market prices 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 our available-for-sale securities (in millions):

	September 30, 2014 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 8.3	$ -	$ -	$ 8.3
Exchange-traded funds	5.0	-	-	5.0
Total - Current	$ 13.3	$ -	$ -	$ 13.3

	December 31, 2013 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 9.9	$ -	$ -	$ 9.9
Exchange-traded funds	3.8	-	-	3.8
Total - Current	$ 13.7	$ -	$ -	$ 13.7

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.

Our assets measured at fair value or disclosed at fair value on a recurring basis as at September 30, 2014 and December 31, 2013 consisted of the following (in millions):

	September 30, 2014 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	$ 8.3	$ 8.3	$ -	$ -
Exchange-traded funds	5.0	5.0	-	-
Total	$ 13.3	$ 13.3	$ -	$ -

	December 31, 2013 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	$ 9.9	$ 9.9	$ -	$ -
Exchange-traded funds	3.8	3.8	-	-
Total	$ 13.7	$ 13.7	$ -	$ -

Accumulated Other Comprehensive Income (Loss)

Unrealized gains or losses on marketable securities are recorded in accumulated other comprehensive income (loss). Accumulated other comprehensive income (loss) at September 30, 2014 consisted of unrealized gains on securities of $25 thousand. Accumulated other comprehensive income (loss) at December 31, 2013 consisted of unrealized gains on securities of $19 thousand.

Comprehensive Income (Loss)

Comprehensive income (loss) includes all changes in equity during a period except those that resulted from investments by or distributions to our 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. Our 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 both raw and packaging materials on our Aversion Oxycodone product and finished goods held for distribution and sale on our Nexafed product. Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value). We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results. Our inventory reserve activities during the nine months ended September 30, 2014 was to record a $0.2 million reserve expense and have actual Nexafed inventory write-offs of $0.45 million.

The related cost of sales on $0.23 million deferred revenue from our Nexafed shipments is excluded from the value of the September 30, 2014 inventories and is reported in our balance sheet in the other current deferred assets account. We will recognize the revenue and cost of sales on these Nexafed shipments once the right of return no longer exists or adequate history and information becomes available to estimate product returns.

Our purchases of ingredients and other materials required in our development and clinical trial activities are expensed as incurred.

Inventories are summarized as follows:

	September 30, 2014	December 31, 2013
	(in thousands)	
Raw and packaging materials	$ 260	$ -
Finished goods	143	501
Total Inventory	403	501
Less: inventory reserve for finished goods	(-)	(250)
Net Inventory	$ 403	$ 251

NOTE 8 - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	September 30, 2014	December 31, 2013
	(in thousands)	
Payroll, payroll taxes, bonus and benefits	$ 339	$ 78
Professional services	228	293
Interest – current portion	69	-
Franchise taxes	9	1
Property taxes	17	15
Contract manufacturing services	-	14
Clinical and regulatory services	179	-
Other	647	140
Total	$ 1,488	$ 541

NOTE 9 – DEBT

On December 27, 2013, we entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford" or the "Lender"), for a term loan to us in the principal amount of $10.0 million (the "Term Loan"). The full principal amount of the Term Loan was funded on December 27, 2013. We may use the proceeds of the Loan Agreement for general working capital and to fund our business requirements. We estimate the fair value of our notes payable to be its carrying value due to its recent funding.

The Term Loan accrues interest at a fixed rate of 8.35% per annum (with a default rate of 13.35% per annum). We are required to make monthly interest−only payments until the Amortization Date and starting on the Amortization Date, we are required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through the maturity date of December 1, 2018. The "Amortization Date" is April 1, 2015, but shall automatically become April 1, 2016 if we achieve 75% of our projected Nexafed cash receipts and 75% of our projected Aversion Oxycodone cash receipts for the fiscal year ending December 31, 2014 (collectively, the "First Revenue Event"). The Amortization Date will be further deferred until April 1, 2017 if the First Revenue Event occurs and in addition we achieve 75% of our projected Nexafed cash receipts and 75% of our projected Aversion Oxycodone cash receipts for the fiscal year ending December 31, 2015 (collectively, the "Second Revenue Event"). In view of the termination of the Pfizer Agreement in April 2014 and the return of Aversion Oxycodone to us, and the absence of sales of Aversion Oxycodone since such date pending the completion of a license agreement with another pharmaceutical company for the manufacture and sale of Aversion Oxycodone, we expect the Amortization Date of the Term Loan with Oxford will be April 1, 2015, at which date we will commence repayment of principal under the Term Loan. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on December 1, 2018. As security for our obligations under the Loan Agreement, we granted Lender a security interest in substantially all of our existing and after−acquired assets, exclusive of our intellectual property assets. Pursuant to the Loan Agreement, we are not allowed to pledge our intellectual property assets to others.

We may voluntarily prepay the Term Loan in full, but not in part, and any prepayment is subject to a prepayment premium equal to 3% of the principal prepaid if prepaid on or prior to December 27, 2014, 2% of the principal prepaid, if prepaid after December 27, 2014 but on or prior to December 27, 2015, and 1% of the principal prepaid if prepaid after December 27, 2015. In addition, at the maturity, termination or upon voluntary or mandatory prepayment of the Term Loan we must pay the Lender an additional one-time interest payment of (A) $795 thousand if the First Revenue Event does not occur, (B) $895 thousand if the First Revenue Event occurs but the Second Revenue Event does not occur, or (C) $995 thousand if both the First Revenue Event and the Second Revenue Event occur. We will incur and accrue additional monthly interest expense over the term of the loan for this additional one-time interest payment using the loan's effective interest rate.

We were obligated to pay customary lender fees and expenses, including a one-time facility fee of $50 thousand and the Lender's expenses in connection with the Loan Agreement. Combined with our own expenses and a $100 thousand consulting placement fee, we incurred $231 thousand in deferred debt issue costs. We will amortize those costs to interest expense over the term of the loan using the loan's effective interest rate.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, limits or restrictions on our ability to incur liens, incur indebtedness, pay dividends, redeem stock, and merge or consolidate and dispose of assets. In addition, it contains customary events of default that entitles the Lender to cause any or all of our indebtedness under the Loan Agreement to become immediately due and payable. The events of default (some of which are subject to applicable grace or cure periods), include, among other things, non−payment defaults, covenant defaults, a material adverse change in the Company, bankruptcy and insolvency defaults and material judgment defaults.

We issued to the Lender warrants to purchase an aggregate of up to 298 thousand shares of our common stock at an exercise price equal to $1.595 per share (the "Warrants"). We recorded $400 thousand as debt discount associated with the fair value of the Warrants and will amortize those costs to interest expense over the term of the loan using the loan's effective interest rate. The Warrants are immediately exercisable for cash or by net exercise and will expire December 27, 2020.
Our interest expense consisted of the following:

	Three months Ended September 30,		Nine months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)			
Interest expense:				
Secured Promissory notes	$ 257	$ -	$ 767	$ -
Debt discount	30	-	89	-
Debt issue costs	17	-	51	-
Total interest expense	$ 304	$ -	$ 907	$ -

The annual principal payments on the long-term debt at September 30, 2014 are as follows for each of the periods ending December 31:

	Annual Principal Payments
	(in thousands)
2014	$ -
2015	1,758
2016	2,522
2017	2,741
2018	2,979
Thereafter	-
Total	$ 10,000

NOTE 10 - COMMON STOCK WARRANTS

We have outstanding common stock purchase warrants ("warrants") exercisable for 298 thousand shares of our common stock having an exercise price of $1.595 per share with an expiration date in December 2020. These warrants contain a cashless exercise feature. Our common stock warrant activity during the nine months ended September 30, 2014 and 2013 is shown below:

	Nine months Ended September 30,			
	2014		2013	
	Number (000's)	Weighted Average Exercise Price	Number (000's)	Weighted Average Exercise Price
Outstanding, beginning	2,154	$ 3.15	1,856	$ 3.40
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	(1,856)	3.40	-	-
Outstanding, ending	298	$ 1.60	1,856	$ 3.40

