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 March 31, 2016

or

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

For the transition period from _____ to_____

Commission File Number 1-10113

Acura Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

New York	**11-0853640**
(State or other Jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
616 N. North Court, Suite 120 **Palatine, Illinois** *(Address of Principal Executive Offices)*	**60067** *(Zip Code)*

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	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 April 29, 2016 the registrant had 11,833,801 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2016

Item 1. Financial Statements

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

	March 31, 2016	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,282	$ 2,485
Marketable securities (Note 7)	7,687	10,837
Accounts receivable, net of allowances of $5 and $91	140	83
Accrued investment income	25	37
Inventories, net (Note 8)	202	276
Prepaid expenses and other current assets	296	417
Total current assets	11,632	14,135
Property, plant and equipment, net (Note 9)	1,028	1,013
Intangible asset, net of accumulated amortization of $414 and $362 (Note 4)	1,586	1,638
Other assets	175	175
Total assets	$ 14,421	$ 16,961
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 375	$ 110
Accrued expenses (Note 10)	1,155	564
Accrued interest	53	-
Other current liabilities	28	45
Sales returns liability	242	205
Debt - current (Note 11)	2,575	2,320
Total current liabilities	4,428	3,244
Debt – non-current portion, net of discount of $167 and $193, and debt issuance costs of $83 and $97 (Note 11)	4,806	5,430
Accrued interest – non-current portion	433	387
Total liabilities	9,667	9,061
Commitments and contingencies (Note 17)		
Stockholders' equity		
Common stock - $.01 par value per share; 100,000 shares authorized, 11,834 and 11,801 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	118	118
Additional paid-in capital	375,325	375,157
Accumulated deficit	(370,694)	(367,310)
Accumulated other comprehensive income (loss)	5	(65)
Total stockholders' equity	4,754	7,900
Total liabilities and stockholders' equity	$ 14,421	$ 16,961

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 March 31,	
	2016	2015
Revenues		
License fee revenue	$ -	$ 5,000
Collaboration revenue	100	-
Royalty revenue	17	-
Product sales, net	107	357
Total revenues, net	224	5,357
Cost and expenses		
Cost of sales (excluding inventory write-down)	102	324
Inventory write-down (Note 8)	-	260
Research and development	1,014	964
Sales, marketing, general and administrative	2,246	2,297
Total costs and expenses	3,362	3,845
Operating (loss) income	(3,138)	1,512
Non-Operating income (expense):		
Investment income	27	35
Interest expense (Note 11)	(249)	(308)
Other expense	(24)	-
Total other expense, net	(246)	(273)
(Loss) income before provision for income taxes	(3,384)	1,239
Provision for income taxes	-	-
Net (loss) income	$ (3,384)	$ 1,239
Other comprehensive income:		
Unrealized gains on securities	70	31
Comprehensive (loss) income	$ (3,314)	$ 1,270
Loss (income) per share:		
Basic	$ (0.28)	$ 0.13
Diluted	$ (0.28)	$ 0.13
Weighted average shares outstanding:		
Basic	11,968	9,793
Diluted	11,968	9,869

See accompanying Notes to Consolidated Financial Statements.

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

	Three months Ended March 31, 2016					
	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	$ Amount	Capital	Deficit	Income (Loss)	Total
Balance at January 1, 2016	11,801	$ 118	$ 375,157	$ (367,310)	$ (65)	$ 7,900
Net loss	-	-	-	(3,384)	-	(3,384)
Other comprehensive income	-	-	-	-	70	70
Share-based compensation	-	-	150	-	-	150
Net distribution of common stock pursuant to restricted stock unit award plan	33	-	18	-	-	18
Balance at March 31, 2016	11,834	$ 118	$ 375,325	$ (370,694)	$ 5	$ 4,754

See accompanying Notes to Consolidated Financial Statements.

