ACURA PHARMACEUTICALS, INC
Form 10-Q
August 03, 2015

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20649

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

or

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

For the transition period from _____ to_____

Commission File Number 1-10113

Acura Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

616 N. North Court, Suite 120

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

847 705 7709

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 S-T (§232.405 of this charter) during the preceding 12 months (or to such shorter period that the registrant was required to submit and post such files).

Yes þ No ¨

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

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

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

As of July 30, 2015 the registrant had 59,006,817 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2015

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited; in thousands except par value)

	June 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$1,268	$ 774
Marketable securities (Note 6)	9,651	11,322
Accounts receivable, net of allowances of $7 and $5	109	76
Accrued investment income	53	66
Inventories, net (Note 7)	217	304
Prepaid expenses and other current assets	623	471
Other current deferred assets	3	218
Total current assets	11,924	13,231
Property, plant and equipment, net	1,121	957
Intangible asset, net of accumulated amortization of $258 and $155 (Note 3)	1,742	1,845
Other assets	175	-
Total assets	$14,962	$ 16,033
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$261	$ 217
Accrued expenses (Note 8)	863	568
Other current liabilities	49	26
Accrued interest	65	70
Sales returns liability	195	-
Deferred revenue	-	353
Current maturities of long-term debt (Note 9)	2,419	1,758
Total current liabilities	3,852	2,992
Long-term debt, net of discount of $251 and $281, and debt issuance costs of $128 and $162 (Note 9)	6,629	7,799
Long-term portion of accrued interest	291	190
Total liabilities	10,772	10,981

Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock: $.01 par value per share; 100,000 shares authorized, 49,217 and 48,848 shares issued and outstanding at 2015 and 2014, respectively	492	488
Additional paid-in capital	367,456	366,898
Accumulated deficit	(363,745)	(362,321)
Accumulated other comprehensive loss	(13)	(13)
Total stockholders' equity	4,190	5,052
Total liabilities and stockholders' equity	$14,962	$ 16,033

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

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,	
	2015	2014	2015	2014
Revenues:				
Royalty revenue	$-	$1	$-	$4
Product sales, net	91	34	448	73
License fee revenue	250	-	5,250	-
Total revenues, net	341	35	5,698	77
Operating expenses:				
Cost of sales (excluding inventory write-down)	98	42	422	80
Inventory write-down (Note 7)	47	68	307	201
Research and development	511	1,281	1,475	2,719
Selling, marketing, general and administrative	2,083	1,916	4,380	4,175
Total operating expenses	2,739	3,307	6,584	7,175
Operating loss	(2,398)	(3,272)	(886)	(7,098)
Non-Operating income (expense):				
Investment income	36	53	71	97
Interest expense (Note 9)	(301)	(302)	(609)	(603)
Other expense	-	-	-	(5)
Total other expense, net	(265)	(249)	(538)	(511)
Loss before income taxes	(2,663)	(3,521)	(1,424)	(7,609)
Provision for income taxes	-	-	-	-
Net loss	$(2,663)	$(3,521)	$(1,424)	$(7,609)
Other comprehensive (loss) income:				
Unrealized (losses) gains on securities	(31)	21	-	50
Total other comprehensive (loss) income	(31)	21	-	50
Comprehensive loss	$(2,694)	$(3,500)	$(1,424)	$(7,559)
Loss per share:				
Basic	$(0.05)	$(0.07)	$(0.03)	$(0.16)
Diluted	$(0.05)	$(0.07)	$(0.03)	$(0.16)
Weighted average shares outstanding:				
Basic	49,233	48,848	49,101	48,846

Diluted	49,233	48,848	49,101	48,846

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited; in thousands)

	Six months Ended June 30, 2015					
	Common Stock		Additional		Accumulated Other Comprehensive	
	Shares	$ Amount	Paid-in Capital	Accumulated Deficit	Income (Loss)	Total
Balance at December 31, 2014	48,848	$ 488	$ 366,898	$ (362,321)	$ (13)	$ 5,052
Net loss	-	-	-	(1,424)	-	(1,424)
Other comprehensive income (loss)	-	-	-	-	-	-
Share-based compensation	-	-	311	-	-	311
Net distribution of common stock pursuant to restricted stock unit award plan	99	1	-	-	-	1
Modification to warrants issued with promissory notes	-	-	33	-	-	33
Issuance of common stock under “at the market” offerings, net of offering costs of $8	270	3	214	-	-	217
Balance at June 30, 2015	49,217	$ 492	$ 367,456	$ (363,745)	$ (13)	$ 4,190

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Six months Ended June 30,	
	2015	2014
Cash Flows from Operating Activities:		
Net loss	$(1,424)	$(7,609)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	59	58
Provision to reduce inventory to net realizable value	307	201
Provision for sales returns	195	-
Share-based compensation	311	455
Amortization of debt discount and debt issue costs	97	93
Amortization of bond premium in marketable securities	76	138
Amortization of intangible asset	103	-
Loss on sales of marketable securities	-	5
Loss on disposal of property and equipment	20	1
Changes in assets and liabilities:		
Accounts receivable	(33)	108
Accrued investment income	13	18
Inventories	(220)	(394)
Prepaid expenses and other current assets	(152)	83
Other current deferred assets	215	(7)
Other assets	(175)	3
Accounts payable	44	(160)
Accrued expenses	295	902
Deferred revenue	(353)	20
Accrued interest – current and long term	96	-
Other current liabilities	23	32
Net cash used in operating activities	(503)	(6,053)
Cash Flows from Investing Activities:		
Purchases of marketable securities	-	(1,540)
Proceeds from sale and maturities of marketable securities	1,595	1,361
Acquisition of product rights	-	(2,000)
Additions to property, plant and equipment	(257)	(47)
Proceeds from disposal of property and equipment	14	-
Net cash provided by (used in) investing activities	1,352	(2,226)
Cash Flows from Financing Activities:		
Proceeds from exercise of stock options	-	8
Proceeds from distribution of restricted stock units	1	1
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	-	(529)

Proceeds from “at-the-market” offering	225	-
Offering transaction costs	(8)	-
Principal payments on debt	(573)	-
Net cash used in financing activities	(355)	(520)
Net increase (decrease) in cash and cash equivalents	494	(8,799)
Cash and cash equivalents at beginning of year	774	12,340
Cash and cash equivalents at end of period	$1,268	$3,541
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest	$414	$348
Income taxes	$-	$-

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 expect per share amounts):

Six months Ended June 30, 2015

1. The exercise price of 298 thousand common stock purchase warrants held by the lender of our debt was changed from $1.595 to $0.504 per share. The change in fair value of $33 was recorded as additional debt discount and will be amortized as interest expense over the remaining term of this debt.

Six months Ended June 30, 2014

2. 829 thousand shares of common stock were eligible for distribution pursuant to our 2005 RSU Plan utilizing various cashless exercise features of the plan. After withholding 4 thousand shares for $7 in exercise costs and withholding 315 thousand shares for $525 in statutory minimum payroll taxes, we issued 510 thousand shares of common stock.
3. Options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features of the stock option plan. 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.

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2015 AND JUNE 30, 2014

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 three proprietary platform technologies which can be used to develop multiple products. Our Aversion® Technology is a mixture of inactive ingredients incorporated into pharmaceutical tablets and capsules intended to address some common methods of product tampering associated with opioid abuse. Oxaydo™ Tablets (formerly known as Oxecta®) (oxycodone HCl, CII), is the first approved product utilizing Aversion® in the United States. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation (collectively, "Egalet") pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is currently approved by the FDA for marketing in the United States in 5mg and 7.5mg strengths. We are advised that Egalet plans to launch Oxaydo in the United States in the third quarter of 2015. 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 our Nexafed Sinus Pressure + Pain product in the United States in February 2015. We have multiple pseudoephedrine products in development utilizing our Impede Technology. On June 15, 2015, we and Bayer Healthcare LLC ("Bayer") entered into a License and Development Agreement to provide Bayer with an exclusive worldwide license to our Impede Technology for an undisclosed methamphetamine resistant pseudoephedrine – containing product, and providing for our joint development of such product utilizing our Impede™ Technology for the U.S. market. Our third technology, Limitx, is designed to retard the release of active drug ingredients when an excess number of tablets are accidently or purposefully ingested. In August 2014, we were awarded a grant from the National Institute on Drug Abuse to advance early stage development of our Limitx technology.

NOTE 2 – ACCOUNTING PRONOUNCEMENTS

Revenue from Contracts with Customers

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers

in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2018.

Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, "*Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*", which will explicitly require management to assess an entity's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. Currently, there is no guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments in this Update provide that guidance. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term "substantial doubt", (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in this update are effective for the first annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the impact of adopting this update on its financial statements.

Presentation of Debt Issue Costs

In April 2015, the FASB issued ASU No. 2015-03, *"Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs."* The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The amendments are effective for financial statements issued for fiscal years beginning after December 15, 2015. Early adoption of the amendments is permitted and the Company elected to adopt this guidance effective April 1, 2015. The Company adopted the guidance to implement the simplified presentation prescribed as the purpose of the amendment. The new guidance has been applied on a retrospective basis, wherein the consolidated balance sheets of December 31, 2014 have been retrospectively adjusted to reflect the effects of applying the new guidance. As a result of the change to the December 31, 2014 consolidated balance sheet, deferred debt issuance costs and long-term debt decreased and increased, respectively, by $162. After the retrospective application to December 31, 2014, subsequent amortization of the deferred debt issuance costs results in an increase to long-term debt.

