SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20649

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 ☑ No ☐

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

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

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

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

As of April 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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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2014

Item 1. Financial Statements

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

	March 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,866	$ 12,340
Marketable securities	13,622	13,733
Accounts receivable, net of allowances of $23 and $28	105	194
Accrued investment income	102	120
Finished good inventories, net	95	251
Prepaid expenses and other current assets	717	629
Other current deferred assets	185	186
Total current assets	23,692	27,453
Property, plant and equipment, net	947	941
Deferred debt issuance costs	214	231
Other assets	7	5
Total assets	$ 24,860	$ 28,630
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 493	$ 274
Accrued expenses	854	541
Other current liabilities	5	5
Deferred revenue	290	287
Total current liabilities	1,642	1,107
Accrued interest – long-term	46	-
Long-term debt, net of debt discount of $370 and $400	9,630	9,600
Other liabilities	-	-
Total liabilities	$ 11,318	$ 10,707
Commitments and contingencies (Note 13)		
Common stock: $.01 par value per shares; 100,000 shares authorized, 48,848 and 48,325 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	488	483
Additional paid-in capital	366,206	366,533
Accumulated deficit	(353,200)	(349,112)
Accumulated other comprehensive income (loss)	48	19
Total stockholders' equity	$ 13,542	$ 17,923
Total liabilities and stockholders' equity	$ 24,860	$ 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 March 31,	
	2014	2013
Revenues:		
Royalty revenue	$ 3	$ 4
Product sales, net	39	-
Total revenues, net	42	4
Operating expenses:		
Cost of sales (excluding inventory write-down)	38	-
Inventory write-down	133	-
Research and development	1,438	2,026
Selling, marketing, general and administrative	2,259	2,222
Total operating expenses	3,868	4,248
Operating loss	(3,826)	(4,244)
Non-operating income (expense):		
Investment income	44	10
(Loss) gain on sales of marketable securities	(5)	16
Interest expense	(301)	-
Total other income (expense)	(262)	26
Loss before income taxes	(4,088)	(4,218)
Provision for income taxes	-	-
Net loss	$ (4,088)	$ (4,218)
Other comprehensive income (loss):		
Unrealized gains (losses) on securities	29	52
Total other comprehensive income (loss)	29	52
Comprehensive loss	$ (4,059)	$ (4,166)
Earnings (loss) per share:		
Basic	$ (0.08)	$ (0.09)
Diluted	$ (0.08)	$ (0.09)
Weighted average shares outstanding:		
Basic	48,842	46,685
Diluted	48,842	46,685

See accompanying Notes to Consolidated Financial Statements.

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

	Three Months Ended March 31, 2014					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	$ Amount				
Balance at December 31, 2013	48,325	$ 483	$ 366,533	$ (349,112)	$ 19	$ 17,923
Net loss	-	-	-	(4,088)	-	(4,088)
Other comprehensive income (loss)	-	-	-	-	29	29
Share-based compensation	-	-	198	-	-	198
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 March 31, 2014	48,848	$ 488	$ 366,206	$ (353,200)	$ 48	$ 13,542

See accompanying Notes to Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2014	2013
Cash Flows from Operating Activities:		
Net loss	$ (4,088)	$ (4,218)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	28	34
Provision to reduce inventory to net realizable value	133	-
Share-based compensation	198	315
Amortization of debt discount and deferred debt issue costs	46	-
Amortization of bond premium in marketable securities	76	-
Loss (gain) on sales of marketable securities	5	(16)
Changes in assets and liabilities		
Accounts receivable, net	89	(18)
Accrued investment income	18	(35)
Finished good inventories	24	(160)
Income taxes refundable	-	23
Prepaid expenses and other current assets	(89)	26
Other current deferred assets	1	(32)
Other assets	(2)	2
Accounts payable	219	355
Accrued expenses	313	364
Deferred revenue	3	37
Accrued interest - long-term	46	-
Net cash used in operating activities	(2,980)	(3,323)
Cash Flows from Investing Activities:		
Purchases of marketable securities	(1,110)	(7,065)
Proceeds from sale and maturities of marketable securities	1,170	7,086
Additions to property, plant and equipment	(34)	-
Net cash provided by investing activities	26	21
Cash Flows from Financing Activities:		
Proceeds from exercise of stock options	8	1
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)
Net cash used in financing activities	(520)	(714)
Net decreases in cash and cash equivalents	(3,474)	(4,016)
Cash and cash equivalents at beginning of year	12,340	7,476
Cash and cash equivalents at end of year	$ 8,866	$ 3,460
Supplemental Disclosures of Cash Flow Information:		
Cash paid (refunded) during the year for:		
Interest	$ 209	$ -
Income taxes, net of refunds	$ -	$ (23)

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
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):

Three Months Ended March 31, 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.

Three Months Ended March 31, 2013

1. 829 thousand shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan and after withholding 3 thousand shares for $7 in exercise costs and withholding 321 thousand shares for $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
MARCH 31, 2014 AND 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 months ended March 31, 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 - 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 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. We received royalty payments of $10 thousand from Pfizer relating to Aversion Oxycodone net sales for the year ended December 31, 2013 and have accrued a royalty receivable of $3 thousand for the quarter ended March 31, 2014. 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.

The Settlement Agreements with Par and Impax do not affect the status of our separate AVERSION® oxycodone patent litigation against each of Sandoz and Ranbaxy pending in the United States District Court for the District of Delaware.

Litigation is inherently uncertain and we cannot predict the outcome of these infringement actions. If Sandoz and/or Ranbaxy prevails in its lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of AVERSION® oxycodone prior to the expiration of our patents in 2025. 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 these 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 3 - REVENUE RECOGNITION

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

Nexafed was launched in mid-December 2012. 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 March 31, 2014 we had deferred the recognition of revenue on $0.3 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 $3 thousand for the three months ended March 31, 2014 on net sales of Aversion Oxycodone by Pfizer of approximately $60 thousand. The Pfizer Agreement was terminated effective April 9, 2014 and Pfizer’s royalty payment obligations ceased as of such date.

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 March 31, 2014 and 2013 were not material.

NOTE 4 - 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 $0.1 million in accrued CRO expenses and clinical trial study and regulatory expenses at March 31, 2014. We did not have any of these accrued expenses at December 31, 2013. At March 31, 2014 and December 31, 2013 we had $0.27 million and $0.36 million, respectively, of prepaid CRO costs and clinical trial study and regulatory expenses.

