

ACURA PHARMACEUTICALS, INC
Form 10-Q
August 04, 2014

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
p ACT OF 1934.**

For the quarterly period ended June 30, 2014

or

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

For the transition period from _____ to _____

Commission File Number 1-10113

Acura Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

New York

*(State or other Jurisdiction of
incorporation or organization)*

11-0853640

(I.R.S. Employer Identification No.)

616 N. North Court, Suite 120

Palatine, Illinois

(Address of Principal Executive Offices)

60067

(Zip Code)

847 705 7709

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 S-T (§232.405 of this 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 July 30, 2014 the registrant had 48,847,982 shares of common stock, \$.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

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Item 1. Financial Statements**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS****(Unaudited; in thousands except par value)**

	June 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$3,541	\$ 12,340
Marketable securities	13,820	13,733
Accounts receivable, net of allowances of \$22 and \$28	86	194
Accrued investment income	102	120
Inventories, net	445	251
Prepaid expenses and other current assets	546	629
Other current deferred assets	193	186
Total current assets	18,733	27,453
Property, plant and equipment, net	928	941
Deferred debt issuance costs	196	231
Other assets	3	5
Intangible asset	2,000	-
Total assets	\$21,860	\$ 28,630
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$114	\$ 274
Accrued expenses (Note 7)	1,444	541
Other current liabilities	37	5
Deferred revenue	307	287
Current maturities of long-term debt	477	-
Total current liabilities	2,379	1,107
Long-term debt, net of debt discount of \$341 and \$400	9,182	9,600
Total liabilities	\$11,561	\$ 10,707
Commitments and contingencies (Note 13)		
	488	483

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Common stock: \$.01 par value per shares; 100,000 shares authorized, 48,848 and 48,325 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively

Additional paid-in capital	366,463	366,533
Accumulated deficit	(356,721)	(349,112)
Accumulated other comprehensive income (loss)	69	19
 Total stockholders' equity	 \$10,299	 \$ 17,923
 Total liabilities and stockholders' equity	 \$21,860	 \$ 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 June 30,		Six months Ended June 30,	
	2014	2013	2014	2013
Revenues:				
Royalty revenue	\$1	\$1	\$4	\$5
Product sales, net	34	-	73	-
Total revenues, net	35	1	77	5
Operating expenses:				
Cost of sales (excludes inventory write-down)	42	-	80	-
Inventory write-down	68	361	201	361
Research and development	1,281	805	2,719	2,831
Selling, marketing, general and administrative	1,916	1,975	4,175	4,197
Total operating expenses	3,307	3,141	7,175	7,389
Operating loss	(3,272)	(3,140)	(7,098)	(7,384)
Non-operating income (expense):				
Investment income	53	71	97	81
(Loss) gain on sales of marketable securities	-	(7)	(5)	9
Interest expense (Note 8)	(302)	-	(603)	-
Total other income (expense)	(249)	64	(511)	90
Loss before income taxes	(3,521)	(3,076)	(7,609)	(7,294)
Provision for income taxes	-	-	-	-
Net loss	(3,521)	\$(3,076)	\$(7,609)	\$(7,294)
Other comprehensive income:				
Unrealized gains (losses) on securities	21	(131)	50	(79)
Total other comprehensive income (expense)	21	(131)	50	(79)
Comprehensive loss	\$(3,500)	\$(3,207)	\$(7,559)	\$(7,373)
Loss per share:				
Basic	\$(0.07)	\$(0.07)	\$(0.16)	\$(0.16)
Diluted	\$(0.07)	\$(0.07)	\$(0.16)	\$(0.16)
Weighted average shares outstanding:				
Basic	48,848	47,228	48,846	47,215
Diluted	48,848	47,228	48,846	47,215

See accompanying Notes to Consolidated Financial Statements.

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

	Six months Ended June 30, 2014					Accumulated Other Comprehensive Income (Loss)	Total
	Common Stock Shares	\$ Amount	Additional Paid-in Capital	Accumulated Deficit			
Balance at December 31, 2013	48,325	\$ 483	\$ 366,533	\$ (349,112)	\$ 19		\$ 17,923
Net loss	-	-	-	(7,609)	-		(7,609)
Other comprehensive income (loss)	-	-	-	-	50		50
Share-based compensation	-	-	455	-	-		455
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 June 30, 2014	48,848	\$ 488	\$ 366,463	\$ (356,721)	\$ 69		\$ 10,299

See accompanying Notes to Consolidated Financial Statements.