NOTE 11 - SHARE-BASED COMPENSATION

Share-based Compensation

We have three share-based compensation plans covering stock options and RSUs 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 comprised the following:

	Three months Ended September 30,		Nine months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)			
Stock options				
Research and development	$ 57	$ 81	$ 170	$ 243
General and administrative	141	234	423	702
Total	$ 198	$ 315	$ 593	$ 945
RSUs				
General and administrative	$ 31	$ -	$ 123	$ -
Combined	$ 229	$ 315	$ 716	$ 945

Stock Option Award Plans

We have one stock option plan in effect, and one stock option plan has expired by its terms, but pursuant to which stock options have been granted and remain outstanding. Our stock option award activity during the nine months ended September 30, 2014 and 2013 is shown below:

	Nine months Ended September 30,			
	2014		2013	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, beginning	3,738	$ 4.99	3,296	$ 5.50
Granted	-	-	75	2.32
Exercised	(31)	1.30	(14)	1.30
Forfeited or expired	(30)	3.60	(75)	5.02
Outstanding, ending	3,677	$ 5.03	3,282	$ 5.46
Options exercisable	3,370	$ 5.33	3,021	$ 5.70

There were no stock option grants during the nine month period ended September 30, 2014. The assumptions used in the Black-Scholes model to determine fair value for the stock option awards granted during the comparable period are shown below:

	Nine months Ended September 30, 2013
Expected dividend yield	0.0%
Risk-free interest rates	1.86%
Average expected volatility	114%
Expected term (years)	10
Weighted average grant date fair value	$ 2.17

During the nine months ended September 30, 2014, 31 thousand NonISOs were exercised by our employees. Our employees elected to have 18 thousand shares withheld in satisfaction of $36 thousand for both the exercise costs and withholding tax obligations resulting in the net issuance of 13 thousand shares of common stock to them. 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.

Restricted Stock Unit Award Plan

We have two Restricted Stock Unit Award Plans for our employees and non-employee directors. Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. The share-based compensation cost to be incurred on a granted RSU is the RSU's fair value, which is the market price of our common stock on the date of grant, less its exercise cost. The compensation cost is amortized to expense over the vesting period of the RSU award.

Under our 2005 Restricted Stock Unit Award Plan (the "2005 RSU Plan"), one-fourth of vested shares of common stock underlying an RSU award were distributed (after payment of $0.01 par value per share) on January 1 of each of 2011 thru 2014. Effective January 1, 2014, all RSUs granted under the 2005 RSU Plan had been distributed. The distribution dates of January 1, 2013 and 2014 each consisting of 0.83 million shares and occurred as follows:

- On January 1, 2013, 0.50 million shares were distributed to the holders while 0.33 million shares were withheld by the Company upon elections made to exchange RSUs in satisfaction of $0.7 million withholding tax obligations; and
- On January 1, 2014, 0.50 million shares were distributed to the holders while 0.33 million shares were withheld by the Company upon elections made to exchange RSUs in satisfaction of $0.5 million withholding tax obligations.

Our 2014 Restricted Stock Unit Award Plan (the "2014 RSU Plan") was approved by shareholders on May 1, 2014 and permits the grant of up to 2.0 million shares of our common stock pursuant to awards under the 2014 RSU Plan. On May 1, 2014, we awarded 36,764 RSUs to each of our 4 non-employee directors. Such RSU awards vest 50% on June 30, 2014 and 25% on each of September 30 and December 31, 2014. Such non-employee director awards allow for non-employee directors to receive payment in cash, instead of stock, for up to 40% of each RSU award. The RSU awards subject to cash settlement are recorded as a liability in the Company's balance sheet. The liability was not material at September 30, 2014. Accordingly the vested portion of the awards containing the cash settlement feature will be marked-to-market each reporting period until they are distributed. Marked-to-market accounting can create fluctuations in our compensation expense including the need to record additional expense. RSU awards are generally distributed on the first business day of the year after vesting, but such distribution can be deferred until a later date at the election of the non-employee director.

A summary of the grants under the 2005 RSU Plan and the 2014 RSU Plan as of September 30, 2014 and 2013 and for the nine months then ended consisted of the following (in thousands):

	Nine months Ended September 30,			
	2014		2013	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
	(in thousands)			
Outstanding, beginning	829	829	1,658	1,658
Granted	147	-	-	-
Distributed	(829)	(829)	(829)	(829)
Vested	-	110	-	-
Forfeited or expired	-	-	-	-
Outstanding, ending	147	110	829	829

NOTE 12 – INCOME TAXES

We account 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, 2014 and December 31, 2013, 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. We have approximately $46.8 million federal income tax benefits at December 31, 2013 derived from $137.6 million Federal NOLs at the U.S. statutory tax rate of 34% and $2.8 million state NOLs, available to offset future taxable income, some of which have limitations for use as prescribed under IRC Section 382. Our NOL carryforwards will expire in varying amounts between 2014 and 2033 if not used, and those expirations will cause fluctuations in our valuation allowances. As of September 30, 2014 we had federal research and development tax credits of approximately $1.1 million, which expire in the years 2024 through 2033, and we had approximately $0.4 million of Indiana state research and development tax credits, which expire in the years 2014 through 2017.

NOTE 13 – 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. (See Note 11). Diluted EPS is based on the treasury stock method and computed based on the same number of shares used in the basic share calculation and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and stock warrants, assuming the exercise of all in-the-money stock options and warrants. Common stock equivalents are excluded from the computation where their inclusion would be anti-dilutive. No such adjustments were made for 2014 or 2013 as the Company reported a net loss for the three and nine month periods, and including the effects of common stock equivalents in the diluted EPS calculation which would have been antidilutive.

A reconciliation of the numerators and denominators of basic and diluted EPS consisted of the following:

	Three months Ended September 30,		Nine months Ended September 30,	
	2014	2013	2014	2013
EPS – basic and diluted				
Numerator: net loss	$ (2,904)	$ (3,190)	$ (10,513)	$ (10,484)
Denominator:				
Common shares	48,848	46,629	48,846	46,468
Vested RSUs	74	829	25	829
Basic and diluted weighted average shares outstanding	48,922	47,458	48,871	47,297
EPS – basic and diluted	$ (0.06)	$ (0.07)	$ (0.22)	$ (0.22)
Excluded securities:				
Common shares issuable:				
Stock options	3,677	3,282	3,677	3,282
Nonvested RSUs	37	-	37	-
Common stock warrants	298	1,856	298	1,856
Total excluded common shares	4,012	5,138	4,012	5,138

NOTE 14 – COMMITMENTS AND CONTINGENCIES

Facility Lease

The Company leases administrative office space in Palatine, Illinois under a lease expiring March 31, 2015 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 addition, Acura was served with a similar complaint by two individual plaintiffs in Nebraska federal court. 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 action, 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. In the New Jersey action, plaintiffs filed approximately 150 lawsuits against us, but served less than 50 individual lawsuits upon us. In the California action, there are 89 pending cases against us, with more than 445 individual plaintiffs.

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 18 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 September 2012, the New Jersey trial court dismissed Acura with prejudice. In Pennsylvania, and California, Generic Defendants, including Acura, also filed dispositive motions based on the *Mensing* decision.

In Pennsylvania, on September 17, 2014, the Supreme Court declined to hear appeals from the Pennsylvania Superior Court's July 29, 2013 decision reversing, on limited grounds, the trial court's November 18, 2011 denial of Generic Defendants' dispositive motions. A further appeal is being taken to the United States Supreme Court requesting that all claims against Generic Defendants should be barred based upon application of federal preemption under *Mensing*. All trial court proceedings have been stayed pending resolution of this lengthy appeal process. To the extent that plaintiffs intend to pursue their claims in the future, if the appeal is denied, Acura nonetheless remains optimistic that most, if not all, of these Philadelphia cases will eventually be dismissed against us based upon the favorable aspects of the Superior Court's narrow preemption ruling and lack of product identification, 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." To date, however, none of these plaintiffs have 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. Legal fees related to this matter are currently covered by our insurance carrier.