NOTE 5 - INVESTMENTS IN MARKETABLE SECURITIES

Investments in marketable securities consisted of the following:

	March 31, 2014 (in millions)	December 31, 2013 (in millions)
Marketable securities:		
Corporate bonds — maturing within 1 year	$ 2.9	$ 3.1
Corporate bonds — maturing after 1 through 4 years	6.4	6.8
Exchange-traded funds	4.3	3.8
Total marketable securities	$ 13.6	$ 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):

	March 31, 2014 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 9.3	$ -	$ -	$ 9.3
Exchange-traded funds	4.3	-	-	4.3
Total - Current	$ 13.6	$ -	$ -	$ 13.6

	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. We had no liabilities at March 31, 2014 meeting fair value measurement.

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

	March 31, 2014 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	$ 9.3	$ 9.3	$ -	$ -
Exchange-traded funds	4.3	4.3	-	-
Total	$ 13.6	$ 13.6	$ -	$ -

	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 March 31, 2014 consisted of unrealized gains on securities of $48 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 6 – INVENTORIES

Inventories consist of finished goods held for sale and distribution on our Nexafed product. Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value). We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results. During the three months ended March 31, 2014, we increased our inventory reserves by $0.1 million. Our gross inventory is valued at $0.35 million and $0.5 million at March 31, 2014 and December 31, 2013, respectively. We have an inventory reserve of $0.25 million at each period end which results in a net reported inventory value of $0.10 million and $0.25 million at March 31, 2014 and December 31, 2013, respectively. The activity in our inventory reserve during the current period was the recording of $0.1 million reserve expense and $0.1 million write-off of previously reserved inventory.

The related cost of sales on deferred revenue of $0.3 million from Nexafed shipments is excluded from the value of the March 31, 2014 inventory 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 active pharmaceutical ingredients and other raw materials required for our development and clinical trial manufacture of product candidates utilizing our Aversion or Impede Technologies are expensed as incurred.

NOTE 7 - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	March 31, 2014	December 31, 2013
	(in thousands)	
Payroll, payroll taxes, bonus and benefits	$ 201	$ 78
Professional services	213	293
Interest - current	70	-
Franchise taxes	-	1
Property taxes	15	15
Contract manufacturing services	-	14
Clinical and regulatory services	108	-
Other fees and services	247	140
Total	$ 854	$ 541

NOTE 8 – 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 its 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"). 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 cash 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 non-operating 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 non-operating 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:

	March 31,	
	2014	2013
	(in thousands)	
Interest expense:		
Promissory notes	$ 254	$ -
Debt discount	30	-
Debt issue costs	17	-
Total interest expense	$ 301	$ -

The annual principal payments on the long-term debt at March 31, 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 9 - COMMON STOCK WARRANTS

We had outstanding common stock purchase warrants ("warrants") at March 31, 2013 exercisable for 1.9 million shares of our common stock at an exercise price of $3.40 per share and an expiration date in August 2014. In connection with the issuance of the $10.0 million secured promissory notes in December 2013, we issued warrants to acquire approximately 298 thousand shares of our common stock at an exercise price of $1.595 per share with an expiration date of December 2020. At March 31, 2014 we have outstanding warrants exercisable for 2.2 million shares of our common stock at a weighted average exercise price of $3.15 per share. All of our outstanding warrants contain a cashless exercise feature.

NOTE 10 - 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 March 31,	
	2014	2013
Research and development expense:		
Stock options	$ 57	$ 81
General and administrative expense:		
Stock options	141	234
Total	$ 198	$ 315

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 three months ended March 31, 2014 and 2013 is shown below:

	Three Months Ended March 31,			
	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	(8)	1.30
Forfeited or expired	-	-	(15)	2.32
Outstanding, ending	3,707	$ 5.02	3,348	$ 5.46
Options exercisable	3,189	$ 5.54	2,866	$ 5.89

There were no stock option grants during the three month period ended March 31, 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:

	Three Months Ended March 31, 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 three months ended March 31, 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 three months ended March 31, 2013, 7 thousand NonISOs were exercised by our employees. Our employees elected to have 4 thousand shares withheld in satisfaction of $13 thousand for both the exercise costs and the withholding tax obligations resulting in the net issuance of 3 thousand common shares to them.

Restricted Stock Unit Award Plan

We have a Restricted Stock Unit Award Plan ("2005 RSU Plan") 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.

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.

A summary of the RSU Plan as of March 31, 2014 and 2013 and for the three months then ended consisted of the following (in thousands):

	Three Months Ended March 31,			
	2014		2013	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	829	829	1,658	1,658
Granted	-	-	-	-
Distributed	(829)	(829)	(829)	(829)
Vested	-	-	-	-
Forfeited or expired	-	-	-	-
Outstanding, ending	-	-	829	829

NOTE 11 – 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 March 31, 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 March 31, 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 12 – EARNINGS PER SHARE ("EPS")

Basic EPS is computed by dividing net income or loss by the weighted average common shares outstanding during a period, including shares weighted related to vested RSUs. (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 month period, and including the effects of common stock equivalents in the diluted EPS calculation would have been antidilutive.

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

	Three Months Ended March 31,	
	2014	2013
	(in thousands except per share data)	
EPS - basic:		
Numerator: net income (loss)	$ (4,088)	$ (4,218)
Denominator:		
Common shares	48,842	45,856
Vested RSUs	-	829
Basic weighted average shares outstanding	48,842	46,685
EPS - basic	$ (0.08)	$ (0.09)
EPS - assuming dilution:		
Numerator: net income (loss)	$ (4,088)	$ (4,218)
Denominator:		
Common shares	48,842	45,856
Vested RSUs	-	829
Stock options	-	-
Common stock warrants	-	-
Diluted weighted average shares outstanding	48,842	46,685
EPS - diluted	$ (0.08)	$ (0.09)
Excluded dilutive securities:		
Common stock issuable:		
Stock options	3,707	3,348
Common stock warrants	2,154	1,856
Total excluded potentially dilutive shares	5,861	5,204

NOTE 13 – 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 state court mass tort proceeding, over 200 lawsuits have been filed against us and Halsey Drug Company alleging that plaintiffs developed neurological disorders as a result of their use of the Reglan brand and/or generic metoclopramide. Plaintiffs have filed approximately 150 lawsuits against us, but have served less than 50 individual lawsuits upon us in the New Jersey action. In the California action, we were not served with any complaints until the spring of 2011 when a single complaint including over 400 plaintiffs was served.