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

	Three months Ended March 31,	
	2016	2015
Cash Flows from Operating Activities:		
Net (loss) income	$ (3,384)	$ 1,239
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation	34	30
Provision to reduce inventory to net realizable value	-	260
Provision for sales returns	37	153
Share-based compensation	150	151
Amortization of debt discount and deferred debt issue costs	40	48
Amortization of bond premium in marketable securities	19	41
Amortization of intangible asset	52	52
Loss on sales of marketable securities	24	-
Changes in assets and liabilities:		
Accounts receivable	(57)	(11)
Accrued investment income	12	3
Inventories	74	(238)
Prepaid expenses and other current assets	121	159
Other current deferred assets	-	214
Accounts payable	265	(56)
Accrued expenses	591	428
Deferred revenue	-	(353)
Accrued interest – current and long term	99	51
Other current liabilities	1	(4)
Net cash (used in) provided by operating activities	(1,922)	2,167
Cash Flows from Investing Activities:		
Proceeds from sale and maturities of marketable securities	3,177	925
Additions to property, plant and equipment	(49)	(46)
Net cash provided by investing activities	3,128	879
Cash Flows from Financing Activities:		
Proceeds from distribution of restricted stock units	-	1
Principal payments on debt	(409)	-
Net cash (used in) provided by financing activities	(409)	1
Net increase in cash and cash equivalents	797	3,047
Cash and cash equivalents at beginning of year	2,485	774
Cash and cash equivalents at end of period	$ 3,282	$ 3,821
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest	$ 110	$ 209

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 and are adjusted to give effect to our one-for-five reverse stock split on August 28, 2015):

Three months Ended March 31, 2015

1. The exercise price of 60 thousand common stock purchase warrants held by the lender of our debt was changed from $7.98 to $2.52 per share. The change in fair value of $33 was recorded as additional debt discount and is being amortized as interest expense over the remaining term of this debt.

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2016 AND MARCH 31, 2015

NOTE 1 - DESCRIPTION OF BUSINESS

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the "Company", "We", "Us" 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® and Limitx™ Technologies are intended to address methods of product tampering associated with opioid abuse while our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine into methamphetamine.

- Oxaydo® Tablets (oxycodone HCl, CII), which utilizes the Aversion Technology, is the first and only approved immediate-release oxycodone product in the United States with abuse deterrent labeling. 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. Egalet launched Oxaydo in the United States late in the third quarter of 2015.
- Nexafed® Tablets (30mg pseudoephedrine) and Nexafed® Sinus Pressure + Pain Tablets (30/325mg pseudoephedrine and acetaminophen), utilizing the Impede Technology, were launched by us into the United States market in December 2012 and February 2015, respectively. We have multiple pseudoephedrine products in development utilizing our Impede Technology. On June 15, 2015, we and Bayer Healthcare LLC 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.
- 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 our first clinical study, Study AP-LTX-400, of our lead Limitx immediate release oral abuse deterrent drug candidate using the opioid hydromorphone HCI (LTX-04). Study AP-LTX-400, or Study 400, is a two cohort, open label, crossover design pharmacokinetic study in healthy adult subjects. The FDA has designated the development program for LTX-04 as Fast Track, which is designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. On April 13, 2016 we announced that topline interim results from Cohort 1 of Study 400 for one test formulation of LTX-04 successfully demonstrated the release of the active opioid ingredient was reduced when three intact tablets were ingested, but that additional formulation development will be required for LTX-04 to deliver a sufficient amount of the active ingredient when one or two tablets are administered. We are also developing an immediate-release hydrocodone bitartrate with acetaminophen product utilizing our Limitx Technology.

Amounts presented have been rounded to the nearest thousand, where indicated, except share and per share data. The equity amounts and all share and per share data of the Company have been retroactively adjusted to reflect a one-for-five reverse stock split effected by us on August 28, 2015.

NOTE 2 – LIQUIDITY MATTERS

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. At March 31, 2016, we had unrestricted cash, cash equivalents and marketable securities (after deduction of a $2.5 million compensating balance requirement under our term loan with Oxford) of $8.5 million, unrestricted working capital of $4.7 million, and an accumulated deficit of $370.7 million. We had a loss from operations of $3.1 million and a net loss of $3.4 million for the three months ended March 31, 2016.