NOTE 3 - LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENTS

Pfizer 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 in exchange for a one-time termination payment of $2.0 million. 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 is being amortized over the remaining useful life of the patent for Aversion Oxycodone. The recorded value of the intangible asset will be periodically assessed for impairment. We also purchased from Pfizer selected raw and packaging material inventories for $260 thousand relating to the Aversion Oxycodone product. During the quarter ended March 31, 2015, we recorded a 100% reserve against these inventories which is reflected in operating expense.

Egalet Agreement

On January 7, 2015, we and Egalet entered into a Collaboration and License Agreement (the "Egalet Agreement") to commercialize Aversion Oxycodone under the tradename Oxaydo. Oxaydo is approved by the FDA for marketing in the United States in 5 mg and 7.5 mg strengths. Under the terms of the Egalet Agreement, we are transferring the approved NDA for Oxaydo to Egalet and Egalet is granted an exclusive license under our intellectual property rights for development and commercialization of Oxaydo worldwide (the "Territory") in all strengths, subject to our right to co-promote Oxaydo in the United States.

In accordance with the Egalet Agreement, we and Egalet have formed a joint steering committee to coordinate commercialization strategies and the development of product line extensions. Egalet will pay a significant portion of the expenses relating to (i) annual NDA PDUFA product fees, (ii) expenses of the FDA required post-marketing study for Oxaydo and (iii) expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States and will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States. Egalet is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Egalet will have final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Egalet may develop Oxaydo for other countries and in additional strengths, in its discretion.

Egalet paid us an upfront payment of $5 million upon signing of the Egalet Agreement and will pay us a $2.5 million milestone on the earlier to occur of (A) the launch of Oxaydo and (B) January 1, 2016. In addition, we will be entitled to a one-time $12.5 million milestone payment when worldwide Oxaydo net sales reach $150 million in a calendar year. We will receive from Egalet a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on Oxaydo net sales during such year (excluding net sales resulting from our co-promotion efforts). In any calendar year in which net sales exceed a specified threshold, we will receive a double digit royalty on all Oxaydo net sales in that year (excluding net sales resulting from our co-promotion efforts). If we exercise our co-promotion rights, we will receive a share of the gross margin attributable to incremental Oxaydo net sales from our co-promotion activities. Egalet's royalty payment obligations commence on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA's Orange Book remains with respect to Oxaydo. Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by Egalet to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Egalet Agreement expires upon the expiration of Egalet's royalty payment obligations in all countries. Either party may terminate the Egalet Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Egalet Agreement, subject to applicable cure periods, or in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws. We also may terminate the Egalet Agreement with respect to the U.S. and other countries if Egalet

materially breaches its commercialization obligations. Egalet may terminate the Egalet Agreement for convenience on 120 days prior written notice, which termination may not occur prior to the second anniversary of Egalet's launch of Oxaydo. Egalet also may terminate the Agreement prior to the launch of Oxaydo on 30 days prior written notice upon the occurrence of serious safety issues, regulatory restrictions and intellectual property issues, in each case involving Oxaydo. Termination does not affect a party's rights accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations (but not expiration), the Egalet Agreement provides for the transition of development and marketing of Oxaydo from Egalet to us, including the conveyance by Egalet to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Egalet's supply of Oxaydo for a transition period.

Paragraph IV ANDA Litigation and License Grants

On or about September 17, 2012, the FDA began accepting ANDAs referencing Oxaydo. To date, we have received Paragraph IV Certification Notices under 21 U.S.C. 355(j) (a Paragraph IV Notice) from five separate generic sponsors of an ANDA for a generic drug listing Oxaydo as the reference listed drug. The Paragraph IV Notices state that each generic sponsor believes that our Aversion Technology patents listed in FDA's Orange Book are invalid, unenforceable or not infringed. We initiated suit against each of Watson Laboratories, Inc. – Florida (Watson), Par Pharmaceutical, Inc., Impax Laboratories, Inc., Sandoz Inc., and 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.

We dismissed our suit against Watson on the grounds that Watson had amended its ANDA from a Paragraph IV Certification to a Paragraph Certification III, which indicated its intent not to market its generic Oxaydo product in advance of our patent expiry.

We have entered into distinct Settlement Agreements with each of Par, Impax, Ranbaxy and Sandoz to settle our patent infringement actions. Par is the first filer of an ANDA for a generic Oxaydo product and is entitled to the 180-day first filer exclusivity under applicable law and FDA regulations. Par is entitled to launch its generic Oxaydo 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 Oxaydo product.

Impax and Sandoz, are entitled to launch their generic Oxaydo 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 Oxaydo® 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 Oxaydo® product is first sold in the U.S. or November 27, 2021, whichever date occurs first). In certain circumstances, our license to Impax and Sandoz would become effective prior to such time. In certain circumstances, Sandoz may be required to pay us a royalty on net profits of their generic Oxaydo product.

We have 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. The Settlement Agreement with Ranbaxy provides that Ranbaxy's current generic of our Oxaydo 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 Oxaydo product.

Notwithstanding the settlement of these prior infringement actions, it is possible that other generic manufacturers may also seek to launch a generic version of Oxaydo and challenge our patents. Any determination in such infringement actions that our patents covering our Aversion Technology and Oxaydo 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.

Bayer Agreement

On June 15, 2015, we and Bayer entered into a License and Development Agreement granting Bayer an exclusive worldwide license to our Impede Technology for use in an undisclosed methamphetamine resistant pseudoephedrine –containing product (the "Bayer Licensed Product") and providing for the joint development of such product utilizing our Impede Technology for the U.S. market. The Agreement also grants Bayer first right to negotiate a license to the Impede technology for certain other products.

We and Bayer will form a joint development committee to coordinate development of the Bayer Licensed Product. We will be eligible to receive reimbursement of certain of our development costs, success-based development and regulatory milestones payments, and low mid-single digit royalties on net sales of the Bayer Licensed product in countries with patent coverage and a reduced royalty elsewhere.

The term of the Agreement with respect to each country expires when royalties are no longer payable with respect to such country. After expiration of the term Bayer retains a license to sell the Bayer Licensed Product on a royalty free basis. Either party may terminate the Agreement in its entirety if the other party materially breaches the Agreement, subject to an applicable cure period, or in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws. Bayer may terminate the Agreement immediately prior to completion of our development obligations or at any time upon six (6) months prior written notice thereafter. We may terminate the Agreement with respect to the U.S. if Bayer ceases or suspends development or commercialization of the Bayer Licensed Product for a certain period of time.

Purdue Pharma

The Company received a $250 thousand payment from Purdue Pharma L.P. in June 2015 relating to a December 2014 agreement to settle a patent interference action on U.S. Patent No. 8,101,630 issued to Acura.

NOTE 4 - REVENUE RECOGNITION

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

Nexafed was launched in mid-December 2012 and Nexafed Sinus Pressure + Pain was launched in February 2015. We sell our Nexafed products in the United States to wholesale pharmaceutical distributors as well as directly to chain drug stores. Our Nexafed products are sold subject to the right of return for a period of up to twelve months after the product expiration. The Nexafed products currently have a shelf life of twenty-four months from the date of manufacture. Given the limited sales history of our Nexafed products, we could not reliably estimate expected returns of the product at the time of shipment to certain customers and accordingly we had deferred revenue. During the first quarter ended March 31, 2015 we determined we had obtained sufficient sales returns history to reasonably estimate future returns. As a result of this change, we recorded a one-time adjustment in the first quarter ended March 31, 2015 to recognize revenue that had previously been deferred, resulting in additional net revenues of $314 thousand after recording an allowance for sales returns of $120 thousand, and cost of sales of $255 thousand. At June 30, 2015, we have a $195 thousand sales returns liability which will be reviewed against sales returns activity each quarter. Revenue is being recognized at the time the products are sold to a customer.

Commencing in February 2013, we began earning royalties based on net sales of Aversion Oxycodone by Pfizer. We 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 our shipping and handling costs in selling expenses. The amounts recorded to selling expenses from the shipments of Nexafed products during each of the six month periods ended June 30, 2015 and 2014 were not material.

NOTE 5 - RESEARCH AND DEVELOPMENT ACTIVITIES

Research and Development (“R&D”) expenses include internal R&D activities, external Contract Research Organization (“CRO”) services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. We make payments to the CRO's based on agreed upon terms and may include payments in advance of a study starting date. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. We did not have any accrued CRO costs and clinical trial study expenses at either June 30, 2015 or December 31, 2014. We did not have any prepaid CRO costs and clinical trial study expenses at either June 30, 2015 or December 31, 2014.

NOTE 6 - INVESTMENTS IN MARKETABLE SECURITIES

Investments in marketable securities consisted of the following (in millions):

	June 30, 2015	December 31, 2014
Marketable securities:		
Corporate bonds - maturing within 1 year	$ 3.0	$ 3.5
Corporate bonds - maturing after 1 year and through March 2017	1.7	2.8
Exchange-traded funds	5.0	5.0
Total marketable securities	$ 9.7	$ 11.3

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

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

	June 30, 2015			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$4.7	$ -	$ -	$ 4.7
Exchange-traded funds	5.0	-	-	5.0
Total – Current	$9.7	$ -	$ -	$ 9.7

	December 31, 2014			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$6.3	$ -	$ -	$6.3
Exchange-traded funds	5.0	-	-	5.0
Total - Current	$11.3	$ -	$ -	$11.3

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, 2015 and December 31, 2014 consisted of the following (in millions):

	June 30, 2015			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	$4.7	$ -	$4.7	$ -
Exchange-traded funds	5.0	5.0	-	-
Total	$9.7	$5.0	$4.7	$ -

	December 31, 2014			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	$6.3	$ -	$ 6.3	$ -
Exchange-traded funds	5.0	5.0	-	-
Total	$11.3	5.0	6.3	-

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, 2015 and December 31, 2014 consisted of unrealized losses on securities of $13 thousand.