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

	Six months Ended June 30,	
	2014	2013
Cash Flows from Operating Activities:		
Net loss	\$(7,609)	\$(7,294)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	58	69
Provision to reduce inventory to net realizable value	201	390
Share-based compensation	455	630
Amortization of debt discount and deferred debt issue costs	93	-
Amortization of bond premium in marketable securities	138	-
Loss (gain) on sales of marketable securities	5	(9)
Loss on disposal of property and equipment	1	-
Changes in assets and liabilities		
Accounts receivable, net	108	(8)
Accrued investment income	18	(91)
Inventories	(394)	(532)
Income taxes refundable	-	43
Prepaid expenses and other current assets	83	(207)
Other current deferred assets	(7)	(49)
Other long-term assets	3	3
Accounts payable	(160)	(666)
Accrued expenses	902	262
Other current liabilities	32	-
Deferred revenue	20	61
Net cash used in operating activities	(6,053)	(7,398)
Cash Flows from Investing Activities:		
Purchases of marketable securities	(1,540)	(7,612)
Proceeds from sale and maturities of marketable securities	1,361	8,604
Additions to property, plant and equipment	(47)	(23)
Acquisition of product rights	(2,000)	-
Net cash (used in) provided by investing activities	(2,226)	969
Cash Flows from Financing Activities:		
Proceeds from exercise of stock options	8	9
Proceeds from distribution of restricted stock units	1	1
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(529)	(716)
Proceeds from "at-the-market" offering	-	251
Offering transaction costs	-	(8)
Net cash used in financing activities	(520)	(463)

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Net decreases in cash and cash equivalents	(8,799)	(6,892)
Cash and cash equivalents at beginning of year	12,340	7,476
Cash and cash equivalents at end of year	\$3,541	\$584

Supplemental Disclosures of Cash Flow Information:

Cash paid (refunded) during the year for:

Interest	\$348	\$-
Income taxes, net of refunds	\$-	\$(43)

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIAR

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

(Unaudited; in thousands)

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

Six months Ended June 30, 2014

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
1. withholding 315 thousand shares for \$525 in statutory minimum payroll taxes; we issued 510 thousand shares of common stock.

Options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features
2. 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.

Six months Ended June 30, 2013

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
1. withholding 321 thousand shares for \$0.7 million in statutory minimum payroll taxes; we issued 505 thousand shares of common stock.

Options to purchase 7 thousand shares of common stock were exercised utilizing various cashless exercise features
2. 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

JUNE 30, 2014 AND JUNE 30, 2013

NOTE 1 - DESCRIPTION OF BUSINESS

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the “Company”, “We”, or “Our”) is a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed two proprietary technologies. Our oxycodone HCl tablets, CII formulated with Aversion® Technology, or Aversion® Oxycodone, is the first approved product utilizing Aversion®. Aversion Oxycodone was marketed by Pfizer Inc. under the brand name Oxecta® pursuant to our license agreement with Pfizer. Such license agreement was terminated effective April 9, 2014 and we have re-acquired all rights to Aversion Oxycodone. We have also developed our Impede® Technology which is a combination of inactive ingredients that prevent the extraction of pseudoephedrine from tablets and disrupt the direct conversion of pseudoephedrine from tablets into methamphetamine. In mid-December 2012 we launched in the United States Nexafed® (pseudoephedrine HCl) tablets formulated with our Impede Technology.

The accompanying unaudited consolidated financial statements of the Company were prepared in accordance with generally accepted accounting principles for interim financial information and instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments considered necessary to present fairly the Company’s financial position, results of operations and cash flows have been made. The results of operations for the three and six months ended June 30, 2014 are not necessarily indicative of results expected for the full year ending December 31, 2014. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto for the year ended December 31, 2013 included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission. The 2013 year-end consolidated balance sheet presented in this Report was derived from the Company’s 2013 year-end audited consolidated financial statements, but does not include all disclosures required by generally accepted accounting principles.

NOTE 2 - LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

In October 2007, we entered into a License, Development and Commercialization Agreement, or the Pfizer Agreement, with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer, to develop and commercialize in the United States, Canada and Mexico certain opioid analgesic products utilizing our Aversion Technology. Aversion Oxycodone was approved by the U.S. Food and Drug Administration, or FDA, on June 17,

2011 and sales of Aversion Oxycodone, under Pfizer's brand name Oxecta, commenced in February 2012. For sales of Aversion Oxycodone occurring on and following February 2, 2013 (the one year anniversary of first commercial sale), Pfizer paid us a royalty of 5% of net sales of Aversion Oxycodone. On September 24, 2012, we entered into a letter agreement with Pfizer which provided for the termination of Pfizer's license to our Aversion Technology used in three development-stage products licensed to Pfizer and for the return of these products to us.