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

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

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

On November 18, 2011, the Philadelphia trial court denied Generic Defendants' dispositive motion. In December 2011, the Generic Defendants appealed this ruling. On April 13, 2012, all trial court proceedings were stayed pending decisions by the Pennsylvania appellate courts. An adverse decision by the Pennsylvania Superior Court was issued in July 2013. Further appeal proceedings are pending. This appeal process eventually could result in dismissal of all of the Philadelphia cases against all generic defendants including Acura, although there can be no assurance in this regard. Legal fees related to this matter are currently covered by our insurance carrier.

In California, the trial court entered a May 25, 2012 Order denying Generic Defendants' dispositive preemption motions. The Generics Defendants' appeals from this order were denied by the California appellate courts. Therefore, subject to further developments, plaintiffs may be permitted to proceed with these lawsuits including state law claims based on (1) failing to communicate warnings to physicians through "Dear Doctor" letters; and (2) failure to update labeling to adopt brand labeling changes. California trial court also has acknowledged the preemptive effect of *Mensing* so that any claim "that would render the generic defendants in violation of federal law if they are found responsible under a state law cause of action, would not be permissible." Nonetheless, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by us. Therefore, we expect the number of plaintiffs with possible claims to be reduced voluntarily or by motion practice. Action will be taken in an effort to dismiss Acura from these cases, although there can be no assurance in this regard. Legal fees related to this matter are currently covered by our insurance carrier.

In Nebraska, the litigation against Acura has been stayed and plaintiffs have agreed to a final dismissal within the next quarter if there is no 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 March 31, 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. We intend to vigorously defend our Company's intellectual property.

Financial Advisor Agreement

In connection with our August 2007 Unit Offering, we are obligated to pay a fee to our then financial advisor upon each exercise of the warrants issued in the Unit Offering, in proportion to the number of warrants exercised. The amount of the fee assuming 100% exercise of the remaining 1.9 million warrants is $0.38 million. The expiration date of these warrants is in August 2014. We have not reflected this obligation as a liability in our consolidated financial statements as the payment is contingent upon the timing and exercise of the warrants by each of the warrant holders. Such fee, if any, will be paid to the financial advisor and be offset against the equity proceeds as the warrants are exercised.

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

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

Forward-Looking Statements

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to:

- our 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;
- 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 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 two 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.

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 February 7, 2014, the FDA advised us their discussion of whether the results of study AP-ADF-301 could support abuse-deterrent labeling is ongoing. 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 12% 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 plan to partner with a strategically focused pharmaceutical company to manufacture and commercialize Aversion Oxycodone in the United States and possibly other territories.

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 $.10 to $.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®	IND submitted to the FDA on December 20, 2012. Pharmacokinetic studies in progress. Awaiting feedback from the FDA on the applicability of the results of Study AP-ADF-301 for NDA submission.
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;
- 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;
- A pharmacokinetic study (Study AP-ADF-303) in about 24 subjects demonstrating dose proportionality of our formulation;
- 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);
- Laboratory studies demonstrating extraction, syringing, swelling and particle size characteristics of our product; and
- An assessment of the routes of abuse of hydrocodone products.

On August 26, 2013, we announced top-line results from Study AP-ADF-301 (Study 301), a phase II clinical study in 40 recreational drug abusers assessing the abuse liability of snorting of our crushed hydrocodone/acetaminophen product. Study 301's primary endpoint indicated Aversion hydrocodone/acetaminophen had slightly lower numeric mean maximum drug liking (Emax: 72.1) compared to an equivalent dose of a generic hydrocodone/acetaminophen tablet (Emax: 75.6) currently on the market, however these results were not statistically significant (p=0.22). The secondary endpoints demonstrated the effects of the Aversion ingredients on drug snorting. Aversion hydrocodone/acetaminophen's mean minimum liking (Emin: 40.2) was less than the comparator (Emin: 50.4) (the difference being statistically significant at p=0.0003). The mean minimum drug liking for Aversion 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.

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 February 7, 2014 the FDA advised us their discussion of whether the results of Study 301 could support abuse-deterrent labeling is ongoing.

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 commenced the pharmacokinetic studies (302, 303 and 304) for Aversion hydrocodone/acetaminophen in the first quarter 2014 and expect to announce results of these studies in the 3rd quarter of 2014.

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.

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 9,000 U.S. pharmacies or about 14% 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. Rite Aid has advised us that it is currently identifying its high meth prone stores and making Nexafed its only stocked 30mg PSE tablet in those stores, displacing all other comparable branded and generic (store brand) products. Rite Aid further advised us that it has distributed Nexafed related educational materials for the pharmacy personnel to all their 4,600 pharmacies to encourage the utilization of Nexafed. Rite Aid commenced reordering Nexafed in April 2014.

We estimate that approximately 46% of Nexafed stocking pharmacies, excluding Rite Aid which is in its early rollout, are repeat customers. In the 4 th quarter of 2013 our top 50 stores purchased, on average, 17.7 boxes of Nexafed per month and the top 300 averaged 9.3 boxes per month. We believe these monthly store purchases indicate strong support by these pharmacies for Nexafed. Purchases by repeat customers are generally below the estimated 23 boxes per month per store national average. We believe this lower purchase rate is due to: (a) a predominately rural store mix for Nexafed that likely has lower per store volume than the national average and (b) a measureable decrease in PSE product sales in stores offering only meth-resistant formulations as documented in an April 2014 investigative article in the Charleston (WV) Gazette.

We have shipped approximately $43 thousand in Nexafed product during the quarter ended March 31, 2014. We have shipped approximately $252 thousand and $402 thousand in Nexafed product during the quarter and year ended December 31, 2013, respectively. We are marketing our 30mg Nexafed product under FDA's regulations applicable to OTC Monograph products. Nexafed tablets are offered in 24-count blister packaged cartons and priced comparable to other branded PSE 30mg tablets.

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
Immediate-release Combination #1	In commercial manufacturing scale-up Launch expected in late 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.

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.

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.

Company's Present Financial Condition

At April 30, 2014 we had cash, cash equivalents and marketable securities of approximately $20.3 million. We estimate that our current cash reserves will be sufficient to fund operations through at least the next 12 months.