NOTE 7 – INVENTORIES

Inventories consist of both raw and packaging materials on our Oxaydo product and finished goods held for distribution and sale on our Nexafed products. During 2014, we purchased raw and packaging material inventories for $260 thousand from Pfizer on the Oxaydo product we reacquired from them. Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value). We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results. During the quarter ended March 31, 2015, we recorded a $260 thousand reserve against the raw and packaging material inventory on our Oxaydo product as Egalet will secure its own material requirements. During the quarter ended June 30, 2015, we applied the reserve against our packaging material inventory and we recorded a $47 thousand reserve against finished good inventory. We recorded finished good inventory reserves of $133 thousand and $68 thousand during each of the first and second quarters of 2014, respectively.

We had recorded Nexafed deferred revenue of $0.35 million at December 31, 2014. The related cost of sales of $0.22 million at December 31, 2014 is reported in our balance sheet in the other current deferred assets account and excluded from the reported year end inventories. We recognize both 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 sales returns. During the first quarter ended March 31, 2015, we determined we had obtained sufficient sales returns history to reasonably estimate future returns. As a result of this change, we recorded a one-time adjustment in the first quarter ended March 31, 2015 to recognize revenue that had previously been deferred, resulting in additional net revenue of $314 thousand and cost of sales of $255 thousand. Revenue is being recognized at the time the products are sold to a customer.

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

Inventories are summarized as follows (in thousands):

	June 30, 2015	December 31, 2014
Raw and packaging materials	$ 126	$ 260
Finished goods	264	44
Total	390	304
Less: reserve for raw materials	(126)	(-)
Less: reserve for finished goods	(47)	(-)
Net	$ 217	$ 304

NOTE 8 - ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	June 30, 2015	December 31, 2014
Payroll, payroll taxes, and benefits	$ 165	$ 94
Professional services	436	253
Franchise taxes	19	13
Property taxes	15	15
Marketing and promotion	150	61
Clinical, non-clinical and regulatory services	24	83
Other fees and services	54	49
Total	$ 863	$ 568

NOTE 9 – DEBT

On December 27, 2013, we entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford" or the "Lender"), for a term loan to the Company 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 are using the proceeds of the Loan Agreement for general working capital and to fund our business requirements. The Term Loan accrues interest at a fixed rate of 8.35% per annum (with a default rate of 13.35% per annum). The Company was required to make monthly interest−only payments until the April 1, 2015 ("Amortization Date") and on the Amortization Date, the Company began to make payments of principal and accrued interest in equal monthly installments of $260 thousand sufficient to amortize the Term Loan through the maturity date of December 1, 2018. 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 of June 30, 2015 we have made $768 thousand in principal payments. As security for its obligations under the Loan Agreement, the Company granted Lender a security interest in substantially all of its existing and after−acquired assets, exclusive of its intellectual property assets. Pursuant to the Loan Agreement, the Company is not allowed to pledge its intellectual property assets to others. Upon the execution of the Loan Agreement, 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 are amortizing it 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.

On January 7, 2015, we and Oxford entered into an amendment to the Loan Agreement. Pursuant to the amendment, (i) the exercise price of the Warrants was lowered from $1.595 to $0.504 per share (the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the amendment) and we recorded additional debt discount of $33 representing the fair value of the warrant modification, (ii) we agreed to maintain a $2.5 million

cash reserve until such time as we have repaid $5.0 million in principal of the Term Loan, and (iii) the Lender consented to the terms of our Collaboration and License Agreement with Egalet relating to our Oxaydo product.

The Company may voluntarily prepay the Term Loan in full, but not in part, and any prepayment is subject to a prepayment premium equal to 2% of the principal prepaid, if prepaid 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 the Company must pay the Lender an additional one-time interest payment of $795 thousand. We will incur and accrue additional monthly interest expense over the term of the loan for this additional one-time interest payment using the loan’s effective cash interest rate.

The Company was 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 the Company’s own expenses and a $100 thousand consulting placement fee, the Company incurred $231 thousand in deferred debt issue costs. We are amortizing these costs, including debt modification additional costs, into interest expense over the term of the loan using the loan’s effective interest rate of 10.16%.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, limits or restrictions on the Company's 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 the Company's 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.

Our debt at June 30, 2015 is summarized below (in thousands):

Debt	Current	Long-term	Total
Balance at Dec 31, 2014	$1,758	$ 8,242	$10,000
Principal payments	(573)	-	(573)
Classification	1,234	(1,234)	-
Balance at Jun 30, 2015	$2,419	$ 7,008	$9,427

Debt Discount	Current	Long-term	Total
Balance at Dec 31, 2014	$ -	$ (281)	$(281)
Modification of warrants	-	(33)	(33)
Amortization expense	-	63	63
Balance at Jun 30, 2015	$-	$ (251)	$(251)

Debt Issuance Costs	Current	Long-term	Total
Balance at Dec 31, 2014	$-	$ (162)	$(162)
Additions	-	-	-
Amortization expense	-	34	34
Balance at Jun 30, 2015	$-	$ (128)	$(128)
Net Debt at Jun 30, 2015	$2,419	$ 6,629	$9,048

Our interest expense during the three and six months ended June 30, 2015 and 2014 consisted of the following (in thousands):

	Three months Ended June 30,		Six months Ended June 30,	
	2015	2014	2015	2014
Interest expense:				
Term loan	$ 251	$ 255	$ 512	$ 510
Debt discount	33	30	63	59

Debt issue costs	17	17	34	34
Total interest expense	$ 301	$ 302	$ 609	$ 603

The remaining annual principal payments on the debt as of June 30, 2015 is as follows (in thousands):

Principal Payments	
2015	$ 1,185
2016	2,522
2017	2,741
2018	2,979
Total	$ 9,427

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NOTE 10 – EQUITY FINANCING

Our universal shelf registration statement on Form S-3 was declared effective by the Securities and Exchange Commission ("SEC") on March 15, 2013. On April 18, 2013, we filed a prospectus supplement with the SEC pursuant to which we may sell shares of our common stock from time to time in "at the market" offerings and certain other transactions, having sales proceeds of up to $13 million. We did not sell any shares of our common stock pursuant to our prospectus supplement during the year ended December 31, 2014. During the three and six months ended June 30, 2015, we sold approximately 270 thousand shares of our common stock for gross proceeds of approximately $0.23 million. Transaction costs were approximately $8 thousand. The net proceeds of approximately $0.22 million will be used for general corporate purposes, which may include working capital, capital expenditures, research, development and marketing expenditures, clinical trial expenditures, acquisitions of new technologies, and possible investments in or acquisitions of, complementary businesses or technologies. In order to allow for the sale of our shares of common stock under our shelf registration statement pursuant to the Placement Agency Agreement and Securities Purchase Agreement described below, on June 30, 2015, we and MLV & Co., LLC, as sales agent, terminated the At Market Issuance Sales Agreement dated April 18, 2013, thereby terminating any further "at the market offerings" under our prospectus supplement filed with the SEC on April 18, 2013.

On June 30, 2015, we entered into a Placement Agency Agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC ("Roth"), pursuant to which we engaged Roth to act as sole placement agent in a registered direct offering (the "Offering") of 9.79 million shares of our common stock, par value $.01. On June 30, 2015, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors (the "Purchasers"), pursuant to which we agreed to sell 9.79 million shares of our common stock at a price of $0.78 per share to the Purchasers in the Offering, for gross proceeds to the Company of approximately $7.63 million, before expenses. The Offering was made pursuant to a prospectus supplement dated June 30, 2015 filed with the Securities and Exchange Commission in connection with a takedown from the Company's shelf registration statement on Form S-3 (File No. 333-187075), which became effective on March 15, 2013, and the related base prospectus included in the Registration Statement, as supplemented by the prospectus supplement. The transactions contemplated by the Placement Agency Agreement and the Purchase Agreement closed on July 7, 2015.

Pursuant to the terms of the Placement Agency Agreement, we paid Roth a cash placement fee equal to 6.5% of the gross proceeds in the Offering and reimbursed Roth $35 thousand for its expenses. We estimate that net proceeds from the Offering, after these and other legal expenses, will be approximately $7.0 million.