We estimate that our current unrestricted cash, cash equivalent and marketable securities will be sufficient to fund the development of our products utilizing our Limitx and Impede Technologies, the commercialization of our Nexafed products and our related operating expenses through the first quarter of 2017. To fund further operations and product development activities, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying balance sheets is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements on a continuous basis, to maintain existing financing and to succeed in its future operations. The Company's financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

NOTE 3 – ACCOUNTING PRONOUNCEMENTS

Revenue from Contracts with Customers

In May 2014, the Financial Accounting Standards Board (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 transition method we will utilize to adopt the standard for use in 2018.

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

In August 2014, the FASB issued ASU 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.

Inventories

In July 2015, the FASB issued ASU No. 2015-11, which amended Accounting Standards Codification ("ASC") Topic 330 Inventory. The amendment simplifies the measurement of inventory, applying to inventories for which cost is determined by methods other than last-in first-out (LIFO) and the retail inventory method (RIM), specifying that an entity should measure inventory at the lower of cost and net realizable value instead of at the lower of cost or market. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, and interim periods therein. The Company is currently assessing the impact the adoption of the amendment will have on its consolidated financial statements and related disclosures.

Leases

In February 2016, the FASB issued ASU 2016-02, *Leases*, which will require most leases (with the exception of leases with terms of less than one year) to be recognized on the balance sheet as an asset and a lease liability. Leases will be classified as an operating lease or a financing lease. Operating leases are expensed using the straight-line method whereas financing leases will be treated similarly to a capital lease under the current standard. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2018 but early adoption is permitted. The new standard must be presented using the modified retrospective method beginning with the earliest comparative period presented. The Company is currently evaluating the effect of the new standard on its consolidated financial statements and related disclosures.

Compensation – Stock Compensation

In March 2016, the FASB issued ASU 2016-09, "Compensation - Stock Compensation (Topic 718), *Improvements to Employee Share-Based Payment Accounting*." ASU 2016-09 allows for simplification of several aspects of the accounting for share-based payment transactions including the income tax consequences, classifications of awards as either equity or liabilities, and classification on the statement of cash flows. Under ASU 2016-09, all excess tax benefits and tax deficiencies (including tax benefits of dividends) on share-based payment awards) should be recognized as income tax expense or benefit in the income statement. ASU 2016-09 also requires recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. ASU 2016-09 further permits the withholding of an amount up to employee's maximum individual tax rate in the relevant jurisdiction without resulting in a liability classification. ASU 2016-09 also requires any excess tax benefits be classified along with other income tax cash flows as an operating activity and cash paid by an employer when directly withholding shares for tax-withholding purposes be to be classified as a financing activity. ASU 2016-09 is effective for public companies for interim and annual periods beginning after December 15, 2016. The Company is currently evaluating the impact of ASU 2016-09 on the Company's consolidated financial condition and results of operations.

NOTE 4 - LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENTS

Egalet Agreement

On January 7, 2015, we and Egalet entered into a Collaboration and License Agreement (the "Egalet Agreement") to commercialize Aversion Oxycodone (formerly known as Oxecta®) 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 transferred the approved New Drug Application, or 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. Eaglet launched Oxaydo in the United States late in the third quarter of 2015.

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 a $5.0 million license fee upon signing of the Egalet Agreement and on October 9, 2015, paid us a $2.5 million milestone in connection with the first commercial sale of Oxaydo. 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 are receiving from Egalet a stepped royalty at percentage rates ranging from mid-single digits to double-digits based on Oxaydo net sales during each calendar year (excluding net sales resulting from our co-promotion efforts). In any calendar year of the agreement 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 as 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. 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.

Bayer Agreement

On June 15, 2015, we and Bayer entered into a License and Development Agreement (the "Bayer 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 Bayer Agreement also grants Bayer first right to negotiate a license to the Impede technology for certain other products.

We and Bayer have formed 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 Bayer 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 Bayer Agreement in its entirety if the other party materially breaches the Bayer 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 Bayer 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 Bayer 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.