In Nebraska, the litigation against Acura was stayed. Plaintiffs have agreed to a dismissal since they have been unable to uncover any evidence of ingestion of generic metoclopramide manufactured by us. Legal fees related to this matter are currently covered by our insurance carrier.

As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of September 30, 2014 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

Westport/Highland Complaint

On April 21, 2014, we obtained a copy of a Complaint filed by Westport Pharmaceuticals, LLC ("Westport") and Highland Pharmaceuticals, LLC ("Highland") in the U.S. District Court for the Eastern District of Missouri naming us as the defendant. To date, we have not been formally served with this Complaint. In the Complaint, each of Westport and Highland are commencing a declaratory judgment action seeking a declaration of non-infringement of our U.S. Patent No. 8,409,616 ("616 Patent") by Westport's Zephrex-D® (pseudoephedrine hydrochloride, 30mg) product, to enable Westport to continue to sell Zephrex-D and to allow retail distributors to continue to sell Zephrex-D, a competing product to Nexafed. The Highland Complaint has been dismissed following the execution by Acura and Highland of a settlement agreement pursuant to which we granted Highland a non-exclusive license to certain Acura patents for use in certain pseudoephedrine – containing products.

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:

- the results of our dispute resolution request with the FDA, including any appeal therefrom, relating to our Aversion hydrocodone/acetaminophen product;
- the results of our development of our Limitx™ technology;
- our ability to fund, or obtain funding for, products developed utilizing our Limitx™ technology;

- our ability to enter into a license agreement for our FDA approved Aversion Oxycodone product;
- our and our licensee's ability to successfully launch and commercialize our products and technologies including Aversion Oxycodone and Nexafed Tablets;
- the results of our meetings or discussions with the FDA relating to our Aversion hydrocodone/acetaminophen product;
- whether the results of studies AP-ADF-302, AP-ADF-303, and AP-ADF-304 relating to our Aversion hydrocodone/acetaminophen product will be acceptable to the FDA;
- whether we will conduct an additional intranasal abuse liability study on our Aversion hydrocodone/acetaminophen product and, if conducted, whether the results of such study will support the filing of a New Drug Application and/or a claim of intranasal abuse deterrence;
- our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- 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 Aversion Technology product candidates;
- our exposure to product liability and other lawsuits in connection with the commercialization of our products;
- the increasing 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;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- 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 process to meet 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;
- 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; and

- whether our Aversion and Limitx™ 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,” “indicates,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in this Report and in our filings with the Securities and Exchange Commission.

Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

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

Company Overview

We are a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. 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. Oxycodone HCl tablets, CII, or Aversion Oxycodone, is the first approved product utilizing Aversion in the United States and we have 7 additional opioid products utilizing Aversion in various stages of development. In April 2014, we reacquired Aversion Oxycodone from our prior licensee and intend to seek a commercialization partner for that product and our Aversion opioids in development. We have also developed Impede® Technology which is a combination of inactive ingredients that prevent the extraction of pseudoephedrine from tablets and disrupt the direct conversion of pseudoephedrine from tablets into methamphetamine. We launched our first Impede Technology product, Nexafed®, into the United States market in December 2012 and we have multiple pseudoephedrine products in development utilizing Impede. In August 2014, we received a grant from the National Institute on Drug Abuse to advance early stage development of our third abuse deterrent technology, Limitx™. Limitx is designed to retard the release of active drug ingredients when too many tablets are accidently or purposefully ingested.

Opioid analgesics are one of the largest prescription drug markets in the United States with 253 million prescriptions dispensed in 2013. Prescription opioids are also the most widely abused drugs with 12 million people abusing or misusing these products annually. We expect our Aversion Technology opioid products to compete primarily in the immediate-release opioid product segment. Because immediate-release opioid products are used for both acute and chronic pain, a prescription, on average, contains 65 tablets or capsules. According to IMS Health, in 2013, sales in the immediate-release opioid product segment were approximately 238 million prescriptions and $2.6 billion, of which ~97% was attributable to generic products. Immediate-release oxycodone tablets represent 16.7 million of these prescriptions or almost 1.6 billion tablets. The FDA approved label for our Aversion Oxycodone product describes the unique, and we believe promotable, abuse deterrent features of our product which we believe makes prescribing our product attractive to some healthcare providers.

Hydrocodone bitartrate with acetaminophen, or hydrocodone/acetaminophen, is the most widely prescribed and often abused opioid product in the United States. Our Aversion hydrocodone/acetaminophen product is the most advanced opioid product in development and the primary focus of our opioid development efforts. On December 5, 2013, we met with the FDA to discuss the results of Study AP-ADF-301, or Study 301, a key abuse liability study for our Aversion hydrocodone/acetaminophen product and whether the results from Study 301 are acceptable for submission in a New Drug Application, or NDA. On May 27, 2014, we announced that the FDA advised us that the data from our Study 301 was insufficient to support an intranasal abuse deterrence description in our product labeling. The FDA indicated that a product will have to have an impact on “drug liking” to support a description of abuse-deterrence through a relevant route of abuse. The FDA’s advice also questioned whether the intranasal route is a relevant route of abuse for hydrocodone/acetaminophen products. We met with the FDA on August 14, 2014 to discuss the development pathway for our Aversion hydrocodone/acetaminophen tablet development candidate, which is intended to provide abuse-deterrent features to address abuse by nasal snorting and injection. The FDA continues to question the relevance of abuse of hydrocodone with acetaminophen products by the intranasal route of administration.

On September 11, 2014, we submitted a formal dispute resolution request with the FDA. The dispute pertains to the FDA's determination that nasal snorting abuse of hydrocodone with acetaminophen products lacks relevance. We believe the available data, as contained in the multiple sources provided to the FDA, strongly supports the conclusion that hydrocodone containing products are known to be abused through snorting, a standard explicitly identified in FDA's January 2013 "Guidance for Industry Abuse-Deterrent Opioids — Evaluation and Labeling". On October 16, 2014, we announced that the FDA denied on procedural grounds our appeal of the position taken by the Division of Anesthesia, Analgesia and Addiction Products ("DAAAP") that abuse by snorting hydrocodone with acetaminophen products lacks relevance. In a letter decision from the Office of Drug Evaluation II, the FDA indicated that DAAAP's comments and correspondence with us to date, as well as the FDA's Draft Guidance on abuse deterrent opioids, should be viewed only as recommendations and opinions, and do not preclude us from completing clinical development of our hydrocodone with acetaminophen product and submitting an NDA for consideration by the FDA. The FDA noted that an Advisory Committee meeting may greatly inform their considerations. The FDA letter ruling also advised us that we may appeal the decision of the Office of Drug Evaluation II to the next level within the FDA. We are currently assessing our development strategy for our Aversion hydrocodone with acetaminophen product, including the merits of appealing the FDA's decision. Even if we were to file an appeal and succeed in such proceeding, in order to continue the development of our hydrocodone/acetaminophen product we will be required to conduct an additional abuse liability study that will need to demonstrate a statistically significant reduction in Drug Liking, of which no assurance can be provided. We are currently in the process of designing this next study and will make a decision on commencing this study in 2015.

We expect that the development program for all our Aversion opioid products in development will be consistent with that of Aversion Oxycodone and our hydrocodone/acetaminophen product candidate.

In 2009, the United States market for over-the-counter market, or OTC, cold and allergy products containing an oral nasal decongestant was approximately $1 billion. In 2012, the DEA reported 11,210 laboratory incidents involving the illegal use of OTC pseudoephedrine products to manufacture the highly addictive drug methamphetamine, or meth. Nexafed, our 30mg pseudoephedrine hydrochloride immediate-release tablet utilizing our Impede Technology, is stocked in approximately 15% of the estimated 65,000 U.S. pharmacies. Many of these pharmacies are either actively recommending Nexafed to their patients or carry Nexafed as their only 30mg pseudoephedrine product. The category for meth-resistant pseudoephedrine products has also been the focus of some, as yet unsuccessful, state legislation seeking to incentivize consumers and pharmacists to utilize these meth-resistant technologies.