During the three months ended March 31, 2014 we recognized $39 thousand of product sales and we had gross shipments of Nexafed totaling $42 thousand. Certain of our customers have accepted a pricing allowance in exchange for forfeiting the right to return Nexafed and therefore we are recognizing revenue upon product shipment to them. Additionally we are recognizing revenue from certain of our other customers based on a pharmacy's Nexafed reorder activity with their own drug wholesaler supplier. For all other customers, given the limited sales history of Nexafed, 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. Our royalty revenue from Pfizer's sale of Aversion Oxycodone began in February 2013 and we are accruing royalties based on the estimate of net product sales of Aversion Oxycodone provided by Pfizer to us. Pursuant to the termination of the license agreement with Pfizer, Pfizer no longer has any royalty obligations to us 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 million term loan from Oxford Finance), 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 March 31, 2014 Compared to Three Months Ended March 31, 2013

	March 31			
	2014	2013	Increase (decrease)	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$ 3	$ 4	$ (1)	nm%
Product sales, net	39	-	39	nm
Total revenues, net	42	4	38	nm
Expenses:				
Cost of sales (excluding inventory write-down)	38	-	38	nm
Inventory write-down	133	-	133	nm
Research and development	1,438	2,026	(588)	(29)
Selling, marketing, general and administrative	2,259	2,222	37	2
Total operating expenses	3,868	4,248	(380)	(9)
Operating loss	(3,826)	(4,244)	(418)	(10)
Non-operating income (expense):				
Investment income	44	10	34	nm
(Loss) gain on sales of marketable securities	(5)	16	(21)	nm
Interest expense	(301)	-	301	nm
Total other income (expense)	(262)	26	(288)	nm
Loss before income taxes	(4,088)	(4,218)	(130)	(3)
Provision for income taxes	-	-	-	-
Net loss	$ (4,088)	$ (4,218)	$ (130)	(3)%

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 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 March 31, 2014 we have deferred $290 thousand of revenue. During the 1st quarter 2014 we recognized revenue of $39 thousand for shipments to customers where the right of return no longer existed either because a pricing allowance was accepted in exchange for forfeiting the right of return or because information became available on pharmacy's reorder activity with their drug wholesaler. We will continue to analyze information to assess the recognition of our revenue but also expect to continue the deferral of some revenue in the foreseeable future. We did not recognize any revenue from product shipments for the three months ended March 31, 2013.

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. We earned royalties of approximately $3 thousand for the quarter ended March 31, 2014 on Pfizer's net sales of Aversion Oxycodone of approximately $60 thousand as compared to $4 thousand in royalty revenue for the period ended March 31, 2013. The Pfizer Agreement was terminated effective April 9, 2014 and Pfizer's royalty payment obligations ceased as of such date.

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 three months ended March 31, 2014 we recorded $0.1 million inventory reserve expense.

Operating Expenses

Research and development ("R&D") expense during the three months ended March 31, 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 $0.6 million between reporting periods. The decrease is primarily due from the nasal abuse liability liking study AP-ADF-301 expenses on our hydrocodone/acetaminophen product candidate which was ongoing during the first quarter 2013.

Selling and marketing expenses during the three months ended March 31, 2014 and 2013 primarily consisted of advertising and marketing activities on Nexafed which was launched in December 2012. Our Nexafed advertising and marketing activities will continue in 2014. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in the 2014 and 2013 results are non-cash share-based compensation expenses of $0.1 million and $0.2 million, respectively. Excluding the share-based compensation expense our selling, marketing general and administrative expenses increased approximately $0.1 million between reporting periods. The increase is primarily due from an increase of $0.3 million in our advertising and marketing expenses for Nexafed offset by a $0.2 million reduction in our legal services relating to our paragraph IV ANDA litigation and maintaining our patent and trademarks.

Non-operating Income (Expense)

During the three months ended March 31, 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 March 31, 2014, other non-operating expense consisted of $0.3 million interest cost associated with our debt.

Income Taxes

The net loss for the three months ended March 31, 2014 and 2013 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Liquidity and Capital Resources

At March 31, 2014, the Company had cash, cash equivalents and marketable securities of $22.4 million compared to $26.1 million at December 31, 2013. The Company had working capital of $22.1 million at March 31, 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 0.8 million, our legal expenses incurred in our paragraph IV ANDA litigation of $0.2 million and in maintaining our patent and trademarks of $0.1 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, the proceeds of our $10.0 million loan from Oxford Finance, 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 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 April 30, 2014, the Company had cash, cash equivalents and marketable securities of approximately $20.3 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.

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 first 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 2, "License, Development, and Commercialization Agreement – Paragraph IV ANDA Litigation", and Note 12, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

Item 1A. Risk Factors

The following risk factors replace and supersede our risk factors set forth in our 2013 Form 10-K:

Our future operating results may vary substantially from anticipated results due to a number of factors, many of which are beyond our control. The following discussion highlights some of these factors and the possible impact of these factors on future results of operations. If any of the following factors actually occur, our business, financial condition, results of operations and/or further growth prospects could be materially adversely affected. In that case the value of our common stock could decline substantially and you may lose all or part of your investment.

Risks Related to Our Business and Industry

We are largely dependent on the commercial success of our Aversion Oxycodone product and our ability to enter into a license agreement with a pharmaceutical company to manufacturer and commercialize Aversion Oxycodone

We anticipate that, for at least fiscal 2014 and 2015, our ability to generate revenues and become profitable will depend in large part on the commercial success of our only FDA approved product, our oxycodone hydrochloride formulated with Aversion Technology, or Aversion Oxycodone. In April 2014, our license Agreement with Pfizer was terminated and we re-acquired all rights to Aversion Oxycodone. Our plan is to enter into a license agreement with a strategically focused pharmaceutical company to manufacture and commercialize Aversion Oxycodone. The commercial success of Aversion Oxycodone will depend on several factors, including our ability to enter into a license agreement with a pharmaceutical partner, and our licensee's ability to:

- obtain and increase market demand for, and sales of, Aversion Oxycodone;
- obtain acceptance of Aversion Oxycodone by physicians and patients;
- obtain and maintain adequate levels of coverage and reimbursement for Aversion Oxycodone from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;
- maintain compliance with regulatory requirements;
- price Aversion Oxycodone competitively and enter into price discounting contracts with third-party payors;
- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms;
- manufacture and supply Aversion Oxycodone to meet commercial demand, including obtaining sufficient quota from the Drug Enforcement Administration; and
- maintain intellectual property protection for Aversion Oxycodone and obtaining favorable drug listing treatment by the FDA to minimize generic competition.