Terminated Pfizer Agreement

In 2007, we entered into License, Development and Commercialization Agreement for Oxaydo (named Oxecta® under a Pfizer trademark) and other Aversion opioid development products with King Pharmaceuticals Research and Development, Inc., which became a subsidiary of Pfizer in 2011 (the "Pfizer Agreement"). In April 2014, we entered into a letter agreement with Pfizer providing for the termination of the Pfizer Agreement and the return to us of Oxaydo and all Aversion product rights in exchange for a one-time termination payment of $2.0 million. Our termination payment of $2.0 million has been recorded in our consolidated financial statements as an intangible asset and is being amortized over the remaining useful life of the patent covering Oxaydo. During each of the three month periods ending March 31, 2016 and 2015, we recognized amortization expense on this intangible asset of $52 thousand. We also purchased from Pfizer in April 2014 selected raw and packaging material inventories relating to Oxaydo for $260 thousand. During first quarter 2015, we recorded a $260 thousand expense from an inventory obsolescence reserve against these inventories.

NOTE 5 - REVENUE RECOGNITION

License Fee Revenue

On January 7, 2015, we and Egalet entered into a Collaboration and License Agreement to commercialize Oxaydo tablets (formerly known as Oxecta) utilizing our Aversion® Technology. Egalet paid us $5.0 million upon signing the Egalet Agreement. The payment was non-refundable and non-creditable when made and we had no further requirements to earn the payment. The amount was recognized as revenue when received (see Note 4).

Collaboration Revenue

Collaboration revenue is derived from reimbursement of development expenses, such as under the Bayer Agreement, and are recognized when costs are incurred pursuant to the agreement. The ongoing research and development services being provided under the collaboration are priced at fair value based upon the reimbursement of labor and expenses incurred pursuant to the collaboration agreements. During the three month period ended March 31, 2016, we recognized collaboration revenue of $100 thousand. We did not recognize any collaboration revenue during the three month period ended March 31, 2015.

Royalty Revenue

In connection with our Collaboration and License Agreement with Egalet to commercialize Oxaydo tablets we will receive a stepped royalty at percentage rates ranging from mid-single digits to double-digits based on Oxaydo net sales during each calendar year over the term of the agreement (excluding net sales resulting from any co-promotion efforts by us). We recognize royalty revenue each calendar quarter based on net sales reported to us by Egalet in accordance with the agreement. Egalet's first commercial sale of Oxaydo occurred in October 2015. We recognized royalty revenue of $17 thousand on Oxaydo net sales during the three month period ended March 31, 2016 (see Note 4).

Product Sales

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 usually 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. During the first quarter of 2015, we determined we had obtained sufficient sales returns history to reasonably estimate future product returns from those customers. We recorded a one-time adjustment in the first quarter of 2015 to recognize revenue that had previously been deferred, resulting in additional net revenues of $314 thousand after recording a liability for sales returns of $120 thousand, and additional cost of sales of $255 thousand. We currently recognize revenue from our Nexafed product line 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, which generally occurs at the time of product shipment. At March 31, 2016 and December 31, 2015, we had a $242 thousand and $205 thousand sales returns liability, respectively, which is reviewed against sales returns activity each calendar quarter for adjustment.

Shipping and Handling Costs

We record shipping and handling costs in selling expenses. The amounts recorded to selling expenses from the shipments of the Nexafed product line during each of the three month periods ended March 31, 2016 and 2015 were not material.

NOTE 6 - 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. During 2015, we entered into a $200 thousand cancelable arrangement for contract manufacturing services on a project to integrate Impede 2.0 technology into our commercially available Nexafed 30mg tablet while moving supply to an alternate contract manufacturer. Approximately $148 thousand and $200 thousand of services was remaining to be performed under this agreement at March 31, 2016 and December 31, 2015, respectively. At March 31, 2016, we had prepaid services costs of $22 thousand under this agreement. No service costs were prepaid under this agreement at December 31, 2015. We did not have prepaid CRO costs or clinical trial study expenses at either March 31, 2016 or December 31, 2015.