NOTE 11 - COMMON STOCK WARRANTS

We have outstanding common stock purchase warrants ("warrants") exercisable for 298 thousand shares of our common stock having an exercise price of $0.504 per share with an expiration date in December 2020. See Note 9 for a discussion of the reduction of the exercise price of the warrants to $0.504 per share. These warrants contain a cashless

exercise feature. Our common stock warrant activity during the six months ended June 30, 2015 and 2014 is shown below:

	Six months Ended June 30,			
	2015		2014	
	Number (000's)	Weighted Average Exercise Price	Number (000's)	Weighted Average Exercise Price
Outstanding, beginning	298	$ 1.60	2,154	$ 3.15
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Outstanding, ending	298	$ 0.50	2,154	$ 3.15

NOTE 12 - 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 (in thousands):

	Three months Ended June 30,		Six months Ended June 30,	
	2015	2014	2015	2014
Research and development expense:				
Stock options	$39	$56	$78	$113
General and administrative expense:				
Stock options	$88	$141	$186	$282
Restricted stock units	24	60	47	60
Subtotal	$112	$201	$233	$342
Total	$151	$257	$311	$455

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, 2015 and 2014 is shown below:

	Six months Ended June 30,			
	2015		2014	
	Number of	Weighted Average	Number of	Weighted Average

	Options (000's)	Exercise Price	Options (000's)	Exercise Price
Outstanding, beginning	4,556	$ 4.14	3,738	$ 4.99
Granted	-	-	-	-
Exercised	-	-	(31)	1.30
Forfeited or expired	(75)	5.25	-	-
Outstanding, ending	4,481	$ 4.13	3,707	$ 5.02
Options exercisable	3,719	$ 4.82	3,295	$ 5.42

No stock options were exercised during the six months ended June 30, 2015. During the six months ended June 30, 2014, a total of 31 thousand stock options were exercised by our employees. Of the total amount of these stock option exercises, 24 thousand of stock options were exercised under various cashless exercise features of the plan. Our employees elected to have 18 thousand shares withheld in satisfaction of $36 thousand for both the exercise costs and withholding tax obligations on those options, resulting in the net issuance of 13 thousand shares of common stock from all stock option exercises.

Restricted Stock Unit Award Plans

We have two Restricted Stock Unit Award Plans for our employees and non-employee directors, a 2005 Restricted Stock Unit Award Plan (the "2005 RSU Plan") and a 2014 Restricted Stock Unit Award Plan (the "2014 RSU Plan"). 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.

A summary of the grants under the RSU Plans consisted of the following (in thousands):

	Six months Ended June 30,			
	2015		2014	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	147	147	829	829
Granted	206	-	147	-
Distributed	(129)	(129)	(829)	(829)
Vested	-	103	-	74
Forfeited or expired	-	-	-	-
Outstanding, ending	224	121	147	74

2005 Restricted Stock Unit Award Plan

Under our 2005 RSU Plan, one-fourth of vested shares of common stock underlying RSU awards of 3.3 million shares will be distributed (after payment of exercise costs of $0.01 par value per share) on January 1 of each of years 2011 thru 2014. 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.

All RSUs granted under the 2005 RSU Plan had been distributed effective January 1, 2014.

2014 Restricted Stock Unit Award Plan

Our 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. As of June 30, 2015, 1.65 million shares are available for award under the 2014 RSU Plan.

Information about the awards under the 2014 RSU Plan is as follows:

- On May 1, 2014, we awarded approximately 37 thousand RSUs to each of our 4 non-employee directors. Such RSU awards vested 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 $26 thousand at December 31, 2014. Accordingly the vested portion of the awards containing the cash settlement feature are being 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.

- On January 2, 2015, we awarded approximately 51.5 thousand RSUs to each of our 4 non-employee directors which also allow for them to receive payment in cash, instead of stock, for up to 40% of each RSU award. Such awards vest 25% at the end of each calendar quarter in 2015. The RSU awards subject to cash settlement are subject to marked-to market accounting and the liability recorded in the Company's balance sheet was $49 thousand at June 30, 2015. Distributions of stock under the January 2, 2015 award cannot be deferred until a later date and the stock under such awards will be distributed on January 4, 2016.

Information about the distribution of shares under the 2014 RSU Plan is as follows:

- On January 2, 2015, 129 thousand RSUs from the May 1, 2014 award were distributed and 18 thousand RSUs were deferred until a future distribution date. Of the 129 thousand RSUs distributed, 99 thousand RSUs were distributed in common stock and 30 thousand RSUs were settled in cash.

NOTE 13 – 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, 2015 and December 31, 2014, 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 $51.5 million federal income tax benefits at December 31, 2014 derived from $151.4 million Federal NOLs at the U.S. statutory tax rate of 34% and $2.9 million state NOLs, available to offset future taxable income, some of which have limitations for use as prescribed under IRC Section 382. Our Federal and state NOLs will expire in varying amounts between 2016 and 2034 if not used, and those expirations will cause fluctuations in our valuation allowances. As of December 31, 2014 we had federal research and development tax credits of approximately $1.1 million, which expire in the years 2024 through 2034. We also had approximately $0.3 million of Indiana state research and development tax credits, which expire in the years 2015 through 2017.

NOTE 14 – 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 Restricted Stock Units ("RSUs") (see Note 12). 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 2015 and 2014 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 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,	
	2015	2014	2015	2014
EPS – basic and diluted				

Numerator: net loss	$(2,663)	$(3,521)	$(1,424)	$(7,609)
Denominator:				
Common shares	49,163	48,848	49,055	48,846
Vested RSUs	70	-	46	-
Basic and diluted weighted average shares outstanding	49,233	48,848	49,101	48,846
EPS – basic and diluted	$(0.05)	$(0.07)	$(0.03)	$(0.16)
Excluded securities:				
Common shares issuable:				
Stock options	4,481	3,707	4,481	3,707
Nonvested RSUs	103	73	103	73
Common stock warrants	298	2,154	298	2,154
Total excluded common shares	4,882	5,934	4,882	5,934

NOTE 15 – COMMITMENTS AND CONTINGENCIES

Purdue Pharma Complaint

In April 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (collectively, "Purdue") commenced a patent infringement lawsuit against us and our Oxaydo product licensee Egalet US, Inc. and its parent Egalet Corporation in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's U.S. patent 8,389,007. The complaint seeks injunctive relief as well as awards of damages and attorneys' fees. We deny the allegations in the complaint, believe they are without merit and are defending the action vigorously.

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, which plaintiffs voluntarily dismissed in December 2014. In this product liability litigation against numerous pharmaceutical product manufacturers and distributors, including Acura, 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 Acura 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 Acura. 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.

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 all of the New Jersey cases pending against Acura with prejudice. It is possible that this ruling may eventually be appealed by plaintiffs at the conclusion of the litigation in the trial court.

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

In Pennsylvania, on November 18, 2011, the trial court denied Generic Defendants' dispositive preemption motions, without prejudice. In July 2013, the Pennsylvania Superior Court issued an adverse decision, and a subsequent appeal to the Pennsylvania Supreme Court was denied. On December 16, 2014, the Generic Defendants filed a Joint Petition for Certiorari with the United States Supreme Court captioned *Teva Pharmaceuticals USA, Inc. et al. v. Dorothy Bentley, et al.*, No. 14-711 (U.S.) seeking reversal of the Pennsylvania state court decision. On April 27, 2015, the U.S. Supreme Court denied this Petition and this matter has been returned to the trial court for further proceedings. Pending a further court order, these proceedings are stayed. On July 16, 2015, the court has scheduled a conference to address lifting the stay and to confirm procedures for further litigation. To the extent, however, that plaintiffs intend to pursue these claims, Acura nonetheless remains optimistic that most, if not all, of these Philadelphia cases will eventually be dismissed against it based upon the favorable aspects of the Superior Court's narrow preemption ruling and lack of product identification, although there can be no assurance in this regard. Legal fees related to this matter are currently covered by Acura's insurance carrier.

In California, the trial court entered a May 25, 2012 Order denying Generic Defendants' dispositive preemption motions. The Generic Defendants' appeals from this order were denied by the California appellate courts. In May 2014, the California Court denied a subsequent demurrer and motion to strike seeking dismissal of plaintiffs' manufacturing defect and defective product claims to the extent that they are barred by federal preemption based upon the June 2013 *Bartlett* decision. Thus far, Acura and most Generic Defendants have not been required to file answers or other responsive pleadings in each individual case in which they are named defendants. However, the individual cases against Acura have been stayed pending further action by the trial court. Subject to further developments, plaintiffs may be permitted to proceed with these lawsuits against Acura 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. The California trial court also has acknowledged the preemptive effect of *Mensing* so that any claim "that would render the generic defendants in violation of federal law if they are found responsible under a state law cause of action, would not be permissible." To date, however, none of these plaintiffs have confirmed they ingested any of the generic metoclopramide manufactured by Acura. 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.

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, 2015 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

Facility Lease

The Company leases administrative office space in Palatine, Illinois under a lease expiring March 31, 2016 for approximately $25 thousand annually.

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 fund or obtain funding for our continuing operations, including the development of our products utilizing our Aversion®, Impede® and Limitx™ technologies;

- our and our licensee’s ability to successfully launch and commercialize our products and technologies, including Oxaydo Tablets and our Nexafed products;

- the pricing and price discounting that may be offered by Egalet for Oxaydo;

- whether we can successfully develop a product under our agreement with Bayer;

- the results of our development of our Limitx™ technology;

- 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 pharmacies to stock our Nexafed products;
- expectations regarding potential market share for our products and the timing of first sales;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
- 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 over-the-counter ("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 commercialized products or product candidates in development;
- 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 Oxaydo or our Aversion and Limitx™ product candidates will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede technology product candidates 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,” “expe “plans,” “anticipates,” “believes,” “indicates,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our 2014 Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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. Accordingly, 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.