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

Paragraph IV ANDA Litigation

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

On September 20, 2012, we announced that we had received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from a generic sponsor of an ANDA for a generic drug listing Aversion Oxycodone as the reference listed drug. Since such date, we have received similar Paragraph IV Notices from three other generic pharmaceutical companies that have filed ANDAs listing Aversion Oxycodone as the reference drug. The Paragraph IV Notices refer to our U.S. Patent Numbers 7,201,920, 7,510,726 and 7,981,439, which cover our Aversion Technology and Aversion Oxycodone. The Paragraph IV Notices state that each generic sponsor believes that such patents are invalid, unenforceable or not infringed. On October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. – Florida (Watson), Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc., and on April 29, 2013, we initiated suit against Ranbaxy, Inc., each in the United States District Court for the District of Delaware alleging infringement of our U.S. Patent No. 7,510,726 listed in the FDA’s Orange Book. The commencement of such litigation prohibits the FDA from granting approval of the filed ANDAs until the earliest of 30 months from the date the FDA accepted the application for filing, or the conclusion of litigation. In January 2013, we dismissed our suit against Watson on the grounds that Watson had amended its ANDA from a Paragraph IV Certification to a Paragraph III Certification, which indicated its intent not to market its generic Aversion Oxycodone product in advance of our patent expiring.

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

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

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

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

On May 21, 2014, we announced that we had entered into a Settlement Agreement with Sandoz Inc. to settle our patent infringement action pending against Sandoz in the United States District Court for the District of Delaware. In the suit, we alleged that a generic of our AVERSION® oxycodone product for which Sandoz is seeking approval to market in the United States pursuant to an ANDA filed with the FDA infringes a U.S. patent owned by us. Under the Settlement Agreement, Sandoz may launch its generic to the AVERSION® oxycodone product in the U.S., through the grant of a non-exclusive license from us that would trigger 180 days following the first sale of a generic to the AVERSION® oxycodone product in the U.S. by an entity that is entitled to the 180 day first-filer exclusivity under applicable law and FDA regulations (or if no entity is entitled to such 180 day exclusivity period, the date on which a generic to the AVERSION® oxycodone product is first sold in the U.S). In certain circumstances, our license to Sandoz would become effective prior to such time. Sandoz is not obligated to pay us a royalty if its current formulation of its generic to the AVERSION® oxycodone product is approved by the FDA. In the event Sandoz changes or modifies the structure of its generic AVERSION® oxycodone product, or materially changes or modifies the amounts or type of any excipient used in the Sandoz formulation disclosed in its ANDA filing with the FDA as of July 30, 2013, Sandoz is required to pay us a royalty based upon the Net Profits (as defined in the Settlement Agreement) derived from the net sales of such changed or modified Sandoz generic AVERSION® oxycodone product in the United States.

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

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

NOTE 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 June 30, 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 \$4 thousand for the six months ended June 30, 2014. The Pfizer Agreement was terminated effective April 9, 2014 and Pfizer's royalty payment obligations ceased as of such date. All royalties owed to us have been received.

Shipping and Handling Costs

We record shipping and handling costs in selling expenses. The amounts recorded to selling expenses from the shipments of Nexafed during each of the three month periods ended June 30, 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 June 30, 2014. We did not have any of these accrued expenses at December 31, 2013. At December 31, 2013, we had \$0.36 million of prepaid CRO costs and clinical trial study and regulatory expenses. We did not have any of these prepaid expenses at June 30, 2014.

NOTE 5 - INVESTMENTS IN MARKETABLE SECURITIES

Investments in marketable securities consisted of the following:

	June 30, 2014 (in millions)	December 31, 2013 (in millions)
Marketable securities:		
Corporate bonds — maturing within 1 year	\$ 3.3	\$ 3.1
Corporate bonds — maturing after 1 through 4 years	6.1	6.8
Exchange-traded funds	4.4	3.8
Total marketable securities	\$ 13.8	\$ 13.7

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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):

	June 30, 2014 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	\$9.3	\$ 0.1	\$ -	\$ 9.4
Exchange-traded funds	4.4	-	-	4.4
Total - Current	\$13.7	\$ 0.1	\$ -	\$ 13.8

December 31, 2013
(in millions)

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	\$9.9	\$ -	\$ -	\$ 9.9
Exchange-traded funds	3.8	-	-	3.8
Total - Current	\$13.7	\$ -	\$ -	\$ 13.7

Fair Value Measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants. Fair values determined based on Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined based on Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. Fair values determined based on Level 3 inputs utilize unobservable inputs and include valuations of assets or liabilities for which there is little, if any, market activity. A financial asset or liability's classification within the above hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

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

June 30, 2014
(in millions)

	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	\$9.4	\$ 9.4	\$ -	\$ -
Exchange-traded funds	4.4	4.4	-	-
Total	\$13.8	\$ 13.8	\$ -	\$ -

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 June 30, 2014 consisted of unrealized gains on securities of \$69 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 both raw and packaging materials on our Aversion Oxycodone product and finished goods held for distribution and sale on our Nexafed product. Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value). We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results. Our inventory reserve activity during the six months ended June 30, 2014 was to record a \$0.2 million reserve expense and actual Nexafed inventory write-offs of \$0.45 million.