We are advancing commercial preparations to launch the first line extension of Nexafed into the U.S. market later in 2014 and have an active development program to develop a sustained-release version of our technology to capitalize on higher sales products in the category. We also are investigating new technologies that would improve on our meth-resistant capabilities.

We also have discovered an early-stage technology, Limitx™, 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. All of our Aversion Technology opioid products are covered by six issued U.S. patents, which 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 above may 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.

Aversion Oxycodone

Aversion Oxycodone 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. Aversion Oxycodone was FDA approved on June 17, 2011 and introduced, by our former licensee, Pfizer Inc., into the U.S. market in February 2012 under the trade name Oxecta®. Pfizer strategically deprioritized their efforts in immediate-release opioids commencing in summer of 2012 and we reacquired the rights to Aversion Oxycodone in April 2014, shortly after Pfizer initiated minimal, non-sales representative promotion in late 2013. We currently expect to partner with a strategically focused pharmaceutical company to manufacture and commercialize Aversion Oxycodone in the United States and possibly other territories by end of this year or early 2015. As such, we now expect the re-launch to occur in the first half of 2015. However, we caution that this expectation can change based on the status of the negotiations, and there can be no assurance that this will be the case.

The 2013 market for immediate-release oxycodone products was 16.7 million dispensed prescription or 1.6 billion tablets. The current market is predominately serviced by generic formulations that contain no abuse deterrent features and sell for approximately $0.10 to $0.40 per tablet, depending on strength. Immediate-release opioids are prescribed by a broad cross-section of healthcare providers including primary care physicians, surgeons and pain specialists. We believe Aversion Oxycodone, given its differentiated label compared to generic products, can offer an alternative for opioid prescribing physicians concerned with the abuse or diversion for abuse of their prescriptions even at premium pricing to generics. Because the target audience for promoting our opioid products is so large, we will seek marketing partners to best capitalize on our opioid opportunities.

The safety and efficacy of Aversion Oxycodone 5mg and 7.5mg tablets was established by demonstrating bioequivalence to commercially available oxycodone immediate-release tablets in the fasted state. Aversion Oxycodone differs from oxycodone tablets when taken with a high fat meal though these differences are not considered clinically relevant, and Aversion Oxycodone can be taken without regard to food. The FDA-approved label for Aversion Oxycodone describes elements unique to our Aversion Technology, which differs from current commercially available oxycodone immediate-release tablets. The label for Aversion Oxycodone includes the results from a clinical study that evaluated the effects of nasally snorting crushed Aversion Oxycodone and commercially available oxycodone tablets, and limitations on exposing Aversion Oxycodone 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 Aversion Oxycodone responded that they would not take the drug again compared to 5% of subjects exposed to immediate-release oxycodone;
- subjects taking Aversion Oxycodone reported a higher incidence of nasopharyngeal and facial adverse events compared to immediate-release oxycodone;
- a decreased ability to completely insufflate two crushed Aversion Oxycodone 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 Aversion Oxycodone than immediate-release oxycodone.

Although we believe these abuse deterrent characteristics differentiate Aversion Oxycodone 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 Aversion Oxycodone has a reduced abuse liability compared to immediate release oxycodone. We have a post-approval commitment with the FDA to perform an epidemiology study to assess the actual impact on abuse of Aversion Oxycodone tablets.

Further, the Aversion Oxycodone 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 Aversion Oxycodone for administration via nasogastric, gastric or other feeding tubes as it may cause an obstruction. Our laboratory studies demonstrated that the Aversion Oxycodone tablet may gel when Aversion Oxycodone is exposed to certain solvents, including water.

Aversion Technology Opioid Products in Development

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

Aversion Technology Tablets	Comparable Brand Name[1]	Status
Hydrocodone bitartrate/acetaminophen	Vicodin®, Lortab®, Norco®	All clinical work is complete except a repeat nasal snorting abuse liability study will be required. We are assessing FDA's view that abuse by nasal snorting lacks relevance before continuing the development program.
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 (derived from the initial Aversion formulation) and will require reformulation.

We anticipate the development program for each of our Aversion opioid products will be consistent with that of Aversion Oxycodone. Because our products use known active ingredients in approved dosage strengths, the safety and efficacy of the Aversion opioid will be established by a series of pharmacokinetic studies demonstrating: (a) bioequivalence to an approved reference drug, (b) food effect of our formulations, and (c) dose proportionality of our formulation.

The abuse deterrent studies of the Aversion products will be consistent with FDA's draft guidance for the development of abuse deterrent opioids with the objective to obtain a description of our studies and/or abuse deterrent features in the product's label. These studies may include in vitro laboratory studies to determine, among other things, syringeability of the formulation, extractability of the opioid, and particle size of the crushed product. We also may conduct human abuse liability studies comparing the abuse liability of Aversion products to currently marketed products.

We may have to perform additional safety and/or efficacy assessment as may be identified by the FDA for each specific formulation during the IND or NDA phase of development. In accordance with the FDA draft guidance, we will likely have a post-approval requirement for each of our products, if approved, to perform an epidemiology study to assess the in-market impact on abuse of our formulation.

We believe that the time to develop each Aversion opioid product from IND to NDA submission can be as short as 18 months to 24 months, provided all studies meet their primary study objectives.

Aversion Hydrocodone/Acetaminophen Development

Our most advanced opioid development product is Aversion hydrocodone/acetaminophen. Our clinical development program for our hydrocodone/acetaminophen product is expected to consist of:

- A nasal abuse liability liking study in about 40 recreational drug users against a reference drug, or Study AP-ADF-301 (*complete*);
- A pharmacokinetic study (Study AP-ADF-302) in about 36 fasted subjects to establish bioequivalence to the FDA's reference listed drug and determine the food effect on our drug (*complete*);
- A pharmacokinetic study (Study AP-ADF-303) in about 24 subjects demonstrating dose proportionality of our formulation (*complete*);
- A pharmacokinetic study (Study AP-ADF-304) in about 24 subjects to establish safety compared to the reference listed drugs tramadol/acetaminophen (for acetaminophen) and hydrocodone bitartrate/ibuprofen (for hydrocodone) (*complete*);
- Laboratory studies demonstrating extraction, syringing, swelling and particle size characteristics of our product (*in progress*);
- An assessment of the routes of abuse of hydrocodone products (*complete*); and
- An additional nasal abuse liability study in recreational drug users against a reference drug (*under strategic review*).

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 hydrocodone/acetaminophen 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. Due to this observed carryover effect, the FDA may review the results of our study differently than we have and/or limit the amount of data we collected in the label for our product if approved by the FDA. As such, we are strategically considering the need to complete an additional nasal abuse liability study.

On December 5, 2013, we met with FDA to discuss if the FDA will consider whether the results of Study 301 are acceptable for submission in a NDA. On May 27, 2014, we announced that the FDA advised us that the data from our Study 301 was insufficient to support an intranasal abuse deterrence claim. The FDA indicated that a product will have to have an impact on “drug liking” to support a claim of abuse-deterrence through a relevant route of abuse. The FDA’s advice also questioned whether the intranasal route is a relevant route of abuse for hydrocodone/ acetaminophen products and recommended that we identify variables that could have impacted the findings from Study 301 before considering or conducting an additional intranasal abuse liability study on our Aversion hydrocodone/ acetaminophen product. We have previously submitted a report to the FDA on the prevalence of abusing hydrocodone products by intranasal administration. We met with the FDA on August 14, 2014 to discuss the development pathway for our Aversion hydrocodone/acetaminophen tablet development candidate, which is intended to provide abuse-deterrent features to address abuse by nasal snorting and injection. The FDA continues to question the relevance of abuse of hydrocodone with acetaminophen products by the intranasal route of administration. The FDA indicated that we may conduct an additional nasal abuse liability study for its Aversion hydrocodone/acetaminophen product candidate.