There can be no assurance that we will be successful in entering into a license agreement for Aversion Oxycodone. If we are successful in entering into such agreement, there can be no assurance that our licensee will devote sufficient resources to the marketing and commercialization of Aversion Oxycodone. Our licensee's marketing of Aversion Oxycodone may result in low market acceptance and insufficient demand for, and sales of, the product. If we are unable to enter into a license agreement for Aversion Oxycodone, or if we enter into such agreement but our licensee fails to successfully commercialize Aversion Oxycodone and increase sales, we may be unable to generate sufficient revenues to sustain or grow our business and we may never become profitable, and our business, financial condition and results of operations will be materially adversely affected.

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

We commenced the launch and commercial distribution of Nexafed in mid-December 2012. Nexafed competes in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in marketing their competing products. Category leading brands are often supported by regional and national advertising and promotional efforts. Nexafed will compete with national brands as well as pharmacy store brands that are offered at a lower price. There can be no assurance that we will succeed in commercializing Nexafed, or that the pricing of Nexafed will allow us to generate significant revenues or profit. Regulations have been enacted in several state or local jurisdictions requiring a doctor's prescription to obtain pseudoephedrine products. An expansion of such restrictions to other jurisdictions or even nationally will adversely impact our ability to market Nexafed as an OTC product and generate revenue from Nexafed product sales. Our failure to successfully commercialize Nexafed and to develop and commercialize other Impede Technology products will have a material adverse effect on our business and financial condition.

If our Aversion Oxycodone licensee is not successful in commercializing Aversion Oxycodone, our revenues and our business will suffer.

In April 2014, we re-acquired all rights to our FDA approved Aversion Oxycodone product upon the termination of our license agreement with Pfizer. Currently, we do not have the infrastructure to commercialize Aversion Oxycodone ourselves or the funding to satisfy the expenses and capital requirements necessary to build such infrastructure. Our plan is to enter into an agreement similar to the Pfizer Agreement with a strategically focus pharmaceutical company to manufacture and commercialize Aversion Oxycodone in the United States and possibly other territories. If we are successful in entering into such license agreement, of which no assurance can be given, upon the termination of such agreement, including due to a party's failure to perform its obligations or responsibilities under the agreement, we would need to enter into a new agreement with another pharmaceutical company, of which no assurance can be given. If we are unable to find a suitable replacement commercialization partner, we would be unable to generate any revenue from Aversion Oxycodone. Even if we are successful at replacing the commercialization capabilities of our licensee, our revenues and/or royalties from Aversion Oxycodone could be adversely impacted.

We expect that the licensee of our Aversion Oxycodone, or its designated third-party supplier, will be the sole commercial source of supply of Aversion Oxycodone. If our licensee's manufacturing facility fails to obtain sufficient DEA quotas for oxycodone, fails to source adequate quantities of active and inactive ingredients, fails to comply with regulatory requirements, or otherwise experiences disruptions in commercial supply of Aversion Oxycodone, product revenue and our royalties could be adversely impacted.

We expect that the licensee of our Aversion Oxycodone will have a diversified product line for which Aversion Oxycodone will vie for such licensee's promotional, marketing, and selling resources. If our licensee fails to commit sufficient promotional, marketing and selling resources to Aversion Oxycodone, product revenue and our expected royalties could be adversely impacted. Additionally, there can be no assurance that our licensee will commit the resources required for the successful commercialization of Aversion Oxycodone.

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

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

Our failure to continue the development of the three development stage products terminated by Pfizer under the Pfizer Agreement, or to successfully establish a license agreement with a pharmaceutical company for the development and commercialization of such products, will adversely impact our ability to develop, market and sell such products and our revenues and business will suffer.

In July 2012, Pfizer exercised its right to terminate the license to the three products in development, or the returned products, under the Pfizer Agreement. The termination of such license provides for the return to us of oxycodone hydrochloride with acetaminophen, hydrocodone bitartrate with acetaminophen [and another undisclosed opioid product]. We have the right to develop the returned products on our own or in partnership with a third party. Our plan for developing, manufacturing and commercializing the returned products includes entering into an agreement similar to the Pfizer Agreement with a strategically focused pharmaceutical company. Such license agreement may also include rights to our Aversion Oxycodone product. However, there can be no assurance that we will be successful in entering into such an agreement. Pending any such agreement, we expect to continue the development of our hydrocodone bitartrate with acetaminophen product on our own. Although we believe we have sufficient cash resources to fund the development of such product and submit a corresponding NDA to the FDA, there can be no assurance that this will be the case. The continued development of our hydrocodone bitartrate with acetaminophen product and the other returned products may require additional financing, which may not be available on acceptable terms, or at all. In the absence of available financing, or our failure to successfully enter into a license agreement with a pharmaceutical company to develop and commercialize the returned products, we may have to limit the size or scope of, or delay or abandon, the development of some or all of the returned products, which would adversely impact our financial condition and results of operations.

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

We had a net loss of $13.9 million and $9.7 million for the years ended December 31, 2013 and 2012, respectively, net income of $10.4 million for the year ended December 31, 2011 and a net loss of $12.7 million and $15.8 million for the years ended December 31, 2010 and 2009, respectively. Our future profitability will depend on several factors, including:

- our receipt of royalties relating to our licensee's sale of Aversion Oxycodone;
- our successful marketing and sale of Nexafed and other products utilizing our Impede Technology, and market acceptance, increased demand for and sales of Nexafed;
- our receipt of milestone payments and royalties relating to our Aversion Technology products in development, including the products returned by Pfizer, from future licensees, of which no assurance can be given; and
- the receipt of FDA approval and the successful commercialization by future licensees (if any) of products utilizing our Aversion Technology and our ability to commercialize our Impede Technology without infringing the patents and other intellectual property rights of third parties.

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

We recognized royalty revenues of $10 thousand and $3 thousand from Pfizer under the Pfizer Agreement relating to net sales of Aversion Oxycodone for the year ended December 31, 2013 and the quarter ended March 31, 2014, respectively. Even if we are successful in entering into a license agreement for Aversion Oxycodone with a pharmaceutical partner and such licensee succeeds in commercializing Aversion Oxycodone, or if we or a licensee succeed in developing and commercializing one or more of our pipeline Aversion Technology products, or if we are successful in commercializing Nexafed or other Impede Technology products, we expect to continue using cash reserves for the foreseeable future. Our expenses may increase in the foreseeable future as a result of continued research and development of our product candidates, maintaining and expanding the scope of our intellectual property, commercializing our Nexafed product, and hiring of additional research and development staff.