Company Overview

We are a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Aversion® Technology is a mixture of inactive ingredients incorporated into pharmaceutical tablets and capsules intended to address some common methods of product tampering associated with opioid abuse. Oxaydo™ Tablets (formerly known as Oxecta®)(oxycodone HCl, CII), is the first approved product utilizing Aversion in the United States. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation (collectively, "Egalet") pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is currently approved by the FDA for marketing in the United States in 5mg and 7.5mg strengths. We are advised that Egalet plans to launch Oxaydo in the United States in the third quarter of 2015. 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 launch our Nexafed Sinus Pressure + Pain product in the United States in February 2015. We have multiple pseudoephedrine products in development utilizing our Impede Technology. On June 15, 2015, we and Bayer Healthcare LLC ("Bayer") entered into a License and Development Agreement (the "Bayer Agreement") pursuant to which we granted Bayer an exclusive worldwide license to our Impede Technology for use in an undisclosed methamphetamine resistant pseudoephedrine – containing product and providing for the joint development of such product using our Impede Technology for the U.S. market. Our third abuse deterrent technology, Limitx, is designed to retard the release of active drug ingredients when too many tablets are accidently or purposefully ingested. We are conducting manufacturing scale-up and plan to conduct a pharmacokinetic study on a hydromorphone product formulation using our Limitx technology under a grant from the National Institute on Drug Abuse of the National Institutes of Health. On April 9, 2015, we announced initiation of development of an immediate release hydrocodone bitartrate with acetaminophen product utilizing our Limitx technology.

Opioid analgesics are one of the largest prescription drug markets in the United States with 250 million prescriptions dispensed in 2014. Prescription opioids are also the most widely abused drugs with 12 million people abusing or misusing these products annually. Oxaydo will compete 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 2014, sales in the immediate-release opioid product segment were approximately 235 million prescriptions and $3.0 billion, of which approximately 98% was attributable to generic products. Immediate-release oxycodone tablets represent 14.8 million of these prescriptions or almost 1.6 billion tablets. The FDA approved label for our Oxaydo 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.

In 2014, the United States retail market for over-the-counter market, or OTC, cold and allergy products containing the pseudoephedrine oral nasal decongestant was approximately $0.7 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. According to the Substance Abuse and Mental Health Services Administration,

users of methamphetamine surged in 2013 to 595,000 people up from 440,000 in 2012. Nexafed, our 30mg pseudoephedrine hydrochloride immediate-release tablet, is stocked in approximately 20% 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. We launched our first line extension, Nexafed Sinus Pressure + Pain, a 30/325mg pseudoephedrine HCl and acetaminophen tablet using our Impede technology in February 2015. 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 have an active development program to develop an extended-release version of our Impede technology to capitalize on higher sales products in the category. We also are investigating new technologies that would improve on our meth-resistant capabilities. On March 23, 2005, we announced preliminary top line results from our pilot clinical study demonstrating bioequivalence of our Nexafed extended release tablets to Johnson & Johnson's Sudafed® 12-hour Tablets. Nexafed extended release tablets utilize our Impede 2.0 enhanced meth-resistant technology. Our Impede 2.0 technology has demonstrated, in the direct conversion, or "one-pot", methamphetamine conversion process performed by an independent pharmaceutical services company, the ability to reduce meth-yields, on average, by 75% compared to Sudafed® Tablets.

In May 2014 we announced that the FDA questioned whether the intranasal route is a relevant route of abuse for hydrocodone/acetaminophen products, which we were developing with our Aversion Technology. In October 2014, the FDA denied on procedural grounds our formal dispute resolution request appealing the position taken by the Division of Anesthesia, Analgesia and Addiction Products ("DAAAP") that abuse by snorting hydrocodone with acetaminophen products lacks relevance. The FDA's April 2015 Abuse-Deterrent Opioid Evaluation and Labeling Guidance (the "FDA's April 2015 Guidance") appears to take the same position by indicating that immediate-release opioid and acetaminophen products are predominantly abused using the oral route and products demonstrating a deterrent effect by the nasal route may not meaningfully reduce overall abuse of the product. In view of the regulatory history of Aversion Hydrocodone/APAP and the FDA's April 2015 Guidance, we have indefinitely suspended further development of our Aversion Hydrocodone/APAP and reallocated resources to our Limitx hydromorphone and hydrocodone/APAP product candidates.

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. Oxaydo is covered by claims in five 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 products that may be developed utilizing our Aversion or Limitx Technologies will be dependent on the results of and the acceptance by the FDA of our and our licensees' studies for each product.

Oxaydo Tablets

Oxaydo (oxycodone HCI tablets) 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. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is approved in 5mg and 7.5mg strengths. We are advised that Egalet plans to launch Oxaydo in the United States in the third quarter of 2015.

The 2014 market for immediate-release oxycodone products was 14.8 million dispensed prescription or 1.6 billion tablets. The current market is predominately serviced by generic formulations that contain no abuse deterrent features and sell for approximately $0.10 to $0.40 per tablet, depending on strength. Immediate-release opioids are prescribed by a broad cross-section of healthcare providers including primary care physicians, surgeons and pain specialists. We believe Oxaydo, 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 Oxaydo 5mg and 7.5mg tablets was established by demonstrating bioequivalence to commercially available oxycodone immediate-release tablets in the fasted state. Oxaydo differs from oxycodone tablets when taken with a high fat meal though these differences are not considered clinically relevant, and Oxaydo can be taken without regard to food. The FDA-approved label for Oxaydo describes elements unique to our Aversion Technology, which differs from current commercially available oxycodone immediate-release tablets. The label for Oxaydo includes the results from a clinical study that evaluated the effects of nasally snorting crushed Oxaydo and commercially available oxycodone tablets, and limitations on exposing Oxaydo 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 Oxaydo responded that they would not take the drug again compared to 5% of subjects exposed to immediate-release oxycodone;
- subjects taking Oxaydo reported a higher incidence of nasopharyngeal and facial adverse events compared to immediate-release oxycodone;
- a decreased ability to completely insufflate two crushed Oxaydo 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 Oxaydo than immediate-release oxycodone.

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

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

Egalet Agreement Covering Oxaydo

On January 7, 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, (collectively, “Egalet”) entered into a Collaboration and License Agreement (the “Egalet Agreement”) to commercialize Oxaydo™ tablets containing our Aversion® Technology. Oxaydo is approved by the FDA for marketing in the United States in 5 mg and 7.5 mg strengths. Under the terms of the Egalet Agreement, we transferred the approved NDA for Oxaydo to

Egalet and Egalet is granted an exclusive license under our intellectual property rights for development and commercialization of Oxaydo worldwide (the “Territory”) in all strengths, subject to our right to co-promote Oxaydo in the United States.

In accordance with the Egalet Agreement, we and Egalet have formed a joint steering committee to oversee commercialization strategies and the development of product line extensions. Egalet will pay a significant portion of the expenses relating to (i) annual NDA PDUFA product fees, (ii) expenses of the FDA required post-marketing study for Oxaydo and (iii) expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States and will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States. Egalet is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Egalet will have final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Egalet may develop Oxaydo for other countries and in additional strengths, in its discretion.

Egalet paid us an upfront payment of $5 million upon signing of the Egalet Agreement and will pay us a $2.5 million milestone on the earlier to occur of (A) the launch of Oxaydo or (B) January 1, 2016. In addition, we will be entitled to a one-time $12.5 million milestone payment when worldwide Oxaydo net sales reach $150 million in a calendar year. In addition, we will receive from Egalet a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on Oxaydo net sales during such year (excluding net sales resulting from our co-promotion efforts). In any calendar year in which net sales exceed a specified threshold, we will receive a double digit royalty on all Oxaydo net sales in that year (excluding net sales resulting from our co-promotion efforts). If we exercise our co-promotion rights, we will receive a share of the gross margin attributable to incremental Oxaydo net sales from our co-promotion activities. Egalet's royalty payment obligations commence on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA's Orange Book remains with respect to the Product). Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by Egalet to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Egalet Agreement expires upon the expiration of Egalet's royalty payment obligations in all countries. Either party may terminate the Egalet Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Egalet Agreement, subject to applicable cure periods, or in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws. We also may terminate the Egalet Agreement with respect to the U.S. and other countries if Egalet materially breaches its commercialization obligations. Egalet may terminate the Egalet Agreement for convenience on 120 days prior written notice, which termination may not occur prior to the second anniversary of Egalet's launch of Oxaydo. Egalet also may terminate the Agreement prior to the launch of Oxaydo on 30 days prior written notice upon the occurrence of serious safety issues, regulatory restrictions and intellectual property issues, in each case involving Oxaydo. Termination does not affect a party's rights accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations (but not expiration), the Egalet Agreement provides for the transition of development and marketing of Oxaydo from Egalet to us, including the conveyance by Egalet to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Egalet's supply of Oxaydo for a transition period.

Impede 1.0 Technology

Our Impede 1.0 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 international, independent laboratory demonstrated our Impede 1.0 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.

Impede 2.0 Technology

We have developed several next generation, or Impede 2.0, prototypes of our Impede Technology to improve the meth-resistance of our technology. We have completed one-pot, direct conversion meth testing performed by our CRO with results as follows:

Product/Formulation	Meth Resistant Technology	Meth Recovery[1]	Purity[2]
Sudafed® 30mg Tablets	none	67 %	62 %
Nexafed 30mg Technology	Impede® 1.0	38 %	65 %
Zephrex-D® 30mg Pills	Tarex®	28 %	51 %
Nexafed 120mg Extended-release tablets	Impede® 2.0	17 %	34 %

[1] Total methamphetamine HCl recovered from the equivalent of 100 PSE 30mg tablets divided by the maximum theoretical yield of 2.7 grams.

[2] Total methamphetamine HCl recovered from the equivalent of 100 PSE 30mg tablets divided by the total weight of powder recovered.