On September 11, 2014, we submitted a formal dispute resolution request with the FDA. The dispute pertains to the FDA's determination that nasal snorting abuse of hydrocodone with acetaminophen products lacks relevance. We believe the available data, as contained in the multiple sources provided to the FDA, strongly supports the conclusion that hydrocodone containing products are known to be abused through snorting, a standard explicitly identified in FDA's January 2013 "Guidance for Industry Abuse-Deterrent Opioids — Evaluation and Labeling". On October 16, 2014, we announced that the FDA denied on procedural grounds our appeal of the position taken by the Division of Anesthesia, Analgesia and Addiction Products (“DAAAP”) that abuse by snorting hydrocodone with acetaminophen products lacks relevance. In a letter decision from the Office of Drug Evaluation II, the FDA indicated that DAAAP’s comments and correspondence with us to date, as well as the FDA’s Draft Guidance on abuse deterrent opioids, should be viewed only as recommendations and opinions, and do not preclude us from completing clinical development of our hydrocodone with acetaminophen product and submitting an NDA for consideration by the FDA. The FDA noted that an Advisory Committee meeting may greatly inform their considerations. The FDA letter ruling also advised us that we may appeal the decision of the Office of Drug Evaluation II to the next level within the FDA. We are currently assessing our development strategy for our Aversion hydrocodone with acetaminophen product, including the merits of appealing the FDA’s decision. Even if we were to file an appeal and succeed in such proceeding, in order to continue the development of our hydrocodone/acetaminophen product we will be required to conduct an additional abuse liability study that will need to demonstrate a statistically significant reduction in Drug Liking, of which no assurance can be provided. We are currently in the process of designing this next study and will make a decision on commencing this study in 2015.

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 have also completed the pharmacokinetic studies (302, 303 and 304) for Aversion hydrocodone/acetaminophen, the preliminary results of which have demonstrated conformance with the FDA’s standard for bioequivalence when compared to the reference drug, and demonstrated dose proportionality, or relatively consistent blood exposure, across all three dosage strengths. Such studies also evaluated blood levels of each of hydrocodone and acetaminophen compared to their respective comparator drugs, and demonstrated that our Aversion hydrocodone/acetaminophen blood levels of hydrocodone were consistent with the comparator product, while acetaminophen peak blood levels were 23% higher than the comparator product based on the geometric mean. A large variability in acetaminophen results was observed in the study. We believe the results of Studies 302, 303 and 304 satisfy the requirement for a New Drug Application (NDA) to establish the safety and pain efficacy of our Aversion hydrocodone/acetaminophen product, however, the interpretation of these results will be subject to FDA’s review and acceptance of our conclusions. Before submitting and NDA, we will need to complete an additional nasal abuse liability study which is currently undergoing an internal strategic review.

U.S. Market Opportunity for Opioid Analgesic Products Utilizing Aversion Technology

The misuse and abuse of controlled prescription drugs (CPDs) in general, and opioid analgesics in particular, continues to constitute a dynamic and challenging threat to the United States and is the nation’s fastest growing drug problem. Results from the 2013 National Drug Threat Assessment conducted by the DEA report that CPD rates of abuse remain high, with individuals abusing CPDs at a higher prevalence rate than any illicit drug except marijuana. Opioid analgesics are the most common type of CPDs taken illicitly and are the CPDs most commonly involved in overdose incidents. According to the Drug Abuse Warning Network (DAWN), the estimated number of emergency department visits involving nonmedical use of prescription opiates/ opioids increased 112 percent—84,671 to 179,787—between 2006 and 2010. Immediate release, or IR, opioid products comprise the vast majority of this abuse compared with extended release, or ER, opioid products.

It is estimated that more than 75 million people in the United States suffer from pain and the FDA estimates more than 45 million people receive a prescription for the opioid hydrocodone annually. For many pain sufferers, opioid analgesics provide their only pain relief. As a result, opioid analgesics are among the largest prescription drug classes in the United States with over 253 million tablet and capsule prescriptions dispensed in 2013 of which approximately 238 million were for IR opioid products and 15 million were for ER opioid products. However, physicians and other health care providers at times are reluctant to prescribe opioid analgesics for fear of misuse, abuse, and diversion of legitimate prescriptions for illicit use.

We expect our Aversion Technology opioid products, to compete primarily in the IR opioid product segment of the United States opioid analgesic market. Because IR opioid products are used for both acute and chronic pain, a prescription, on average, contains 65 tablets or capsules. According to IMS Health, in 2013, sales in the IR opioid product segment were approximately $2.6 billion, of which ~97% was attributable to generic products. Due to fewer identified competitors and the significantly larger market for dispensed prescriptions for IR opioid products compared to ER opioid products, we have initially focused on developing IR opioid products utilizing our Aversion Technology. Aversion oxycodone and our Aversion Technology products in development include the active opioid ingredients representing approximately 76% of the U.S. IR Opioid Product segment. A summary of the IR opioid product prescription data for 2013 is provided below:

IR Opioid Products[1]	2013 US Prescriptions (Millions)[2]	% of Total
Hydrocodone	128	54%
Oxycodone	52	22
Tramadol	41	17
Codeine	11	5
3 Others	6	2
Total	238	100%

[1] Includes all salts and esters of the opioid and opioids in combination with other active ingredients such as acetaminophen.

[2] IMS Health, 2013

Product Labeling for Aversion Technology Products

In January 2013, the FDA published draft guidance for industry on the evaluation and labeling of abuse-deterrent opioids. While this guidance is non-binding on the FDA, it outlines FDA's current thinking on the labeling of abuse-deterrent products. FDA encourages sponsors to seek approval of proposed product labeling that sets forth the results of physiochemical, physiologic, pharmacodynamic, pharmacokinetic, and/or formal post-marketing studies that appropriately characterizes the abuse-deterrent properties of a product. To date, FDA has limited data correlating the potentially abuse-deterrent properties of certain opioid drug products with actual reduction in abuse or adverse events associated with abuse. When the data predict or show that a product's potentially abuse-deterrent properties can be expected to, or actually do, result in a significant reduction in that product's abuse potential, these data, together with an accurate characterization of what the data mean, should be included in product labeling.

We or our licensee may seek to include descriptions of studies that characterize the abuse-deterrent properties in the label for our Aversion Technology products in development. Although the FDA approved label for Aversion Oxycodone contains limitations on exposing Aversion Oxycodone tablets to water and other solvents and administration through feeding tubes, the FDA approved Aversion Oxycodone label does not contain a description of the I.V. injection studies we performed to characterize the abuse deterrent properties of Aversion Oxycodone. We have committed to the FDA to undertake epidemiological studies to assess the actual consequences of abuse of Aversion Oxycodone in the market. The extent to which a description of the abuse-deterrent properties or results of epidemiological or other studies will be added to or included in the FDA approved product label for our products in development will be the subject of our discussions with the FDA as part of the NDA review process, even after having obtained approval of Aversion Oxycodone. Further, because the FDA closely regulates promotional materials, even if FDA initially approves labeling that includes a description of the abuse deterrent properties of the product, the FDA's Office of Prescription Drug Promotion, or OPDP, will continue to review the acceptability of promotional labeling claims and product advertising campaigns for our marketed products.

Patents and Patent Applications

In April 2007, the United States Patent and Trademark Office, or USPTO, issued to us U.S. Patent No. 7,201,920 titled “Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms,” or the 920 Patent. The 54 allowed claims in the 920 Patent encompass certain pharmaceutical compositions intended to deter the most common methods of prescription opioid analgesic product misuse and abuse. These patented pharmaceutical compositions include the mixture of functional inactive ingredients and specific opioid analgesics such as oxycodone HCl and hydrocodone bitartrate among others. The 920 Patent expires in March, 2025.

In January 2009, the USPTO issued to us U.S. Patent No. 7,476,402, or the 402 Patent, with 18 allowed claims. The 402 Patent encompasses certain combinations of kappa and mu opioid receptor agonists and other ingredients intended to deter opioid analgesic product misuse and abuse. The 402 Patent expires in November, 2023.