We will need to generate revenues from direct product sales or indirectly from royalties on sales to achieve and maintain profitability. If we cannot successfully commercialize Nexafed, if our licensee does not successfully commercialize Aversion Oxycodone, or if we or our licensee (if any) cannot successfully develop, obtain regulatory approval and commercialize our products in development, we will not be able to generate such royalty revenues or achieve future profitability. Our failure to achieve or maintain profitability would have a material adverse impact on our operations, financial condition and on the market price of our common stock.

We must rely on current cash reserves, revenues from Nexafed sales, and the proceeds of our term loan to fund operations.

Pending the receipt of royalties under a license agreement that we expect to enter into with a pharmaceutical company to manufacture and commercialize Aversion Oxycodone, and milestone payments and royalties under license agreements similar to the Pfizer Agreement that we may enter into with other pharmaceutical companies relating to our products in development, in each case of which no assurance can be given, we must rely on our current cash reserves, revenues from our sales of Nexafed, and the proceeds of our $10 million term loan from Oxford Finance to fund operations and product development activities. No assurance can be given that current cash reserves, revenues from Nexafed product sales, or the term loan from Oxford Finance will be sufficient to fund continued operations and the development of our product candidates until such time as we generate revenues from a license agreement for Aversion Oxycodone or any of our products in development. Moreover, no assurance can be given that we will be successful in raising additional financing or, if funding is obtained, that such funding will be sufficient to fund operations until we enter into a license agreement for Aversion Oxycodone and generate royalties under such agreement, or until product candidates utilizing our Aversion and Impede Technologies may be commercialized. In the event our cash reserves are insufficient to fund continued operations, we may need to suspend some or all of our product development efforts or possibly discontinue operations.

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

The commercial success of our Aversion Technology products will depend upon our and our licensees' ability to obtain FDA approved labeling describing such products' abuse deterrent features or benefits. Our or our licensees' failure to achieve FDA approval of product labeling containing such information will prevent or substantiality limit our and our licensees' advertising and promotion of such abuse deterrent features in order to differentiate Aversion Technology products from other immediate release opioid products containing the same active ingredients, and would have a material adverse impact on our business and results of operations. The FDA's January 2013 draft guidance, while not binding on the FDA, outlines the FDA's current views on the labeling of abuse deterrent products. The 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, the 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 a product's potential abuse-deterrent properties can be expected to, or actually do, result in a significant reduction in that product's abuse potential, those data, together with an accurate characterization of what the data mean, should be included in product labeling. We intend to utilize certain clinical and laboratory studies for our opioid products in development to support a label describing the abuse-deterrent features of such products. However, the extent to which such information is included in the FDA approved product label is the subject of our and our licensees' discussions with, and agreement by, the FDA as part of the NDA review process for each of our product candidates. The outcome of those discussions with the FDA will determine whether we or our licensees will be able to market our products with labeling that sufficiently differentiates them from other products that have comparable therapeutic profiles. While the FDA approved label for Aversion Oxycodone includes the results from a clinical study which evaluated the effects of nasally snorting crushed Aversion Oxycodone and commercially available oxycodone tablets and limitations on wetting or dissolving Aversion Oxycodone, it does not, however, include the results of our laboratory studies intended to evaluate Aversion Oxycodone's potential to limit extraction of oxycodone HCl from dissolved Aversion Oxycodone Tablets and resist conversion into an injectable, or IV solution. The absence of the results of these extraction and syringe studies in the FDA approved label for Aversion Oxycodone may substantially limit our licensee's ability to differentiate Aversion Oxycodone from other immediate release oxycodone products, which would have a material adverse effect on market acceptance of Aversion Oxycodone and on our business and results of operations.

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

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

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

We are committing a majority of our resources to the development of product candidates utilizing our Aversion and Impede Technologies. Notwithstanding the receipt of FDA approval of Aversion Oxycodone and our marketing of Nexafed, there can be no assurance that any other product candidate utilizing our Aversion or Impede Technologies will meet FDA's standards for commercial distribution. Further, there can be no assurance that other product candidates that may be developed using Aversion Technology or Impede Technology will achieve the targeted end points in the required clinical studies or perform as intended in other pre-clinical and clinical studies or lead to an NDA submission or filing acceptance. Our failure to successfully develop and achieve final FDA approval of our product candidates in development will have a material adverse effect on our financial condition.

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

Drugs that have been deemed safe and effective by the FDA for use by the general public without a prescription are classified as OTC drug products. Certain OTC drug products may be commercialized without premarket review by the FDA if the standards set forth in the applicable regulatory monograph are met. An OTC monograph provides the marketing conditions for the applicable OTC drug product, including active ingredients, labeling, and other general requirements, such as compliance with cGMP and establishment registration. Any product which fails to conform to each of the general conditions and a monograph is subject to regulatory action. Further, although the FDA regulates OTC drug product labeling, the FTC regulates the advertising and marketing of OTC drug products. We believe that Nexafed is classified for OTC sale under an FDA OTC monograph, which will allow us to commercialize them without submitting an NDA or ANDA to the FDA. We have also determined that, provided we adhere to the FDA's requirements for OTC monograph products, including product labeling, we can advertise and promote the extraction characteristics and benefits of Nexafed which are supported by our research studies. No assurance can be given, however, that the FDA will agree that Nexafed may be sold under the FDA's OTC monograph product regulations or that the FDA or FTC will not object to our advertisement and promotion of Nexafed's extraction characteristics and benefits. If the FDA determines that Nexafed does not conform to the OTC monograph or if we fail to meet the general conditions, once commercialized, the product may be removed from the market and we may face various actions including, but not limited to, restrictions on the marketing or distribution of such products, warning letters, fines, product seizure, or injunctions or the imposition of civil or criminal penalties. Any of these actions may materially and adversely affect our financial condition and operations. Additionally, the FDA has recently announced that it is considering material changes to how it regulates OTC drug products and held hearing in late March 2014 for public comment. Changes to the existing OTC regulations could result in a requirement that Acura file an NDA or ANDA for Nexafed or other Impede Technology products in order to commercialize such products. If the FDA requires that we submit a NDA or ANDA to obtain marketing approval for Nexafed or other Impede Technology products, this would result in substantial additional costs, suspend the commercialization of Nexafed and require FDA approval prior to sale, of which no assurance can be provided. In such case, the label for Nexafed or other Impede Technology products would be subject to FDA review and approval and there can be no assurance that we will be able to market Nexafed or other Impede Technology products with labeling sufficient to differentiate it from products that have comparable therapeutic profiles. If we are unable to advertise and promote the extraction characteristics of Nexafed or other Impede Technology products, we may be unable to compete with national brands and pharmacy chain store brands.