The related cost of sales on deferred revenue of \$0.3 million from Nexafed shipments is excluded from the value of the June 30, 2014 inventories and is reported in our balance sheet in the other current deferred assets account. We will recognize the revenue and cost of sales on these Nexafed shipments once the right of return no longer exists or adequate history and information becomes available to estimate product returns.

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

Inventories are summarized as follows:

	June 30, 2014	December 31, 2013
	(in thousands)	
Raw and packaging materials	\$ 260	\$ -
Finished goods	185	501
	445	501
Less: inventory reserve for finished goods	(-)	(250)
Total	\$ 445	\$ 251

NOTE 7 - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

December 31,

	June 30, 2014	2013
	(in thousands)	
Payroll, payroll taxes, bonus and benefits	\$219	\$ 78
Professional services	214	293
Interest - current	162	-
Franchise taxes	8	1
Property taxes	15	15
Contract manufacturing services	-	14
Clinical and regulatory services	175	-
Other	651	140
Total	\$1,444	\$ 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 our business requirements. We estimate the fair value of our notes payable to be its carrying value due to its recent funding.

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

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

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

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

Our interest expense consisted of the following:

	Three months ended		Six months ended	
	June 30,		June 30,	
	2014	2013	2014	2013
	(in thousands)			
Interest expense:				
Secured Promissory notes	\$255	\$ -	\$ 510	\$ -
Debt discount	30	-	59	-
Debt issue costs	17	-	34	-
Total interest expense	\$302	\$ -	\$ 603	\$ -

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

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

NOTE 9 - COMMON STOCK WARRANTS

We have common stock purchase warrants (“warrants”) exercisable for 1.9 million shares of our common stock with 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 having an exercise price of \$1.595 per share with an expiration date in December 2020. At June 30, 2014, we have total outstanding warrants exercisable for 2.2 million shares of our common stock having a weighted average exercise price of \$3.15 per share. All of these 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		Six months ended	
	June 30,		June 30,	
	2014	2013	2014	2013
	(in thousands)			
Stock options				
Research and development	\$56	\$81	\$ 113	\$ 162
General and administrative	141	234	282	468
Total	\$197	\$315	\$ 395	\$ 630
RSUs				
General and administrative	\$92	\$-	\$ 92	\$ -
Combined	\$289	\$315	\$ 487	\$ 630

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 six months ended June 30, 2014 and 2013 is shown below:

	Six months Ended June 30,			
	2014		2013	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, beginning	3,738	\$ 4.99	3,296	\$ 5.50
Granted	-	-	75	2.32
Exercised	(31)	1.30	(14)	1.30
Forfeited or expired	-	-	(15)	2.32
Outstanding, ending	3,707	\$ 5.02	3,342	\$ 5.46
Options exercisable	3,295	\$ 5.42	2,970	\$ 5.80

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

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

During the six months ended June 30, 2014, 31 thousand NonISOs were exercised by our employees. Our employees elected to have 18 thousand shares withheld in satisfaction of \$36 thousand for both the exercise costs and withholding tax obligations resulting in the net issuance of 13 thousand shares of common stock to them. During the six months ended June 30, 2013, 14 thousand NonISOs were exercised by our employees. Our employees elected to have 4 thousand shares withheld in satisfaction of \$14 thousand for both the exercise costs and the withholding tax obligations resulting in the net issuance of 10 thousand common shares to them.

Restricted Stock Unit Award Plan

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

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

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

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

Our 2014 Restricted Stock Unit Award Plan (the “2014 RSU Plan”) was approved by shareholders on May 1, 2014 and permits the grant of up to 2.0 million shares of our common stock pursuant to awards under the 2014 RSU Plan. On May 1, 2014, we awarded 36,764 RSUs to each of our 4 non-employee directors. Such RSU awards vest 50% on June 30, 2014 and 25% on each of September 30 and December 31, 2014. Such non-employee director awards allow for non-employee directors to receive payment in cash, instead of stock, for up to 40% of each RSU award. The RSU awards subject to cash settlement are recorded as a liability in the Company’s balance sheet. The liability was not material at June 30, 2014. Accordingly the vested portion of the awards containing the cash settlement feature will be marked-to-market each reporting period until they are distributed. Marked-to-market accounting can create fluctuations in our compensation expense including the need to record additional expense. RSU awards are generally distributed on the first business day of the year after vesting, but such distribution can be deferred until a later date at the election of the non-employee director. A summary of the grants under the 2005 RSU Plan and the 2014 RSU Plan as of June 30, 2014 and 2013 and for the six months then ended consisted of the following (in thousands):