We have demonstrated in a pilot clinical study the bioequivalence of a formulation of our Nexafed extended release tablets utilizing our Impede 2.0 technology to Sudafed® 12-hour Tablets. We also are assessing the one-pot results of immediate-release Impede 2.0 formulations, along with manufacturability and other pertinent information to determine our strategy for introducing Impede 2.0 into our Nexafed product line.

Nexafed Products

Our Nexafed product line consists of immediate release tablets which utilize our patented Impede 1.0 Technology. Nexafed is a 30mg pseudoephedrine tablet and Nexafed Sinus Pressure + Pain is a 30/325 mg pseudoephedrine and acetaminophen tablet. 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 yields. 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 tablet 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 13,000 pharmacies or about 20% 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. In late 2014, Kmart and Kroger initiated chain-wide stocking of Nexafed.

We estimate that approximately 53% of Nexafed stocking pharmacies are repeat customers, excluding Rite Aid and Kroger which purchase directly from us and we therefore do not have individual store data.

In February 2015, we began initial shipments of Nexafed Sinus Pressure + Pain. We are marketing this product consistent with our Nexafed marketing efforts to pharmacists concerned with meth abuse of their products. We are not aware of any branded non-prescription product that contains PSE and acetaminophen believing that brands containing these ingredients have either been discontinued or reformulated with phenylephrine. We expect Nexafed Sinus Pressure + Pain to compete primarily against Advil® Cold and Sinus (PSE/ibuprofen) and to a lesser extent Aleve®-D and Sudafed® Pressure + Pain which are extended-release products.

We are marketing our Nexafed product and our Nexafed Sinus Pressure + Pain product under FDA's regulations applicable to OTC Monograph products. Nexafed and Nexafed Sinus Pressure + Pain tablets are offered in 24-count blister packaged cartons.

Impede Technology Products 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 pseudoephedrine HCl in combination with other cold and allergy active ingredients	Nexafed Sinus Pressure + Pain launched Other formulations being considered
Extended-release formulation utilizing Impede 2.0 technology	Pilot pharmacokinetic testing demonstrated bioequivalence to Sudafed® 12-hour Tablets
Extended – release combination products	Formulations being considered
Methamphetamine resistant pseudoephedrine – containing product	In development pursuant to Bayer Agreement

We currently expect to initiate a pre-IND meeting with the FDA to discuss the results from our pharmacokinetic and meth testing studies to determine the development path for our extended-release development product, which, we believe, will require and NDA or ANDA submission to the FDA.

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. Within the United States, we may consider additional 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.

Bayer Agreement

On June 15, 2015, we and Bayer entered into a License and Development Agreement pursuant to which we granted Bayer an exclusive worldwide license to our Impede™ Technology for use in an undisclosed methamphetamine resistant pseudoephedrine-containing product and providing for the joint development of such product using our Impede Technology for the U.S. market. The Agreement also grants Bayer first right to negotiate a license to the Impede™ Technology for certain other products. We are eligible to receive reimbursement of certain our development expenses, success-based development and regulatory milestone payments, and low mid-single digit royalties on the net sales of the developed product in countries with patent coverage and a reduced royalty elsewhere.

U.S. Market Opportunity for Impede PSE Products

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 2014, a data service reported approximately $0.7 billion in retail sales of non-prescription products containing PSE. The top retail selling PSE OTC cold/allergy products in 2014 were:

Reference Brand[1]	Brand Company	Active Ingredient(s)	2014 Retail Sales ($ Millions)
Claritin-D	Bayer	PSE & Loraditine[2]	$ 208.0
Allegra-D	Chattem	PSE & Fexofenadine[2]	$ 101.3
Zyrtec-D	Pfizer	PSE & Ceterizine[2]	$ 101.7
Advil Sinus	Pfizer	PSE & Ibuprofen	$ 58.4
Sudafed 12 Hour	J&J	PSE[2]	$ 82.3
Sudafed 30mg	J&J	PSE	$ 70.4

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

[2] Extended release PSE formulations

The 2014 market for 30mg PSE tablets, including store brands was approximately 470 million tablets or 19 million boxes of 24 tablets. Nexafed is currently priced at $3.99 for a box of 24 tablets and Nexafed Sinus Pressure + Pain is currently priced at $7.50 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. We believe Johnson and Johnson, after a several year hiatus, will be reintroducing Sudafed 30mg tablets, without any meth resistant technology, into the US market in July 2015 with a factory price consistent with Nexafed but with steep discounting to consumer in an effort to reestablish market share.

Product Labeling for Impede Technology Products

We are marketing our Nexafed and Nexafed Sinus Pressure + Pain products 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 products which is supported by our published research studies.

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

Limitx™ Technology

Limitx™ technology is an early stage technology intended to address abuse by excess oral consumption of multiple tablets and provide a margin of safety during accidental over-ingestion of tablets. In proof of concept laboratory tests, Limitx™ tablets demonstrated the ability to limit the release of the active ingredient from tablets when multiple tablets are simultaneously introduced into simulated gastric fluid. Using ..055N HCl dissolution bath, a single Limitx tablet released most of its active ingredient within 15 minutes while eight Limitx tablets in the same bath released the equivalent of one tablet's active ingredient in 15 minutes. Eight immediate-release tablets of a marketed product comparator released most of its active ingredient in 15 minutes compared with over 2 hours for the eight Limitx tablets.

The FDA's 2015 Guidance singles out immediate-release combination products with acetaminophen as being predominately abused by the oral route and that reducing nasal snorting of these products may not be meaningful. The initial Limitx™ formulation utilizes hydromorphone as its sole active ingredient. We intend to initiate formulation development of a hydrocodone/APAP product candidate utilizing our Limitx technology upon the conclusion of formulation optimization for our Limitx hydromorphone product. We have been issued a Notice of Allowance by the USPTO for our patent application covering our Limitx™ technology.

Development of our Limitx technology is being supported by a $300 thousand grant (the "Grant") by the National Institute on Drug Abuse ("NIDA") of the National Institutes of Health, of which we have received $214 thousand in July 2015. Phase I of development is to create an optimized formulation of our hydromorphone product candidate that can be commercially manufactured and is suitable for human testing. In Phase I, we will be developing a formulation and manufacturing process that mimics, at research scale batches, commercial manufacturing scale equipment and test and evaluate the tablets in our proof of concept dissolution apparatus. We have successfully manufactured small scale batches of the key micro-particle at our Culver facility but believe the manufacturing process used will not be scalable for commercial batches. We have completed the installation of new equipment for use in this process and run multiple test batches using different processing parameters. The initial test batches demonstrated that the micro-particles produced on the new equipment had slightly altered release characteristics than our early prototype formulations that we deemed unfavorable. We have begun experimenting with adding additional inactive ingredients into the micro-particle processing which has yielded some early promising results.

In Phase II, we will perform human pharmacokinetic testing of our hydromorphone product candidate to characterize the release of drug in vivo. NIDA funding of Phase II development, for which an application has already been submitted, will be contingent upon (1) assessment by NIDA of the Phase I progress report and its determination that the Phase I milestones were achieved, (2) review and approval of other documents necessary for continuation, and (3) availability of funds. No assurance can be given that Phase II development funding will be provided by NIDA. We are assessing whether this initial pharmacokinetic study will require the filing of an Investigational New Drug application, or IND, with the FDA or if it can be executed under IND exemptions in the regulations.

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

Aversion Technology Development Opioid Products

On April 9, 2015, we announced the indefinite suspension of further development of our Aversion hydrocodone/APAP product candidate. We currently have 6 additional opioids at various stages of formulation development using the Aversion technology which are not being actively developed. We intended to focus our

Aversion technology development efforts on the relaunch of Oxaydo and the development of potential line extension of Oxaydo at Egalet's request.

In the event development of some or all of our Aversion product candidates is re-commenced, each will require an abuse deterrent study consistent with FDA's 2015 Guidance. 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. It is also expected that development will include human abuse liability studies comparing the abuse liability of Aversion products to currently marketed products. Because our products use known active ingredients in approved dosage strengths, the safety and efficacy of the Aversion opioid will need to 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.

Further development will likely also entail 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's 2015 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.

There can be no assurance that we will re-commence development of our Aversion candidates or if re-commenced, that we will receive FDA approval for any of such product candidates.

U.S. Market Opportunity for Opioid Analgesic Products

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 250 million tablet and capsule prescriptions dispensed in 2014 of which approximately 235 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 and Limitx 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 2014, sales in the IR opioid product segment were approximately $3.0 billion, of which ~98% 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 and Limitx Technologies. A summary of the IR opioid product prescription data for 2014 is provided below:

IR Opioid Products[1]	2014 US Prescriptions (Millions)[2]	% of Total	
Hydrocodone	119	50	%
Oxycodone	54	23	%
Tramadol	45	19	%
Codeine	12	5	%

3 Others	5	3	%
Total	235	100	%

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

[2] IMS Health, 2014

Despite considerable publicity regarding the abuse of OxyContin® extended-release tablets and other ER opioid products, U.S. government statistics suggest that far more people have used IR opioid products non-medically than ER opioid products. These statistics estimate that nearly four times as many people have misused the IR opioid products Vicodin®, Lortab® and Lorcet® (hydrocodone bitartrate/acetaminophen brands and generics) than OxyContin®. We estimate 60-95% of the 37 million lifetime U.S. opioid abusers have engaged in the non-medical use of the active ingredients in our IR opioid product candidates. As indicated in the following chart, the top five abused opioid products are available only as IR opioid products.