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

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

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

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

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

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

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

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

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

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

Our drug products, including Nexafed, require precise, high quality manufacturing. Failure by our contract manufacturers to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could materially adversely affect our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMP and other applicable government regulations; however, beyond contractual remedies that may be available to us, we do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

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

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

Even if we comply with all the FDA regulatory requirements, we or our licensees may not obtain regulatory approval for any of our product candidates in development. For example, we previously submitted a NDA to the FDA for an Aversion Technology product containing niacin, intended to provide impediments to over-ingesting the product. Such niacin containing product was not approved by the FDA. If we or our licensees fail to obtain regulatory approval for any of our product candidates in development, we will have fewer commercialized products and correspondingly lower revenues. Even if regulatory approval of our products in development is received, such approval may involve limitations on the indicated uses or promotional claims we or our licensees may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles but without abuse deterrent features (see risk factor above entitled "Our and our licensees ability to market and promote Aversion Oxycodone and other Aversion Technology products by describing the abuse deterrent features of such products will be determined by the FDA approved label for such products"). Such events would have a material adverse effect on our operations and financial condition. We may market certain of our products without the prior application to and approval by the FDA. The FDA may subsequently require us to withdraw such products and submit NDA's for approval prior to re-marketing.

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

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

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

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

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

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

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

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

We believe that opportunities exist to enter into license agreements with pharmaceutical partners for the development and commercialization of our Aversion product candidates in development (including the products returned to us by Pfizer under the Pfizer Agreement) in the United States and worldwide, and for the development and commercialization of additional Aversion Technology and Impede Technology product candidates for other abused and misused drugs, such as tranquilizers, stimulants, sedatives and nasal decongestants in the United States and worldwide. However, there can be no assurance that we will be successful in entering into such license agreements in the future. If we are unable to enter into such agreements, our ability to develop and commercialize our product candidates, and our financial condition and results of operations, would be materially adversely affected.

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

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

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

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

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

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

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

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

Our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers.

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

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

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, beginning in 2011;
- An increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- A new Medicare Part D coverage gap discount program, under which manufacturers must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in 2011;
- Extension of manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research;
- A revision to the definition of "average manufacturer price" for reporting purposes; and
- Encouragement for the development of comparative effectiveness research, which may reduce the extent of reimbursement for our products if such research results in any adverse findings.

At this time, it remains uncertain what the full impact of these provisions will be on the pharmaceutical industry generally or our business in particular. The full effects of these provisions will become apparent as these laws are implemented and the Centers for Medicare & Medicaid Services and other agencies issue applicable regulations or guidance as required by the Healthcare Reform Law. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

If we are unable to establish sales and marketing capabilities for our products that are not licensed to third parties, our revenues and our business will suffer.

We do not currently have an extensive organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. If we do not license the commercialization of a product, we may have to build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish or fund adequate sales, marketing and distribution capabilities, whether independently or with third parties, it will impair our ability to sell products and have a material adverse effect on our operations.

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

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

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

Our success depends on our ability to obtain and maintain patent protection for products developed utilizing our technologies, in the United States and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual questions. Notwithstanding our receipt of U.S. Patent No. 7,201,920 and U.S. Patent No. 7,510,726 from the USPTO encompassing our opioid products utilizing our Aversion Technology, and U.S. Patent No. 7,981,439 encompassing certain non-opioid products utilizing our Aversion Technology, there is no assurance that any of our patent claims in our other pending non-provisional and provisional patent applications relating to our technologies will issue or if issued, that any of our existing and future patent claims will be held valid and enforceable against third-party infringement or that our products will not infringe any third-party patent or intellectual property. Moreover, any patent claims relating to our technologies may not be sufficiently broad to protect our products. In addition, issued patent claims may be challenged, potentially invalidated or potentially circumvented. Our patent claims may not afford us protection against competitors with similar technology or permit the commercialization of our products without infringing third-party patents or other intellectual property rights.

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

Our success also depends on maintaining the confidentiality of our trade secrets and know-how. We seek to protect such information by entering into confidentiality agreements with employees, potential licensees, raw material suppliers, contract research organizations, contract manufacturers, consultants and other parties. These agreements may be breached by such parties. We may not be able to obtain an adequate, or perhaps any, remedy to such a breach. In addition, our trade secrets may otherwise become known or be independently developed by our competitors. Our inability to protect our intellectual property or to commercialize our products without infringing third-party patents or other intellectual property rights would have a material adverse affect on our operations and financial condition.

We also rely on or intend to rely on our or our licensees' trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. However, our trademark applications may not be approved. Third parties may also oppose our or our licensees' trademark applications or otherwise challenge our use of the trademarks. In the event that our or our licensees' trademarks are successfully challenged, we or our licensees could be forced to rebrand our product, which could result in loss of brand recognition and could require us or our licensees to devote resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks, or we may not have adequate resources to enforce our trademarks.

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

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

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

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

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

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

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

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

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

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

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

Generic manufacturers are using litigation and regulatory means to seek approval for generic versions of Aversion Oxycodone, which could cause our and our licensee's sales to suffer.

Under the Hatch-Waxman Act, the FDA can approve an ANDA for a generic version of a branded drug and what is referred to as a Section 505(b)(2) NDA, for a branded variation of an existing branded drug, without requiring such applicant to undertake the full clinical testing necessary to obtain approval to market a new drug. An ANDA applicant usually needs to only submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

The Hatch-Waxman Act requires an applicant for a drug that references one of our branded drugs to notify us of their application if they assert in their application that the patents we have listed in the Orange Book will not be infringed or otherwise are invalid or unenforceable (a Paragraph IV Certification). Upon receipt of this notice, we have 45 days to bring a patent infringement suit in federal district court against such applicant. If such a suit is commenced, the FDA is generally prohibited from granting approval of the ANDA or Section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor or expiration of the patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) NDAs. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove this uncertainty. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the applicant for the patents subject to the litigation.

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, 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. The above actions are referred to as the "Paragraph IV Proceedings." In January 2013, we dismissed our suit against Watson Laboratories 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.

The Settlement Agreements with Par and Impact do not affect the status of our separate AVERSION® oxycodone patent litigation against each of Sandoz and Ranbaxy pending in the United States District Court for the District of Delaware.