	Six months Ended June 30,			
	2014		2013	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
	(in thousands)			
Outstanding, beginning	829	829	1,658	1,658
Granted	147	-	-	-
Distributed	(829)	(829)	(829)	(829)
Vested	-	74	-	-
Forfeited or expired	-	-	-	-
Outstanding, ending	147	74	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 June 30, 2014 and December 31, 2013, all our remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss (“NOL”) carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which

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

NOTE 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 10). Diluted EPS is based on the treasury stock method and computed based on the same number of shares used in the basic share calculation and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and stock warrants, assuming the exercise of all in-the-money stock options and warrants. Common stock equivalents are excluded from the computation where their inclusion would be anti-dilutive. No such adjustments were made for 2014 or 2013 as the Company reported a net loss for the three and six month periods, and including the effects of common stock equivalents in the diluted EPS calculation which would have been antidilutive.

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

	Three months Ended June 30,		Six months Ended June 30,	
	2014	2013	2014	2013
EPS – basic and diluted				
Numerator: net loss	\$(3,521)		\$(3,076)	
Denominator:				
Common shares	48,848	46,399	48,846	46,386
Vested RSUs	-	829	-	829
Basic and diluted weighted average shares outstanding	48,848	47,228	48,846	47,215
EPS – basic and diluted	\$(0.07)		\$(0.16)	
Excluded securities:				
Common shares issuable:				
Stock options	3,707	3,342	3,707	3,342
Nonvested RSUs	73	-	73	-
Common stock warrants	2,154	1,856	2,154	1,856
Total excluded common shares	5,934	5,198	5,934	5,198

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 action, over 200 lawsuits have been filed against us and Halsey Drug Company alleging that plaintiffs developed neurological disorders as a result of their use of the Reglan brand and/or generic metoclopramide. In the New Jersey action, plaintiffs filed approximately 150 lawsuits against us, but served less than 50 individual lawsuits upon us. In the California action, there are 89 pending cases against us, with more than 445 individual plaintiffs.

In the lawsuits filed to date, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by us. We discontinued manufacture and distribution of generic metoclopramide more than 18 years ago. In addition, we believe the June 23, 2011 decision by the U.S. Supreme Court in *PLIVA v. Mensing* (“*Mensing* decision”) holding that state tort law failure to warn claims against generic drug companies are pre-empted by the 1984 Hatch-Waxman Act Amendments and federal drug regulations will assist us in favorably resolving these cases. We have consistently maintained the position that these claims are without merit and intend to vigorously defend these actions.

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

In Pennsylvania, on November 18, 2011, 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 and a decision is expected later this year. 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 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 June 30, 2014 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

Westport/Highland Complaint

On April 21, 2014, we obtained a copy of a Complaint filed by Westport Pharmaceuticals, LLC (“Westport”) and Highland Pharmaceuticals, LLC (“Highland”) in the U.S. District Court for the Eastern District of Missouri naming us as the defendant. To date, we have not been formally served with this Complaint. In the Complaint, each of Westport and Highland are commencing a declaratory judgment action seeking a declaration of non-infringement of our U.S. Patent No. 8,409,616 (“616 Patent”) by Westport’s Zephrex-D® (pseudoephedrine hydrochloride, 30mg) product, to enable Westport to continue to sell Zephrex-D and to allow retail distributors to continue to sell Zephrex-D, a competing product to Nexafed. 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;

- the results of our meetings or discussions with the FDA relating to our Aversion hydrocodone/acetaminophen product;

- whether we will conduct an additional intranasal abuse liability study on our Aversion hydrocodone/ acetaminophen product and whether the results of such study will support a claim of intranasal abuse deterrence;

- our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;

- the market acceptance of and competitive environment for any of our products;

- the willingness of wholesalers and pharmacies to stock Nexafed Tablets;

- expectations regarding potential market share for our products and the timing of first sales;