Product Labeling for Abuse-Deterrent Opioid Products

In April 2015, the FDA published guidance for industry on the evaluation and labeling of abuse-deterrent opioids. While the 2015 FDA Guidance is non-binding on the FDA, it outlines FDA's current thinking on the development and labeling of abuse-deterrent products. The 2015 FDA Guidance provides for three distinct levels of pre-marketing studies that are potentially eligible for inclusion in the labeling: (1) laboratory-based in vitro manipulation and extraction studies, (2) pharmacokinetic studies, and (3) clinical abuse potential studies. The Guidance further prescribes additional post-approval or epidemiology studies to determine whether the marketing of a product with abuse-deterrent properties results in meaningful reductions in abuse, misuse, and related adverse clinical outcomes, including addiction, overdose, and death in the post-approval setting, which can also be included in the labeling. FDA notes "the science of abuse deterrence is relatively new. Both the technologies involved and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. For these reasons, FDA will take a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent opioid products".

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

Patents and Patent Applications

We have the following issued patents covering, among other things, Oxaydo and our Aversion technology:

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
7,201,902 (US)	Pharmaceutical compositions including a mixture of functional inactive ingredients and specific opioid analgesics	Apr. 2007	Mar. 2025
7,510,726 (US)	A wider range of compositions than those described in the 7,201,920 Patent	Mar. 2009	Nov. 2023
7,981,439 (US)	Pharmaceutical compositions including any water soluble drug susceptible to abuse	Jul. 2011	Aug. 2024

8,409,616 (US)	Pharmaceutical compositions of immediate-release abuse deterrent dosage forms	Apr. 2013	Nov. 2023
8,637,540 (US)	Pharmaceutical compositions of immediate-release abuse deterrent opioid products	Jan. 2014	Nov. 2023

We have the following issued patents related to our Aversion technology:

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
7,476,402 (US)	Pharmaceutical compositions of certain combinations of kappa and mu opioid receptor agonists and other ingredients intended to deter opioid analgesic product misuse and abuse	Jan. 2009	Nov. 2023
8,822,489 (US)	Pharmaceutical compositions of certain abuse deterrent products that contain polymers, surfactant and polysorb 80	Jul. 2014	Nov. 2023
2004294953 (AUS)	Abuse deterrent pharmaceuticals	Apr. 2010	Nov. 2024
2010200979 (AUS)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,547,334 (CAN)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,647,360 (CAN)	Abuse deterrent pharmaceuticals	May 2012	Apr. 2027
175863 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
221018 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024

We have the following issued patent covering, among other things, our Nexafed product line and Impede 1.0 and 2.0 technologies:

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
8,901,113 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Dec. 2014	Feb. 2032

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

In June 2015, we received a Notice of Allowance for the USPTO for our patent application covering our Limitx Technology.

In addition to our issued U.S. patents, we have filed multiple U.S. patent applications and international patent applications relating to compositions containing abusable active pharmaceutical ingredients as well as applications covering our Impede 1.0 and 2.0 Technologies and filed U.S. patent applications for our Limitx Technology. Except for the rights granted in the Egalet Agreement, we have retained all intellectual property rights to our Aversion Technology, Impede Technology, Limitx Technology and related product candidates.

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

In April, 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (collectively, “Purdue”) commenced a patent infringement lawsuit against us and our Oxaydo™ product licensee Egalet US, Inc. and its parent Egalet Corporation in the United States District Court for the District of Delaware alleging our Oxaydo product

infringes Purdue's U.S. Patent No. 8,389,007. The complaint seeks injunctive relief as well as awards of damages and attorneys' fees. We deny the allegations in the complaint, believe they are without merit and are defending the action vigorously.

Reference is made to the Risk Factors contained in our Annual Report on Form 10-K for the year ended December 31, 2014 for a discussion, among other things, of patent applications and patents owned by third parties, including claims that may encompass our Aversion Technology and Oxaydo tablets, and the risk of infringement, interference or opposition proceedings that we may be subject to arising from such patents and patent applications.

Company's Present Financial Condition

At June 30, 2015, we had cash, cash equivalents and marketable securities of $10.9 million compared to $12.1 million of cash, cash equivalents and marketable securities at December 31, 2014. We have a $2.5 million compensating balance requirement as a debt provision at June 30, 2015. Excluding the compensating balance requirement, the Company had unrestricted working capital of $5.6 million at June 30, 2015 compared to working capital of $10.2 million at December 31, 2014. We had an accumulated deficit of approximately $364 million and $362 million at June 30, 2015 and December 31, 2014, respectively. We had loss from operations of $0.9 million and net loss of $1.4 million for the six months ended June 30, 2015, compared to a loss from operation of $7.1 million and a net loss of $7.6 million for the six months ended June 30, 2014. As of July 30, 2015, our unrestricted cash, cash equivalents and marketable securities, less our compensating balance requirement of $2.5 million, was $14.9 million.

To fund our continued operations, we expect to rely on our current cash resources, milestone and royalty payments, if any, that may be made under the Egalet Agreement, development reimbursement payments, milestones and royalty payments that may be made under the Bayer Agreement, milestones and royalty payments that may be made under future license agreements with other pharmaceutical company partners, of which there can be no assurance of obtaining, and revenues from our commercialization of our Nexafed products. 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 products, or invest in other areas.

Our losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of pre-clinical studies, clinical trials, and clinical trial product supplies associated with our product candidates. Salaries and other personnel-related costs include the non-cash stock-based compensation associated with stock options and restricted stock units granted to employees and non-employee directors.

Three months Ended June 30, 2015 Compared to Three months Ended June 30, 2014

	Three Months Ended June 30,			
	2015	2014	Increase (decrease)	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$ -	$ 1	$ (1)	(100)%
Product sales, net	91	34	57	168
License fee	250	-	250	100
Total revenues, net	341	35	306	874

Operating expenses:				
Cost of sales	98	42	56	133
Inventory write-down	47	68	(21)	(31)
Research and development	511	1,281	(770)	(60)
Selling, marketing, general and administrative	2,083	1,916	167	9
Total operating expenses	2,739	3,307	(568)	(17)
Operating loss	(2,398)	(3,272)	(874)	(27)
Non-operating income (expense):				
Investment income	36	53	(17)	(32)
Interest expense	(301)	(302)	(1)	-
Total other expense, net	(265)	(249)	16	4
Loss before income taxes	(2,663)	(3,521)	(858)	(24)
Provision for income taxes	-	-	-	-
Net loss	$ (2,663)	$ (3,521)	$ (858)	(24)%

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Revenue and Cost of Sales

Product Sales

Nexafed® was launched in December 2012. Nexafed® Sinus Pressure + Pain was launched in February 2015. The Company sells the Nexafed® product line in the United States to wholesale pharmaceutical distributors and as well as directly to chain drug stores. The product line is sold subject to the right of return for a period of up to twelve months after the product expiration. Both products currently have a shelf life of twenty-four months from the date of manufacture.

Given the limited sales history of Nexafed, we could not reliably estimate expected returns of the product at the time of shipment to certain customers and accordingly we had deferred revenue. As of December 31, 2014, we had $353 thousand of deferred revenue on our balance sheet related to Nexafed shipments which occurred since its commercial launch. During the first quarter ended March 31, 2015, we determined we had obtained sufficient sales returns history to reasonably estimate future returns. As a result of this change, we recorded a one-time adjustment in the first quarter ended March 2015 to recognize revenue that had previously been deferred, resulting in additional net revenue of $314 thousand. Revenue is being recognized at the time the product is sold to a customer.

Royalty Revenue

In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer Inc., (which agreement has since been terminated effective April 2014) we began to earn royalties on Oxecta net sales starting in February 2013. We recorded royalties of approximately $1 thousand for the three months ended June 30, 2014 on Pfizer’s net sales of Oxecta of approximately $20 thousand. The Pfizer Agreement was terminated effective April 9, 2014 and Pfizer’s royalty payment obligations ceased as of such date.

License Fees

On January 7, 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, (collectively, “Egalet”) entered into a Collaboration and License Agreement (the “Egalet Agreement”) to commercialize Oxaydo™ tablets containing our Aversion® Technology. Egalet paid us an upfront payment of $5.0 million upon signing of the Egalet Agreement.

The Company received a $250 thousand payment from Purdue Pharma L.P. in June 2015 relating to a December 2014 agreement to settle a patent interference action on U.S. Patent No. 8,101,630 issued to Acura.

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 first quarter ended March 31, 2015, we determined we had obtained sufficient sales returns history to reasonably estimate future returns. As a result of this change, we recorded a one-time adjustment in the first quarter ended March 2015 to recognize revenue that had previously been deferred, resulting in additional cost of sales of $255 thousand. For the three months ended June 30, 2015 and 2014, cost of sales was $98 thousand and $42 thousand, respectively.

During the quarter ended June 30, 2015 and 2014, we recorded $47 thousand and $68 thousand inventory reserve expense against finished goods, respectively.

Operating Expenses

Research and development expense (R&D) during the three months ended June 30, 2015 and 2014 was primarily for our Aversion or our Impede Technologies development including costs of preclinical and non-clinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in each of the three month 2015 and 2014 results are non-cash share-based compensation expenses of $39 thousand and $56 thousand million, respectively. Excluding the share-based compensation expense, our R&D expenses decreased approximately $0.8 million between reporting periods primarily from a reduction in development expenses on product candidates.