Litigation is inherently uncertain and we cannot predict the outcome of the Paragraph IV Proceedings. If Sandoz and/or Ranbaxy prevails in its lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of AVERSION® oxycodone prior to the expiration of our patents in 2025. Any determination in these 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 affect on our operations and financial condition.

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

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by patients, health care providers or others that sell or consume our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale. We are currently covered by clinical trial product liability insurance on a claims-made basis and for product liability insurance covering our sale and distribution of Nexafed. This coverage may not be adequate to cover any product liability claims. Product liability coverage is expensive. In the future, we may not be able to maintain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims. Any claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

We believe potential competitors may be developing opioid abuse deterrent technologies and products. Such potential competitors include, but may not be limited to, Pain Therapeutics, Pfizer Inc., Purdue Pharma, Atlantic Pharmaceuticals, Egalet Corporation, KemPharm, Shionogi, Nektar Therapeutics, Signature Therapeutics, QRx Pharma, Tris Pharma, Pisgah Labs, and Collegium Pharmaceuticals, Inc. These companies appear to be focusing their development efforts on ER Opioid Products, except for Atlantic Pharmaceuticals, while the majority of our Aversion Technology opioid analgesic product candidates under development are IR Opioid Products.

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

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

If we fail to comply with the covenants and other obligations under our term loan, the lender may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.

In December 2013, we (including our wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc. ("APT")) entered into a loan and security agreement with Oxford Finance LLC ("Oxford") pursuant to which we borrowed $10 million from Oxford. Under this agreement, we are subject to a variety of affirmative and negative covenants, including required financial reporting, limitations on certain dispositions and licensing of assets, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under this loan and security agreement, we granted Oxford a security interest in substantially all of our assets, other than intellectual property assets, and pledged to Oxford the stock of APT. Our failure to comply with the terms of the loan and security agreement, the occurrence of a material adverse change in our business, operations or condition (financial or otherwise) or prospects, the material impairment in our prospect of repayment, a material impairment in the perfection or priority of the Oxford's lien on our assets or the value of Oxford's collateral, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our loan, coupled with prepayment penalties, an additional interest payment of between $795,000 and $995,000, potential foreclosure on our assets, and other adverse results.

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

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

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

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

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

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

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

Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of Net Operating Loss, or NOL, carryforwards and other tax attributes. We have determined that an ownership change (as defined by Section 382 of the Internal Revenue Code) did occur as a result of restructuring that occurred in 2004. Neither the amount of our NOL carryforwards nor the amount of limitation of such carryforwards claimed by us have been audited or otherwise validated by the Internal Revenue Service, which could challenge the amount we have calculated. The recognition and measurement of our tax benefit includes estimates and judgment by our management, which includes subjectivity. Changes in estimates may create volatility in our tax rate in future periods based on new information about particular tax positions that may cause management to change its estimates.

Risks Relating to our Common Stock

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

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

Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.

During the 12-month period ended March 31, 2014, our stock traded as high as $3.78 per share and as low as $1.35 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors could include:

- results from our clinical development programs, including the data from our ongoing Phase 3 clinical trial evaluating our Aversion hydrocodone/acetaminophen product;
- FDA actions related to our products in development;
- FDA actions related to any of our potential products;
- announcements regarding a license agreement for Aversion Oxycodone or our product candidates;
- announcements regarding the progress of our preclinical programs;
- our success in the commercialization of our Nexafed product;
- announcements regarding the sales of our Nexafed product;
- failure of any of our products in development, if approved, to achieve commercial success;
- quarterly variations in our results of operations or those of our competitors;
- our ability to develop and mark new and enhanced products on a timely basis;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies;
- additions or departures of key personnel;
- commencement of, or our involvement in, litigation;
- the inability of our contract manufacturers to provide us with adequate commercial supplies of our products;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board or management;
- general economic conditions and slow or negative growth of our market; and
- political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of our products and potential products may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

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

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

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

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the then current trading price of our common stock. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the then current trading price of our common stock.

In accordance with the terms of the Securities Purchase Agreement dated August 20, 2007 between us and the investors named therein, we filed a registration statement with and declared effective by the SEC, to register the shares included in our Units issued pursuant to the Securities Purchase Agreement, including shares underlying warrants included in the Units. In addition, pursuant to the exercise of previously granted piggyback registration rights, each of Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP and Essex Woodlands Health Ventures V, L.P. have exercised their piggyback registration rights to include an aggregate of 26,584,016 shares in such registration statement. As a result, approximately 26,278,000 shares (representing approximately 48% of our shares outstanding on a fully-diluted basis, including all derivative securities, whether or not currently exercisable) are available for resale by selling stockholders under the registration statement. If some or all of the shares included in such registration statement are sold by our affiliates and others it may have the effect of depressing the trading price of our common stock. In addition, such sales could make it more difficult for us to raise capital if needed in the future.

In April 2013, we entered into an at-the-market equity facility, or ATM, with MLV & Co. LLC, or MLV, as sales agent under which we may sell up to approximately $13.0 million of our common stock under our prospectus supplement by any method deemed to be an "at-the-market" offering under SEC rules. As of March 31, 2014 we sold cumulatively approximately $3.3 million of common stock and issued 1,940,652 shares under the ATM. If we continue to sell shares under the ATM, such sales will dilute our existing shareholders and could cause the market price of our common stock to decline significantly. The availability of the ATM to us, as well as any sales of our common stock under the ATM, should we elect to continue to use it, could encourage short sales by third parties, which could contribute to the further decline of our stock price.

If we do not meet the continued listing standards of the NASDAQ Capital Market, our common stock could be delisted from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.

Our common stock is listed on the NASDAQ Capital Market, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If we fail to satisfy its continued listing standards, such as, for example, NASDAQ Listing Rule 5450(a)(1), which requires that the closing bid price of our common stock shall not fall below $1.00 for thirty consecutive business days. Failure to comply with NASDAQ's continued listing standards will result in the issuance of a non-compliance letter and/or initiation of delisting proceedings by NASDAQ.

If our securities are delisted from trading on the NASDAQ Capital Market and we are not able to list our securities on another exchange, such as the NYSE, our securities could then be quoted on the OTC Bulletin Board or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

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.

April 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

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.

April 30, 2014

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

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

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

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

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

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

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

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

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

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

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

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

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

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

April 30, 2014

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

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

In connection with the Quarterly Report of Acura Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending March 31, 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.

April 30, 2014

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

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