- our ability to enter into additional license agreements for our Aversion Technology product candidates;
 - our exposure to product liability and other lawsuits in connection with the commercialization of our products;
 - the increasing cost of insurance and the availability of product liability insurance coverage;
 - the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- the ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development process to meet OTC Monograph standards as applicable;

the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates;

changes in regulatory requirements;

adverse safety findings relating to our product candidates;

whether the FDA will agree with our analysis of our clinical and laboratory studies;

whether further studies of our product candidates will be required to support FDA approval;

whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and will be able to promote the features of our abuse discouraging technologies; and

whether our Aversion 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,” “expect,” “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 May 27, 2014, we announced that the FDA advised us that the data from our Study 301 was insufficient to support an intranasal abuse deterrence claim. The FDA indicated that a product will have to have an impact on “drug liking” to support a claim of abuse-deterrence through a relevant route of abuse. The FDA’s advice also questioned whether the intranasal route is a relevant route of abuse for hydrocodone/ acetaminophen products and recommended that we identify variables that could have impacted the findings from Study 301 before considering or conducting an additional intranasal abuse liability study on our Aversion hydrocodone/ acetaminophen product. We have previously submitted a report to the FDA on the prevalence of abusing hydrocodone products by intranasal administration. We are currently scheduled to meet with the FDA on August 14, 2014 to discuss the FDA’s expectations in this area. 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 14% 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.

In June, 2014 we entered into an agreement with Purdue Pharma to settle a patent interference filing before the Patent Trial and Appeal Board of the United States Patent and Trademark Office brought by Purdue with respect to one of Acura's issued patents relating to extended release oxycodone products (the "Acura ER Patent"). Under the settlement agreement, Acura conceded priority of the sole claim in the Acura ER Patent to Purdue and its earlier priority pending patent application. The settlement agreement and the Acura ER Patent do not cover our Aversion Oxycodone product, our Aversion hydrocodone/ acetaminophen product or our other immediate release Aversion products in development.

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
		IND submitted to the FDA on December 20, 2012.
Hydrocodone bitartrate/acetaminophen	Vicodin®, Lortab®, Norco®	Pharmacokinetic studies in progress. FDA meeting scheduled for August 14, 2014 to discuss FDA's determination relating to results of Study AP-ADF-301
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;
- An assessment of the routes of abuse of hydrocodone products; and
- Depending on the results of our August 14, 2014 FDA meeting, an additional nasal abuse liability study in recreational drug users against a reference drug.

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 May 27, 2014, we announced that the FDA advised us that the data from our Study 301 was insufficient to support an intranasal abuse deterrence claim. The FDA indicated that a product will have to have an impact on “drug liking” to support a claim of abuse-deterrence through a relevant route of abuse. The FDA’s advice also questioned whether the intranasal route is a relevant route of abuse for hydrocodone/ acetaminophen products and recommended that we identify variables that could have impacted the findings from Study 301 before considering or conducting an additional intranasal abuse liability study on our Aversion hydrocodone/ acetaminophen product. We have previously submitted a report to the FDA on the prevalence of abusing hydrocodone products by intranasal administration. We are currently scheduled to meet with the FDA on August 14, 2014 to discuss the FDA’s expectations in this area.

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:

2013 US			
IR Opioid Products ⁽¹⁾	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 9,300 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 47% of Nexafed stocking pharmacies, excluding Rite Aid which purchases directly from us, are repeat customers.

We have shipped approximately \$53 thousand in Nexafed product during the quarter ended June 30, 2014 and \$96 thousand during the six months ended June 30, 2014. Prior to a drop in shipments in June due to the cold/allergy off-season, Nexafed shipments in May 2014 were 70% higher than January 2014 shipments. 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
Immediate-release pseudoephedrine HCl in combination with other cold and allergy active ingredients	Launch expected in late 2014
Extended-release formulation	Formulations being considered
	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. In July, CVS pharmacies announced the removal of older single-ingredient PSE products from their West Virginia stores. We believe the vast majority of West Virginia pharmacies now stock either no single-ingredient PSE products or exclusively meth-resistant products. The West Virginia Gazette recently reported that PSE purchases in the state are down 30%

and meth lab seizures in the state are trending down 20% compared to 2013.

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

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

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

² Extended release PSE formulations

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

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

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

Product Labeling for Impede Technology Products

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

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

Company's Present Financial Condition

At July 30, 2014 we had cash, cash equivalents and marketable securities of approximately \$16.5 million. We estimate that our current cash reserves will be sufficient to fund operations through at least the next 12 months.