Selling and marketing expenses during the three months ended June 30, 2015 and 2014 was primarily of advertising and marketing activities on the Nexafed product line. Our Nexafed advertising and marketing activities will continue in 2015. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the three month 2015 and 2014 results are non-cash share-based compensation expenses of $0.1 million and $0.2 million, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses increased by $0.3 million between reporting periods, resulting primarily from an increase in advertising and marketing activities and our legal expenses.

Non-Operating Income (Expense)

During the three months ended June 30, 2015 and 2014, non-operating expense consisted principally of interest expense on the $10.0 million promissory note we entered into on December 27, 2013 less investment income derived from our investments.

Income Taxes

Our results for 2015 includes no federal or state income tax expense as we have no assurance of realizing operating income for the annual period of 2015. Our results for 2014 included no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Six months Ended June 30, 2015 Compared to Six months Ended June 30, 2014

	Six Months Ended June 30,			
	2015	2014	Increase (decrease)	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$ -	$ 4	$ (4)	(100)%
Product sales, net	448	73	375	513
License fee	5,250	-	5,250	100
Total revenues, net	5,698	77	5,621	100
Operating expenses:				
Cost of sales	422	80	342	428
Inventory write-down	307	201	106	53
Research and development	1,475	2,719	(1,244)	(46)
Selling, marketing, general and administrative	4,380	4,175	205	5
Total operating expenses	6,584	7,175	(591)	(8)
Operating loss	(886)	(7,098)	(6,212)	(88)
Non-operating income (expense):				
Investment income	71	97	(26)	(27)
Interest expense	(609)	(603)	6	1
Other expense	-	(5)	(5)	(100)
Total other expense, net	(538)	(511)	27	5
Loss before income taxes	(1,424)	(7,609)	(6,185)	(81)
Provision for income taxes	-	-	-	-
Net loss	$ (1,424)	$ (7,609)	$ (6,185)	(81)%

Revenue and Cost of Sales

Product Sales

Nexafed® was launched in December 2012. Nexafed® Sinus Pressure + Pain was launched in February 2015. The Company sells the Nexafed® product line in the United States to wholesale pharmaceutical distributors and as well as directly to chain drug stores. The product line is sold subject to the right of return for a period of up to twelve months after the product expiration. Both products currently have a shelf life of twenty-four months from the date of manufacture.

Given the limited sales history of Nexafed, we could not reliably estimate expected returns of the product at the time of shipment to certain customers and accordingly we had deferred revenue. As of December 31, 2014, we had $353 thousand of deferred revenue on our balance sheet related to Nexafed shipments which occurred since its commercial launch. During the first quarter ended March 31, 2015, we determined we had obtained sufficient sales returns history to reasonably estimate future returns. As a result of this change, we recorded a one-time adjustment in the first quarter ended March 2015 to recognize revenue that had previously been deferred, resulting in additional net revenue of $314 thousand. Revenue is being recognized at the time the product is sold to a customer.

Royalty Revenue

In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer Inc., (which agreement has since been terminated effective April 2014) we began to earn royalties on Oxecta net sales starting in February 2013. We recorded royalties of approximately $4 thousand for the six months ended June 30, 2014 on Pfizer’s net sales of Oxecta of approximately $80 thousand. The Pfizer Agreement was terminated effective April 9, 2014 and Pfizer’s royalty payment obligations ceased as of such date.

License Fees

On January 7, 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, (collectively, “Egalet”) entered into a Collaboration and License Agreement (the “Egalet Agreement”) to commercialize Oxaydo™ tablets containing our Aversion® Technology. Egalet paid us an upfront payment of $5.0 million upon signing of the Egalet Agreement.

The Company received a $250 thousand payment from Purdue Pharma L.P. in June 2015 relating to a December 2014 agreement to settle a patent interference action on U.S. Patent No. 8,101,630 issued to Acura.

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 first quarter ended March 31, 2015 we determined we had obtained sufficient sales returns history to reasonably estimate future returns. As a result of this change, we recorded a one-time adjustment in the first quarter ended March 2015 to recognize revenue that had previously been deferred, resulting in additional cost of sales of $255 thousand. For the six months ended June 30, 2015 and 2014, cost of sales was $422 thousand and $80 thousand, respectively.

During the six months ended June 30, 2015 and 2014, we recorded $47 thousand and $201 thousand inventory reserve expense against finished goods, respectively. During the six months ended June 30, 2015, we recorded a $260 thousand reserve against raw and packaging material inventories we purchased from Pfizer for the Oxaydo product we reacquired from them.

Operating Expenses

Research and development expense (R&D) during the six months ended June 30, 2015 and 2014 was primarily for our Aversion or our Impede Technologies development including costs of preclinical and non-clinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in each of the six month 2015 and 2014 results are non-cash share-based compensation expenses of $0.1 million. Excluding the share-based compensation expense, our R&D expenses decreased approximately $1.2 million between reporting periods primarily from a reduction in development expenses on product candidates.

Selling and marketing expenses during the six months ended June 30, 2015 and 2014 was primarily of advertising and marketing activities on the Nexafed product line. Our Nexafed advertising and marketing activities will continue in 2015. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the six month 2015 and 2014 results are non-cash share-based compensation expenses of $0.2 million and $0.3 million, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses increased by $0.3 million between reporting periods, resulting primarily from increases in advertising and marketing activities and our legal expenses.

Non-Operating Income (Expense)

During the six months ended June 30, 2015 and 2014, non-operating expense consisted principally of interest expense on the $10.0 million promissory note we entered into on December 27, 2013 less investment income derived from our investments.

Income Taxes

Our results for 2015 includes no federal or state income tax expense as we have no assurance of realizing operating income for the annual period of 2015. Our results for 2014 included no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Liquidity and Capital Resources

At June 30, 2015, we had cash, cash equivalents and marketable securities $10.9 million compared to $12.1 million at December 31, 2014. We have a $2.5 million compensating balance requirement under our Oxford term loan. Excluding the compensating balance requirement, we had unrestricted working capital of $5.6 million at June 30, 2015 compared to $10.2 million at December 31, 2014.

Pending the receipt of further milestones and royalty payments under the Egalet Agreement, development reimbursement payments, milestones and royalty payments that may be made under the Bayer Agreement, milestones and royalty payments that may be made under similar agreements for our products in development 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 products sales and our cash and marketable securities to fund the development of our Impede Technology, Limitx Technology and Aversion Technology and related administrative and operating expenses. Our future sources of revenue, if any, will be derived from milestone payments and royalties under the Egalet Agreement, the Bayer Agreement and similar agreements for our products in development with other pharmaceutical company partners, for which there can be no assurance, and from the commercialization of our Nexafed products and other Impede Technology products that we expect to develop.

As of July 30, 2015, our unrestricted cash, cash equivalents and marketable securities, less our compensating balance requirement of $2.5 million, was approximately $14.9 million. We estimate that such unrestricted cash reserves and marketable securities will be sufficient to fund the development of Impede Technology, Limitx Technology and Aversion Technology product candidates, and related operating expenses at least through the next 12 months.

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

NASDAQ Notification

On September 18, 2014 the Company received a written notification from NASDAQ notifying the Company that it had failed to comply with the $1.00 minimum bid price requirement in NASDAQ Listing Rule 5550(a)(2)(the “Rule”) because the bid price for the Company’s common stock over a period of 30 consecutive business days prior to such date had closed below the minimum $1.00 per share requirement for continued listing. In accordance with NASDAQ’s Listing Rule 5810(c)(3)(A), the Company had a period of 180 calendar days, or until March 17, 2015, to regain compliance with the Rule. After determining that it would not be in compliance with the Rule by March 17, 2015, the Company notified NASDAQ and applied for an extension of the cure period, as permitted under the original notification.

In accordance with NASDAQ Listing Rule 5810(c)(3)(A), NASDAQ granted a second grace period of 180 calendar days, or until September 14, 2015, to regain compliance with the minimum closing bid price requirement for continued listing. In order to regain compliance, the minimum closing bid price per share of the Company’s common stock must be at least $1.00 for a minimum of ten consecutive business days. If the Company fails to regain compliance by September 14, 2015, the Company’s stock will be subject to delisting by NASDAQ.

If the Company’s bid price does not rise of its own accord, the Company intends to effect a reverse stock split at some point during the NASDAQ’s second grace period expiring September 14, 2015 in order to comply with the minimum bid requirement.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with other listing requirements.

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company’s 2014 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 2014 Annual Report are also applicable to 2015.

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 2015 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

The information required by this Item is incorporated by reference to Note 3, "License, Development, and Commercialization Agreement – Paragraph IV ANDA Litigation and License Grants", and Note 15, "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 2014 Annual Report on Form 10-K:

We Require Additional Funding

We anticipate that we will require additional financing or entry into license or collaborative agreements with third parties providing for net proceeds to the Company. No assurance can be given that the Company will be successful in obtaining any such financing or in securing license or collaborative agreement with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaborative agreements will provide for payments to the Company sufficient to continue to fund operations. Although the Company believes it has cash and marketable securities sufficient to fund operations through at least the next 12 months, in the absence of such financing or third-party license or collaborative agreements, the Company may be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. Even assuming the Company is successful in securing additional sources of financing to fund continued operations, there can be no assurance that the proceeds of such financing will be sufficient to fund operations until such time, if at all, that the Company generates sufficient revenue from our products and product candidates to sustain and grow our operations.

Item 6. Exhibits

The exhibits required by this Item are listed below.

10.1	License and Development Agreement dated as of June 5, 2015 between the Registrant and Bayer HealthCare LLC (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.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation 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, 2015

ACURA
PHARMACEUTICALS, INC.

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

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