In March 2009, the USPTO issued to us U.S. Patent No. 7,510,726, or the 726 Patent, with 20 allowed claims. The ‘726 Patent encompasses a wider range of abuse deterrent compositions than our ’920 Patent. The 726 Patent expires in November, 2023.

In July 2011, the USPTO issued to us U.S. Patent No. 7,981,439, or the 439 Patent, with 7 allowed claims. The 439 Patent encompasses certain compositions including any water soluble drug of abuse intended to deter the most common methods of prescription opioid analgesic product misuse and abuse. The 439 Patent expires in August, 2024.

In January 2012, the USPTO issued to us U.S. Patent No. 8,101,630, or the 630 Patent with a single claim that encompasses an extended release abuse deterrent dosage form of oxycodone or a pharmaceutically acceptable salt thereof. The 630 Patent expires in August, 2024. In July 2014, we ceded priority of the ‘630 patent to a patent application filed by Purdue Pharma and expect this patent to be rescinded.

In April 2013, the USPTO issued to us U.S. Patent No. 8,409,616, or the 616 Patent, that encompasses certain immediate-release abuse deterrent dosage forms. The 616 Patent expires in November, 2023.

In January 2014, the USPTO issued to us U.S. Patent No. 8,637,540, or the 540 Patent, that encompasses certain immediate-release abuse deterrent opioid products. The 540 Patent expires in November, 2023.

In July 2014, the USPTO issued to us U.S. Patent No. 8,822,489, or the 489 Patent, that encompasses certain abuse deterrent products that contain polymers, surfactant and polysorb 80. The 489 Patent expires in November 2023.

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

In 2012 and 2013, we received Paragraph IV Certification Notices from five generic sponsors of an ANDA for a generic drug listing our Aversion® Oxycodone product as the reference listed drug. The Paragraph IV Notices referred to our 920, 726 and 439 Patents, which cover our Aversion® Technology and our Aversion® Oxycodone product. We filed suit against each of such generic sponsors, Watson Laboratories, Inc., Par Pharmaceutical, Inc., Impax Laboratories, Inc., Sandoz Inc. and Ranbaxy Inc., in the United States District Court for the District of Delaware alleging infringement of our 726 Patent listed in the FDA’s Orange Book. Our litigation against Watson Laboratories was dismissed by us following Watson Laboratories’ change of its Paragraph IV Certification to a Paragraph III Certification, indicating it would not launch its generic product until the expiry of our applicable Patents. Our litigation against the remaining generic sponsors was settled during the period October 2013 through May 2014 on an individual basis, upon mutual agreement between us and such generic sponsors. None of such settlements impacted the validity or enforceability of our Patents. See “Note 3. Paragraph IV ANDA Litigation” for a discussion of the settlements relating to such patent litigation.

Reference is made to the Risk Factors contained in item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013 for a discussion, among other things, of patent applications and patents owned by third parties, including claims that may encompass our Aversion Technology and Aversion oxycodone tablets.

Impede Technology Overview

Our Impede Technology, a proprietary mixture of inactive ingredients, prevents the extraction of pseudoephedrine, or PSE, from tablets using known extraction methods and disrupts 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 by filtration 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 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 Clinical Research Organization, or 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, multiple one-pot tests and 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 developing a next generation of our Impede Technology in order to improve the meth-resistance of our technology. The U.S. Drug Enforcement Administration, or DEA, may grant exemptions from the purchase requirements and behind-the-counter status of PSE under the Combat Methamphetamine Epidemic Act of 2005, or CMEA. We believe a more robust formulation along with in-market data demonstrating a reduction in meth lab incidents may qualify for this exemption, although there can be no assurance this will be the case.

Nexafed

Our Nexafed product is an immediate-release 30mg 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. While the 30mg PSE tablet is not the largest selling PSE product on the market, we believe it is the most often used product to make meth due to: (a) its relatively low selling price and (b) its simpler formulation provides better meth. However, as meth-resistant products become pervasive, we believe meth cooks will migrate to other, larger selling, PSE containing 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 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 are capitalizing 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 are using telemarketing, direct mail, and online and journal advertising to educate pharmacists about Nexafed and encourage pharmacists to recommend Nexafed to their customers.

We launched Nexafed commercially in mid-December 2012 into the United States OTC market for cold and allergy products. We have built a distribution system of several regional and national drug wholesalers for redistribution to pharmacies which includes the three largest U.S. drug wholesalers: McKesson, Cardinal Health and AmerisourceBergen. We also ship directly to the warehouses of certain pharmacy chains. Nexafed is currently stocked in approximately 9,900 U.S. pharmacies or about 15% of the estimated 65,000 U.S. pharmacy outlets. Initial adoption was primarily in independent pharmacies in predominately rural communities with high meth awareness. Chain pharmacies, with more centralized control of the pharmacy operations, began adopting in mid-2013, including Kroger, Publix, Fruth and Bartells. Some pharmacists are actively recommending Nexafed to their customers while some have replaced all 30mg PSE products, brand and generic, with Nexafed. Rite Aid, the nation's fourth largest pharmacy operator, began purchasing Nexafed in late 2013. Many chain pharmacies reset their cough/cold product offering in advance of the winter cold/flu season. We are in active discussion with some chains to have Nexafed as part of their store resets this winter.

We estimate that approximately 52% of Nexafed stocking pharmacies are repeat customers, excluding Rite Aid which purchases directly from us and we therefore do not have individual store data.

We have shipped approximately $68 thousand in Nexafed product during the quarter ended September 30, 2014 and $164 thousand during the nine months ended September 30, 2014. 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.

Impede Technology Product in Development

Given the fragmented nature of the PSE market with products containing multiple active ingredients, we are developing additional products for our Nexafed franchise:

Impede Technology Product	Status
Nexafed Sinus	In commercial manufacturing scale-up Launch expected in early December 2014
Immediate-release pseudoephedrine HCl in combination with other cold and allergy active ingredients	Formulations being considered
Extended-release formulation	Development initiated

We also have been working on a next generation Impede Technology, an improvement for our Nexafed franchise which is an enhancement on the methamphetamine resistance of our current technology in the one-pot methamphetamine conversion method. As part of this effort, we now have a comprehensive database on meth recoveries from most major and meth-resistant PSE containing products marketed in the US. We consider this information a competitive advantage in developing follow-on meth-resistant products and technologies as all products tested yield substantial quantities of meth that can be improved upon.

Our objective is to establish our own Nexafed franchise in the United States with multiple product offerings, including both immediate and extended release products utilizing both single and combinations of active ingredients. We aim to make meth-resistant PSE product the standard of care in all U.S. pharmacies. We will evaluate possible licensing of our Impede Technology with commercial partners outside the United States. Within the United States, we may consider licenses with appropriate partners that can: (a) help advance our distribution network with the goal of making meth-resistant products the standard of care in all U.S. pharmacies, and/or (b) extend our internal development resources to develop difficult to formulate products, such as extended-release.

U.S. Market Opportunity for Impede PSE Products

Methamphetamine is a highly addictive illicit drug used non-medically by an estimated 13 million people at some point in their lifetime. In 2006, the Combat Methamphetamine Epidemic Act, or CMEA, was enacted in response to an alarming increase in and widespread conversion of PSE containing products into methamphetamine. Among other things, the CMEA requires retail stores to maintain their inventory of PSE containing products in a secured location and restricts the amount of PSE products a store can sell to an individual customer. Implementation of the CMEA initially reduced the number of illegal methamphetamine laboratory seizures reported by the Drug Enforcement Administration, or DEA, as the then most commonly used process for conversion of PSE to methamphetamine required substantial quantities of PSE. However, a newer process for converting PSE to methamphetamine requires less PSE. Possibly as a result of this new conversion process, the DEA reported 2010 clandestine methamphetamine laboratory seizures increased 84% over the low reported in 2007. Laboratory seizures were down 12% and 5.5% in 2011 and 2012, respectively, although certain states continue to see increases. In response to the ongoing methamphetamine problem, several local jurisdictions (state, counties and/or local municipalities) have enacted or propose to enact legislation to require a physician's prescription to obtain a PSE-containing product. For example, a bill passed the West Virginia Senate in 2014 requiring all PSE products to have a prescription with an exemption for meth-resistant products like Nexafed, however, this bill failed to pass in the state Assembly. In July, CVS pharmacies announced the removal of older single-ingredient PSE products from their West Virginia stores. We believe the vast majority of West Virginia pharmacies now stock either no single-ingredient PSE products or exclusively meth-resistant products. The West Virginia Gazette recently reported that PSE purchases in the state are down 30% and meth lab seizures in the state are trending down 20% compared to 2013.

PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products. PSE is sold in products as the only active ingredient in both immediate and extended-release products. In addition, PSE is combined with other cold, sinus and allergy ingredients such as pain relievers, cough suppressants and antihistamines. PSE also competes against phenylephrine, an alternate nasal decongestant available in non-prescription products. In 2009, AC Nielsen reported approximately $1.0 billion in retail sales of non-prescription products containing either PSE or phenylephrine as a nasal decongestant, of which approximately 47% contained PSE. The top selling brands of OTC cold/allergy products in 2009 were:

Brand[1]	Company	Active Ingredient(s)	2009 Retail Sales ($ Millions)
Claritin-D	Merck	PSE & Loraditine[2]	$ 113.0
Mucinex-D	Rickett Benckiser	PSE & Guaifenesin[2]	$ 72.2
Zyrtec-D	Pfizer	PSE & Ceterizine[2]	$ 52.2
Advil Sinus	Pfizer	PSE & Ibuprofen	$ 30.9
Sudafed 12 Hour	J&J	PSE[2]	$ 24.9
Sudafed 30mg	J&J	PSE	$ 20.8

[1] Branded product only. Does not include store brand sales.

[2] Extended release PSE formulations

The 2009 market for 30mg PSE tablets, including store brands was approximately 372 million tablets or 15.5 million boxes of 24 tablets. Nexafed is currently priced at $3.99 for a box of 24 tablets.

The market for cold, sinus and allergy products is highly competitive and many products have strong consumer brand recognition and, in some cases, prescription drug heritage. Category leading brands are often supported by national mass marketing and promotional efforts. Consumers often have a choice to purchase a less expensive store brand. Store brands contain the same active ingredients as the more popular national brands but are not supported by large marketing campaigns and are offered at a lower price. Non-prescription products are typically distributed through retail outlets including drug store chains, food store chains, independent pharmacies and mass merchandisers. The distribution outlets for PSE products are highly consolidated. According to Chain Drug Review, the top 50 drug, food and mass merchandising chains operate approximately 40,000 pharmacies in the U.S., of which 58% are operated by the four largest chains. Stocking decisions and pharmacists recommendations for these chain pharmacies are often centralized at the corporate headquarters.

Our 2010 market research study showed that 93% of the 204 pharmacists surveyed believe that PSE has superior efficacy as a nasal decongestant compared to phenylephrine. In our 2012 survey of 215 chain and independent pharmacists, 164 indicated they had influence over the pharmacies' product offerings. Of such pharmacists, 70% indicated they were likely to stock or recommend stocking Nexafed in their pharmacies. The 215 surveyed pharmacists also indicated a willingness to recommend Nexafed to over 50% of their customers who seek a pharmacist's advice for a single ingredient nasal decongestant.

Product Labeling for Impede Technology Products

We are marketing our Nexafed product pursuant to the FDA's OTC Monograph regulations, which require that our product have labeling as specified in the regulations. We are advertising the extraction characteristics and methamphetamine-resistant benefits of our Nexafed product which is supported by our published research studies.

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

Limitx™ Technology

Limitx™ technology is a novel, early stage technology intended to address abuse by excess oral consumption of multiple tablets and provide a margin of safety during accidental over-ingestion of tablets. In proof of concept laboratory tests, Limitx™ demonstrated the ability to limit the release of the active ingredient from tablets when multiple tablets are simultaneously introduced into simulated gastric fluid. While the initial Limitx™ formulation utilizes hydromorphone as its sole active ingredient, if such development proves successful, of which no assurance can be given, it is expected that the technology could incorporate other opioids as well. The need for abuse deterrent formulations which address excess oral consumption was stressed in the January 2013 FDA draft guidance for abuse deterrent opioids. We have patents pending with the U.S. Patent and Trademark office covering our Limitx™ technology.

Limitx™ is being developed pursuant to a $300,000 grant (the "Grant") by the National Institute On Drug Abuse ("NIDA") of the National Institutes of Health. Phase I of development is to create an optimized formulation suitable for human testing. Phase II will encompass human testing to characterize the abuse deterrent features of the formulation. Under the terms of the Grant, we must complete Phase I development by February 28, 2015. NIDA funding of Phase II development, for which an application has already been submitted, will be contingent upon (1) assessment by NIDA of the Phase I progress report and determination that the Phase I milestones were achieved, (2) review and approval of other documents necessary for continuation, and (3) availability of funds. No assurance can be given that Phase II development funding will be provided by NIDA.

Phase I Research on the Company's hydromorphone tablet utilizing Limitx™ technology is supported by the National Institute On Drug Abuse of the National Institutes of Health under Award Number R44DA037921. The results and content of any such research is solely the responsibility of Acura and does not necessarily represent the official views of the National Institutes of Health.

Company's Present Financial Condition

At October 30, 2014 we had cash, cash equivalents and marketable securities of approximately $14.0 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, 2014 we had shipments of Nexafed totaling $164 thousand. We recognized revenue of $218 thousand from Nexafed product sales. 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, we currently cannot reliably estimate expected returns of the product from these customers at the time of shipment. Accordingly, we are 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. Pfizer no longer has a royalty obligation to us on Pfizer's sale of Aversion Oxycodone as our license agreement with Pfizer was terminated effective April 9, 2014.

To fund our continued operations, we expect to rely on our current cash resources (which includes the proceeds of our $10.0 million term loan from Oxford Finance having principal debt repayments beginning April 1, 2015), milestones and royalty payments that may be made under future license agreements with 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, hire additional personnel, commercialize our Nexafed Tablets, or invest in other areas.

Three months Ended September 30, 2014 Compared to Three months Ended September 30, 2013

	Three Months Ended September 30,			
	2014	2013	Increase (decrease)	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$ -	$ 3	$ (3)	nm%
Product sales, net	145	80	65	81
Total revenues, net	145	83	62	75
Expenses:				
Cost of sales (excludes inventory write-down)	108	78	30	39
Inventory write-down	-	-	-	-
Research and development	955	1,289	(334)	(26)
Selling, marketing, general and administrative	1,728	1,941	(213)	(11)
Total operating expenses	2,791	3,308	(517)	(16)
Operating loss	(2,646)	(3,225)	(579)	(18)
Non-operating income (expense):				
Investment income	46	55	(9)	nm
Loss on sales of marketable securities	-	(20)	(20)	nm
Interest expense	(304)	-	304	nm
Total other income (expense)	(258)	35	293	nm
Loss before income taxes	(2,904)	(3,190)	(286)	(9)
Provision for income taxes	-	-	-	-
Net loss	$ (2,904)	$ (3,190)	$ (286)	(9)%

nm = not meaningful

Revenues

Product Sales

We launched Nexafed commercially in mid-December 2012. Given the limited sales history of Nexafed, we could not reliably estimate expected returns of the product at the time of shipment. Accordingly, we have deferred recognition of revenue and the related cost of sales on selected product shipments of Nexafed until the right of return no longer exists or adequate history and information is available to estimate product returns. At September 30, 2014 we have deferred $228 thousand of revenue. During each of the three month periods ended September 30, 2014 and 2013, we recognized revenue of $145 thousand and $80 thousand, respectively, 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.

Royalty Revenue

In connection with the Pfizer Agreement, we began to earn royalties equal to 5% of Aversion Oxycodone net sales starting in February 2013. The Pfizer Agreement was terminated effective April 9, 2014 and Pfizer's royalty payment obligations ceased as of such date. We earned royalties of approximately $3 thousand for the three month period ending September 30, 2013.