During the six months ended June 30, 2014 we had shipments of Nexafed totaling \$96 thousand. We recognized revenue of \$73 thousand from Nexafed product sales. Certain of our customers have accepted a pricing allowance in exchange for forfeiting the right to return Nexafed and therefore we are recognizing revenue upon product shipment to them. Additionally we are recognizing revenue from certain of our other customers based on a pharmacy's Nexafed reorder activity with their own drug wholesaler supplier. For all other customers, given the limited sales history of Nexafed, we currently cannot reliably estimate expected returns of the product from these customers at the time of shipment. Accordingly, we are deferring recognition of revenue on these product shipments of Nexafed until the right of return no longer exists or adequate history and information is available to estimate product returns. Pfizer no longer has a royalty obligation to us on Pfizer's sale of Aversion Oxycodone as our license agreement with Pfizer was terminated effective April 9, 2014.

To fund our continued operations, we expect to rely on our current cash resources (which includes the proceeds of our \$10.0 million term loan from Oxford Finance having principal debt repayments beginning April 1, 2015), milestones and royalty payments that may be made under future license agreements with pharmaceutical company partners, of which there can be no assurance of obtaining, and revenues from our commercialization of our Nexafed Tablets. Our cash requirements for operating activities may increase in the future as we continue to conduct pre-clinical studies and clinical trials for our product candidates, maintain, defend, and expand the scope of our intellectual property, hire additional personnel, commercialize our Nexafed Tablets, or invest in other areas.

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

	June 30		Increase (decrease)		
	2014	2013		Percent	
	\$000's		\$000's		
Revenues:					
Royalty revenue	\$ 1	\$ 1	-	nm	%
Product sales, net	34	-	34	nm	
Total revenues, net	35	1	34	nm	
Expenses:					
Cost of sales (excludes inventory write-down)	42	-	42	nm	
Inventory write-down	68	361	(293)	(81))
Research and development	1,281	805	476	59	
Selling, marketing, general and administrative	1,916	1,975	(59)	(3))
Total operating expenses	3,307	3,141	166	5	
Operating loss	(3,272)	(3,140)	132	4	
Non-operating income (expense):					
Investment income	53	71	(18))	nm
Loss on sales of marketable securities	-	(7)	(7))	nm
Interest expense	(302)	-	302		nm
Total other income (expense)	(249)	64	(313)		nm
Loss before income taxes	(3,521)	(3,076)	445	15	
Provision for income taxes	-	-	-	-	
Net loss	\$(3,521)	\$(3,076)	\$445	15	%

nm = not meaningful

Revenues***Product Sales***

We launched Nexafed commercially in mid-December 2012. Given the limited sales history of Nexafed, we could not reliably estimate expected returns of the product at the time of shipment. Accordingly, we have deferred recognition of revenue and the related cost of sales on selected product shipments of Nexafed until the right of return no longer exists or adequate history and information is available to estimate product returns. At June 30, 2014 we have deferred

\$307 thousand of revenue. During the three months ended June 30, 2014 we recognized revenue of \$34 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 June 30, 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 \$1 thousand in each of the three month periods ending June 30, 2014 and 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 June 30, 2014 we recorded \$0.1 million inventory reserve expense.

Operating Expenses

Research and development ("R&D") expense during the three months ended June 30, 2014 and 2013 were primarily for our Aversion or our Impede Technologies development, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in each of the 2014 and 2013 results are non-cash share-based compensation expenses of \$0.1 million. Excluding the share-based compensation expense, our R&D expenses increased approximately \$0.5 million between reporting periods. The increase is primarily due from the resumption of our development work during the quarter on our Aversion hydrocodone/acetaminophen product candidate.

Selling and marketing expenses during the three months ended June 30, 2014 and 2013 primarily consisted of advertising and marketing activities on Nexafed. 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 each of the 2014 and 2013 results are non-cash share-based compensation expenses of \$0.2 million. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased approximately \$0.1 million between reporting periods. The decrease is primarily due to our legal services relating to our paragraph IV ANDA litigation activities.

Non-operating Income (Expense)

During the three months ended June 30, 2014 and 2013, other non-operating income consisted principally of investment income derived from our cash reserves being invested in marketable securities in accordance with a Board of Director approved investment policy. Our marketable securities are classified as available-for-sale and are recorded at fair value based on quoted market prices. Our marketable securities may be sold within one year in response to changes in market prices or interest rates, to realign our investment concentrations or to meet our working capital needs and we may realize a gain or loss upon sale. During the three months ended June 30, 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 June 30, 2014 and 2013 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Six months Ended June 30, 2014 Compared to Six months Ended June 30, 2013