NOTE 7 - INVESTMENTS IN MARKETABLE SECURITIES

Investments in marketable securities consisted of the following:

	March 31, 2016 (in millions)	December 31, 2015 (in millions)
Marketable securities:		
Corporate bonds - maturing within 1 year	$ 2.9	$ 3.1
Corporate bonds - maturing after 1 year and through March 2017	-	0.4
Exchange-traded funds	4.8	7.3
Total marketable securities	$ 7.7	$ 10.8

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:

	March 31, 2016 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 2.9	$ -	$ -	$ 2.9
Exchange-traded funds	4.8	-	-	4.8
Total - Current	$ 7.7	$ -	$ -	$ 7.7

	December 31, 2015 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 3.6	$ -	$ (0.1)	$ 3.5
Exchange-traded funds	7.3	-	-	7.3
Total - Current	$ 10.9	$ -	$ (0.1)	$ 10.8

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 March 31, 2016 and December 31, 2015 consisted of the following:

	March 31, 2016 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	$ 2.9	$ -	$ 2.9	$ -
Exchange-traded funds	4.8	4.8	-	-
Total	$ 7.7	$ 4.8	$ 2.9	$ -

	December 31, 2015 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	$ 3.5	$ -	$ 3.5	$ -
Exchange-traded funds	7.3	7.3	-	-
Total	$ 10.8	$ 7.3	$ 3.5	$ -

Accumulated Other Comprehensive Income (Loss)

Unrealized gains or losses on marketable securities are recorded in accumulated other comprehensive income (loss). Accumulated other comprehensive income (loss) at March 31, 2016 consisted of unrealized gains on securities of $5 thousand. Accumulated other comprehensive income (loss) at December 31, 2015 consisted of unrealized losses on securities of $65 thousand.

NOTE 8 – INVENTORIES

Inventories consist of raw materials and finished goods on our Nexafed product at March 31, 2016. 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 expense against the Oxaydo raw and packaging material inventory we purchased from Pfizer. Our purchases of ingredients and other materials required in our development and clinical trial activities are expensed as incurred.

Inventories are summarized as follows:

	March 31, 2016	December 31, 2015
	(in thousands)	
Raw and packaging materials	$ 15	$ -
Finished goods	193	346
Total	208	346
Less: reserve for finished goods	(6)	(70)
Net	$ 202	$ 276

Inventory reserve activity during the three months ended March 31, 2016 and 2015 was as follows:

	2016	2015
	(in thousands)	
Balance at beginning of year	$ 70	$ -
Reserve expense - raw and packaging	-	260
	70	260
Inventory write-offs - finished goods	(64)	-
Balance at March 31	$ 6	$ 260

NOTE 9 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are stated at cost of $2,802 thousand and $2,754 thousand, less accumulated depreciation of $(1,774) thousand and $(1,741) thousand at March 31, 2016 and December 31, 2015, respectively. We have no leasehold improvements. Betterments are capitalized and maintenance and repairs are charged to operations as incurred. When a depreciable asset is retired from service, the cost and accumulated depreciation is removed from the respective accounts.

Our depreciation expense was $34 thousand and $30 thousand for the three month periods ended March 31, 2016 and 2015, respectively. Depreciation expense is recorded on a straight-line basis over the estimated useful lives of the related assets. The estimated useful lives of the major classification of depreciable assets are:

Building and improvements	10 - 40 years
Land and improvements	20 - 40 years
Machinery and equipment	7 - 10 years
Scientific equipment	5 - 10 years
Computer hardware and software	3 - 10 years

NOTE 10 - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	March 31, 2016	December 31, 2015
	(in thousands)	
Payroll, payroll taxes, and benefits	$ 167	$ 101
Professional services	576	171
Franchise taxes	7	6
Property taxes	17	15
Marketing and promotion	56	115
Clinical, non-clinical and regulatory services	206	92
Other fees and services	126	64
Total	$ 1,155	$ 564

NOTE 11 – 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 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 March 31, 2016, we have made $2.4 million 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 60 thousand shares of our common stock at an exercise price equal to $7.98 per share (after adjustment for our one-for-five reverse stock split) (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. The fair value of the warrants was determined using the Black-Scholes option-pricing model. Significant assumptions used in the Black-Scholes model were:

Expected dividend yield	0.0%
Risk-free interest rate	2.4%
Expected volatility	92%
Expected term (years)	7

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 $7.98 to $2.52 per share (the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the amendment and after giving effect to our one-for-five reverse stock split) and we recorded additional debt discount of $33 thousand representing the fair value of the warrant modification, (ii) we agreed to maintain $2.5 million cash reserves 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 1% of the principal prepaid. 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 are accruing 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. As of March 31, 2016, we have accrued and accumulated $433 thousand of additional interest.

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 is summarized below (in thousands):

Long-term Debt	Current	Long-term	Total
Balance at Dec 31, 2015	$ 2,320	$ 5,720	$ 8,040
Principal payments	(409)	-	(409)
Classification	664	(664)	-
Balance at Mar 31, 2016	$ 2,575	$ 5,056	$ 7,631

Debt Discount	Current	Long-term	Total
Balance at Dec 31, 2015	$ -	$ (193)	$ (193)
Modification of warrants	-	-	-
Amortization expense	-	26	26
Balance at Mar 31, 2016	$ -	$ (167)	$ (167)

Deferred Debt Issuance Costs	Current	Long-term	Total
Balance at Dec 31, 2015	$ -	$ (97)	$ (97)
Amortization expense	-	14	14
Balance at Mar 31, 2016	$ -	$ (83)	$ (83)
Long-term Debt, net at Mar 31, 2016	$ 2,575	$ 4,806	$ 7,381

Our interest expense for the three months ended March 31, 2016 and 2015 consisted of the following (in thousands):

	2016	2015
Interest expense:		
Term loan	$ 209	$ 260
Debt discount	26	31
Debt issue costs	14	17
Total interest expense	$ 249	$ 308

The annual principal payments of the debt at March 31, 2016 are as follows:

Year	Annual Principal Payments (in thousands)
2016	$ 1,911
2017	2,741
2018	2,979
Total	$ 7,631

NOTE 12 – EQUITY FINANCING

Our universal shelf registration statement on Form S-3 was declared effective by the U.S. Securities and Exchange Commission (“SEC”) on March 30, 2016. We may file with the SEC a prospectus supplement to our S-3 registration statement to sell common stock or other equity or debt securities, from time to time, in “at the market” offerings and certain other transactions. In the event we file a prospectus supplement with the SEC and engage in the sale of our equity or debt securities under the S-3 registration statement, we expect that the net proceeds from any such transactions will be used for general corporate purposes, including working capital, research, development and marketing expenses, clinical trial expenditures and capital expenditures.

NOTE 13 - COMMON STOCK WARRANTS

We have outstanding common stock purchase warrants (“warrants”) exercisable for 60 thousand shares of our common stock having an exercise price of $2.52 per share (after giving effect to our one-for-five reverse stock split) with an expiration date in December 2020. See Note 11 for a discussion of the reduction of the exercise price of these warrants to $2.52 per share which were originally issued in connection with the issuance of the $10.0 million secured promissory notes in December 2013. These warrants contain a cashless exercise feature.

Our warrant activity during the three month periods ended March 31, 2016 and 2015 is shown below (in thousands except price data):

	March 31,			
	2016		2015	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, beginning	60	$ 2.52	60	$ 7.98
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Modification	-	-	-	(5.46)
Outstanding, ending	60	$ 2.52	60	$ 2.52

NOTE 14 - SHARE-BASED COMPENSATION

Share-based Compensation

We have four 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. 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 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 from all types of issued instruments comprised the following (in thousands):

	Three Months Ended March 31,	
	2016	2015
Research and development expense:		
Stock options	$ 43	$ 39
Restricted stock units	-	-
Subtotal	$ 43	$ 39
General and administrative expense:		
Stock options	77	98
Restricted stock units	30	14
Subtotal	$ 107	$ 112
Total	$ 150	$ 151