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, 2014 and 2013 were primarily for our Aversion or our Impede Technologies development, 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 2014 and 2013 results are non-cash share-based compensation expenses of $0.1 million. Excluding the share-based compensation expense, our R&D expenses decreased approximately $0.3 million between reporting periods. The decrease is primarily due to the nasal abuse liability liking study AP-ADF-301 expenses on our Aversion hydrocodone/acetaminophen product candidate which was ongoing during the three month period ended September 30, 2013 and completed later in the fourth quarter of 2013.

Selling and marketing expenses during the three months ended September 30, 2014 and 2013 primarily consisted of advertising and marketing activities on Nexafed. We are continuing our Nexafed advertising and marketing activities. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the 2014 and 2013 results are non-cash share-based compensation expenses of $0.2 million. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased approximately $0.2 million between reporting periods. The decrease is primarily due to legal services relating to our paragraph IV ANDA litigation activities concluding in May 2014.

Non-operating Income (Expense)

During the three months ended September 30, 2014 and 2013, other non-operating income consisted principally of investment income derived from our cash reserves being invested in marketable securities in accordance with a Board of Director approved investment policy. Our marketable securities are classified as available-for-sale and are recorded at fair value based on quoted market prices. Our marketable securities 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 and we may realize a gain or loss upon sale. During the three months ended September 30, 2014, other non-operating expense consisted of $0.3 million interest cost associated with our debt funded in December 2013.

Income Taxes

The net loss for the three months ended September 30, 2014 and 2013 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Nine months Ended September 30, 2014 Compared to Nine months Ended September 30, 2013

	Nine Months Ended September 30,			
	2014	2013	Increase (decrease)	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$ 4	$ 8	$ (4)	nm%
Product sales, net	218	80	138	172
Total revenues, net	222	88	134	152
Expenses:				
Cost of sales (excludes inventory write-down)	188	78	110	141
Inventory write-down	201	361	(160)	(44)
Research and development	3,674	4,120	(447)	(11)
Selling, marketing, general and administrative	5,903	6,138	(235)	(4)
Total operating expenses	9,966	10,697	(731)	(7)
Operating loss	(9,744)	(10,609)	(865)	(8)
Non-operating income (expense):				
Investment income	143	136	7	nm
(Loss) gain on sales of marketable securities	(5)	(11)	(6)	nm
Interest expense	(907)	-	907	nm
Total other income (expense)	(769)	125	894	nm
Loss before income taxes	(10,513)	(10,484)	29	(4)
Provision for income taxes	-	-	-	-
Net loss	$ (10,513)	$ (10,484)	$ 29	nm%
nm = not meaningful				

Revenues

Product Sales

We launched Nexafed commercially in mid-December 2012. Given the limited sales history of Nexafed, we could not reliably estimate expected returns of the product at the time of shipment. Accordingly, we have deferred recognition of revenue and the related cost of sales on selected 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. At September 30, 2014 we have deferred $228 thousand of revenue. During the nine months ended September 30, 2014 and 2013 we recognized revenue of $218 thousand and $80 thousand, respectively, 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.

Royalty Revenue

In connection with the Pfizer Agreement, we began to earn royalties equal to 5% of Aversion Oxycodone net sales starting in February 2013. The Pfizer Agreement was terminated effective April 9, 2014 and Pfizer's royalty payment obligations ceased as of such date. We earned royalties of approximately $4 thousand and $8 thousand for the nine months ended September 30, 2014 and 2013, respectively.

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 nine months ended September 30, 2014 and 2013, we recorded $0.2 million and $0.4 million, respectfully, of inventory reserve expenses.

Operating Expenses

Research and development ("R&D") expense during the nine months ended September 30, 2014 and 2013 were primarily for our Aversion or our Impede Technologies development, 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 2014 and 2013 results are non-cash share-based compensation expenses of $0.2 million. Excluding the share-based compensation expense, our R&D expenses decreased approximately $0.4 million between reporting periods. The decrease is primarily due to the nasal abuse liability liking study AP-ADF-301 expenses on our Aversion hydrocodone/acetaminophen product candidate which was ongoing during the nine month period ended September 30, 2013 and completed later in the fourth quarter of 2013.

Selling and marketing expenses during the nine months ended September 30, 2014 and 2013 primarily consisted of advertising and marketing activities on Nexafed. We are continuing our Nexafed advertising and marketing activities. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the 2014 and 2013 results are non-cash share-based compensation expenses of $0.5 million and $0.7 million, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses remained relatively unchanged between reporting periods. The legal services relating to our paragraph IV ANDA litigation activities concluded in May 2014.

Non-operating Income (Expense)

During the nine months ended September 30, 2014 and 2013, other non-operating income consisted principally of investment income derived from our cash reserves being invested in marketable securities in accordance with a Board of Director approved investment policy. Our marketable securities are classified as available-for-sale and are recorded at fair value based on quoted market prices. Our marketable securities 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 and we may realize a gain or loss upon sale. During the nine months ended September 30, 2014, other non-operating expense consisted of $0.9 million interest cost associated with our debt funded in December 2013.

Income Taxes

The net loss for the nine months ended September 30, 2014 and 2013 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Liquidity and Capital Resources

At September 30, 2014, the Company had cash, cash equivalents and marketable securities of $14.6 million compared to $26.1 million at December 31, 2013. The Company had working capital of $13.1 million at September 30, 2014 compared to $26.3 million at December 31, 2013. 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 $1.9 million, our legal expenses incurred from our paragraph IV ANDA litigation of $0.3 million and for maintaining our patent and trademarks of $0.6 million. The decrease in our cash position includes our payment of employees' withholding taxes of $0.5 million associated with their option exercises and RSU exchanges during such period.

Pending the receipt of milestone and royalty payments under license agreements similar to the Pfizer Agreement anticipated to be negotiated and executed with other pharmaceutical company partners, of which no assurance can be given, we must rely on revenues from our Nexafed sales and our current cash reserves, including interest income from the investment of our cash reserves, to fund the development of our Aversion Technology, Impede Technology, Limitx Technology and related administrative and operating expenses. Our future sources of revenue, if any, will be derived from milestone payments and royalties under license agreements similar to the Pfizer Agreement with other pharmaceutical company partners, for which there can be no assurance, and from the commercialization of our Nexafed tablets and other Impede Technology products that we expect to develop.

At October 30, 2014, the Company had cash, cash equivalents and marketable securities of approximately $14.0 million. We estimate that our current cash reserves will be sufficient to fund operations through at least the next 12 months.

The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our product candidates and the resources we devote to the development and commercialization of our product candidates

NASDAQ Notification

On September 18, 2014, we received a letter from the Listing Qualifications Staff of the NASDAQ Stock Market notifying us that because the closing bid price of our common stock has been below $1.00 for 30 consecutive business days, it no longer complies with the requirements for continued listing on the NASDAQ Capital Market. The NASDAQ notice does not impact our current listing on the NASDAQ Capital Market at this time and our common stock will continue to trade under the symbol "ACUR". In accordance with NASDAQ rules, we have been provided a period of 180 calendar days, or until March 17, 2015, in which to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days during this 180 day period. If we do not satisfy this requirement by March 17, 2015, NASDAQ will determine whether the Company meets the applicable market value of publicly held shares requirement for continued listing and all other applicable standards for initial listing on the NASDAQ Capital Market (except the bid price requirement). If Acura meets such criteria, it may be eligible for an additional 180 day compliance period. If we do not regain compliance, our common stock will be subject to delisting.

We intend to monitor the bid price of our common stock between now and March 17, 2015, and will consider available options to regain compliance with the listing requirements. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with other listing requirements.

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company's 2013 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 2013 Annual Report are also applicable to 2014.

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 2014 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 3, "License, Development, and Commercialization Agreement – Paragraph IV ANDA Litigation", and Note 14, "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, 2014

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

Exhibit 31.1

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, 2014

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

Exhibit 31.2

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, 2014

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

Exhibit 32.1

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, 2014 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, 2014

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

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