	June 30		Increase (decrease)		
	2014	2013		Percent	
	\$000's		\$000's		
Revenues:					
Royalty revenue	\$4	\$5	\$(1)	nm	%
Product sales, net	73	-	73	nm	
Total revenues, net	77	5	72	nm	
Expenses:					
Cost of sales (excludes inventory write-down)	80	-	80	nm	
Inventory write-down	201	361	(160)	(44)	
Research and development	2,719	2,831	(112)	(4)	
Selling, marketing, general and administrative	4,175	4,197	(22)	(1)	
Total operating expenses	7,175	7,389	(214)	(3)	
Operating loss	(7,098)	(7,384)	(286)	(4)	
Non-operating income (expense):					
Investment income	97	81	16	nm	
(Loss) gain on sales of marketable securities	(5)	9	(14)	nm	
Interest expense	(603)	-	603	nm	
Total other income (expense)	(511)	90	(601)	nm	
Loss before income taxes	(7,609)	(7,294)	315	(4)	
Provision for income taxes	-	-	-	-	
Net loss	\$(7,609)	\$(7,294)	\$315	(4)	%

nm = not meaningful

Revenues***Product Sales***

We launched Nexafed commercially in mid-December 2012. Given the limited sales history of Nexafed, we could not reliably estimate expected returns of the product at the time of shipment. Accordingly, we have deferred recognition of revenue and the related cost of sales on selected product shipments of Nexafed since its launch until the right of return no longer exists or adequate history and information is available to estimate product returns. At June 30, 2014 we have deferred \$307 thousand of revenue. During the six months ended June 30, 2014 we recognized revenue of

\$73 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 six months ended June 30, 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 \$4 thousand for the six months 2014 on Pfizer's net sales of Aversion Oxycodone of approximately \$60 thousand as compared to \$5 thousand in royalty revenue for the same period ended June 30, 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 six months ended June 30, 2014 we recorded \$0.2 million inventory reserve expense.

Operating Expenses

Research and development (“R&D”) expense during the six months ended June 30, 2014 and 2013 were primarily for our Aversion or our Impede Technologies development, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in each of the 2014 and 2013 results are non-cash share-based compensation expenses of \$0.1 million and \$0.2 million, respectively. Excluding the share-based compensation expense, our R&D expenses decreased approximately \$0.1 million between reporting periods. The decrease is primarily due from the nasal abuse liability liking study AP-ADF-301 expenses on our Aversion hydrocodone/acetaminophen product candidate which was ongoing during the six month period ended June 30, 2013 and completed in 2013.

Selling and marketing expenses during the six months ended June 30, 2014 and 2013 primarily consisted of advertising and marketing activities on Nexafed. 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 each of the 2014 and 2013 results are non-cash share-based compensation expenses of \$0.4 million and \$0.5 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 our legal services relating to our paragraph IV ANDA litigation activities.

Non-operating Income (Expense)

During the six months ended June 30, 2014 and 2013, other non-operating income consisted principally of investment income derived from our cash reserves being invested in marketable securities in accordance with a Board of Director approved investment policy. Our marketable securities are classified as available-for-sale and are recorded at fair value based on quoted market prices. Our marketable securities may be sold within one year in response to changes in market prices or interest rates, to realign our investment concentrations or to meet our working capital needs and we may realize a gain or loss upon sale. During the six months ended June 30, 2014, other non-operating expense consisted of \$0.6 million interest cost associated with our debt.

Income Taxes

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

Liquidity and Capital Resources

At June 30, 2014, the Company had cash, cash equivalents and marketable securities of \$17.4 million compared to \$26.1 million at December 31, 2013. The Company had working capital of \$16.4 million at June 30, 2014 compared to \$26.3 million at December 31, 2013. The decrease in our cash position is primarily due to our period's net operating loss which is adjusted for non-cash share-based compensation expenses. Our net loss includes our advertising and marketing activities on Nexafed of \$1.4 million, our legal expenses incurred in our paragraph IV ANDA litigation of \$0.3 million and in maintaining our patent and trademarks of \$0.4 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 July 30, 2014, the Company had cash, cash equivalents and marketable securities of approximately \$16.5 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 second 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 13, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

Item 1A. Risk Factors

Investors in our common stock should consider the following risk factor, in addition to those risk factors set forth in our 2013 Form 10-K:

We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data storage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit confidential information, and it is critical that we do so in a secure manner in order to maintain the confidentiality and integrity of such confidential information. Our information technology systems are potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners, vendors, or from attacks by malicious third parties. Maintaining the secrecy of this confidential, proprietary, and/or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful access or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination or misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material effect on our business, financial position, results of operations and/or cash flow.

Item 6. Exhibits

The exhibits required by this Item are listed below.

- 10.1 Letter Agreement dated April 9, 2014 between King Pharmaceuticals Research and Development Inc. and us terminating License, Development and Commercialization Agreement dated October 30, 2007 (certain information has been omitted and filed separately with the Securities and Exchange Commission and confidential treatment has been requested with respect to the omitted portion).
- 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.

July 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