Stock Option Award Plans

We have two stock option plans in effect, and one stock option plan has expired by its terms, but pursuant to which stock options have been granted and remain outstanding. Our stock option award activity during the three month periods ended March 31, 2016 and 2015 is shown below:

	Three months Ended March 31,			
	2016		2015	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, beginning	1,198	$ 15.67	911	$ 20.70
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited or expired	-	-	(15)	26.25
Outstanding, ending	1,198	$ 15.67	896	$ 20.65
Options exercisable	876	$ 20.64	715	$ 25.00

The intrinsic value of the option awards which were vested and outstanding at March 31, 2016 and December 31, 2015 was $70 thousand and $6 thousand, respectively. The total remaining unrecognized compensation cost on unvested option awards outstanding at March 31, 2016 was $591 thousand, and is expected to be recognized in operating expense over the 20 months remaining in the requisite service period.

Restricted Stock Unit Award Plan

We have a Restricted Stock Unit Award Plan (the "2014 RSU Plan") for our employees and non-employee directors. Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. The share-based compensation cost to be incurred on a granted RSU is the RSU's fair value, which is the market price of our common stock on the date of grant, less its exercise cost. The compensation cost is amortized to expense over the vesting period of the RSU award.

A summary of the grants under the RSU Plans consisted of the following:

	Three months Ended March 31,			
	2016		2015	
	(in thousands)			
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	45	45	30	30
Granted	88	-	41	-
Distributed	(42)	(42)	(26)	(26)
Vested	-	22	-	10
Forfeited or expired	-	-	-	-
Outstanding, ending	91	25	45	14

Our 2014 RSU Plan was approved by shareholders on May 1, 2014 and permits the grant of up to 400 thousand shares of our common stock pursuant to awards under the 2014 RSU Plan. As of March 31, 2016, 242 thousand shares are available for award under the 2014 RSU Plan.

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

- On January 2, 2015, we awarded approximately 10.3 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 $22 thousand at March 31, 2015. Distributions of stock under the January 2, 2015 award cannot be deferred until a later date and the stock under such awards was distributed on January 4, 2016.
- On January 4, 2016, we awarded approximately 22.0 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 2016. 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 $28 thousand at March 31, 2016. Distributions of stock under the January 4, 2016 award 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.

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

- On January 2, 2015, 25.8 thousand RSUs from the May 1, 2014 award were distributed and 3.6 thousand RSUs were deferred until a future distribution date. Of the 25.8 thousand RSUs distributed, 19.8 thousand RSUs were distributed in common stock and 6 thousand RSUs were settled in cash.
- On January 4, 2016, 41.2 thousand RSUs from the January 2, 2015 award were distributed and 1.2 thousand RSUs from the May 1, 2014 award were distributed. Approximately 2.4 thousand RSUs from the May 1, 2014 award are being deferred until a future distribution date. Of the 42.4 thousand RSUs distributed, 32.8 thousand RSUs were distributed in common stock and 9.6 thousand RSUs were settled for $23.8 thousand.

NOTE 15 – INCOME TAXES

We account for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities and are accounted for using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At both March 31, 2016 and December 31, 2015, 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 $52.8 million federal income tax benefits at December 31, 2015 derived from $155.2 million Federal NOLs at the U.S. statutory tax rate of 34% and $2.0 million state NOLs, available to offset future taxable income, some of which already have limitations for future use as prescribed under IRC Section 382. Our Federal and state NOLs will expire in varying amounts between 2016 and 2035 if not used, and those expirations will cause fluctuations in our valuation allowances. As of December 31, 2015, we had federal research and development tax credits of approximately $1.2 million, which expire in the years 2024 through 2034. We also had approximately $0.2 million of Indiana state research and development tax credits, which expire in the years 2016 and 2017.

NOTE 16 – 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 14). 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 2016 as the Company reported a net loss for the three month period, and including the effects of 1.3 million common stock equivalents in the diluted EPS calculation would have been antidilutive. The weighted-average common shares outstanding (diluted) computation is not impacted during any period where the exercise price of a stock option is greater than the average market price. There were 716 thousand non-dilutive equity awards outstanding at March 31, 2015 that are not included in the period's weighted-average common shares outstanding (diluted) computation.

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

	Three months Ended March 31,	
	2016	2015
	(in thousands except per share data)	
EPS - basic		
Numerator: net income (loss)	$ (3,384)	$ 1,239
Denominator:		
Common shares	11,963	9,789
Vested RSUs	5	4
Basic weighted average shares outstanding	11,968	9,793
EPS - basic	$ (0.28)	$ 0.13
EPS – assuming dilution		
Numerator: net income (loss)	$ (3,384)	$ 1,239
Denominator:		
Common shares	11,963	9,789
Vested RSUs	5	34
Stock options	-	33
Common stock warrants	-	13
Diluted weighted average shares outstanding	11,968	9,869
EPS - diluted	$ (0.28)	$ 0.13
Excluded securities:		
Common stock issuable:		
Stock options	1,198	716
Common stock warrants	60	-
Non-vested RSUs	66	-
Total excluded potentially dilutive shares	1,324	716

NOTE 17 – COMMITMENTS AND CONTINGENCIES

Purdue Pharma Complaints

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 " 007 patent"). The complaint seeks injunctive relief as well as awards of damages and attorneys' fees. In January 2016, the District Court issued a claim construction order in the patent infringement action. The order stated that the term polyvinylpyrrolidone as that term is defined in the claims of the Purdue patent covers all polymeric forms of vinylpyrrolidone, including crospovidone used in Oxaydo. We deny the allegations in the complaint, believe they are without merit and are defending the action vigorously.

In April 2016, Purdue commenced a second patent infringement lawsuit against us and Egalet in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's newly issued U.S. Patent No. 9,308,171 (the " 171 Patent"). 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 will defend the action vigorously.

As is the case with patent litigation, there is a risk that the Court may enjoin the making, using, selling and offering for sale Oxaydo and/or may find that Oxaydo infringes the 007 patent and/or the 171 patent. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to the Purdue infringement matters as of March 31, 2016.

In December 2014, the Company entered into an agreement with Purdue Pharma L.P. to settle a patent interference action regarding certain intellectual property held by Acura (U.S. Patent No. 8,101,630). The dispute centered upon the issue of which company has priority in developing the invention. The parties agreed to forgo protracted litigation and the uncertainties arising therefrom by entering an agreement whereby the Company conceded Purdue Pharma's claim of priority in exchange for certain financial consideration to us including an immediate non-refundable payment of $500 thousand. In June 2015, the Company received an additional $250 thousand payment from Purdue Pharma relating to the December 2014 agreement.

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 19 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.

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. From July, 2015 to date, the court has been moving forward with procedural steps to narrow this litigation, including requests for plaintiffs to voluntarily discontinue cases, such as those filed against Acura, where there is no case-specific product identification. Acura is optimistic that 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 that the lawsuits filed by most, if not all, plaintiffs will be dismissed voluntarily. 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 March 31, 2016 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, 2017 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 Limitx™ and Impede® technologies;

- the expected results of clinical studies relating to LTX-04, the date by which such study results will be available and whether LTX-04 will ultimately receive FDA approval;

- whether LIMITX will retard the release of opioid active ingredients as dose levels increase;
- whether we will be able to reformulate LTX-04 to provide an efficacious level of drug when one or two tablets are taken;
- whether our LIMITX technology can be expanded into extended-release formulations;
- our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our LIMITX and Impede® 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, timing of commercial launch 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;
- 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,” “expects,” “plans,” “anticipates,” “believes,” “indicates,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our 2015 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® and Limitx™ Technologies are intended to address methods of product tampering associated with opioid abuse while our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine into methamphetamine. Oxaydo Tablets (oxycodone HCl, CII), which utilizes the Aversion Technology, is the first and only approved immediate-release oxycodone product in the United States with abuse deterrent labeling. 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. Egalet launched Oxaydo in the United States late in the third quarter of 2015. We launched our first Impede Technology product, Nexafed, into the United States market in December 2012 and launched 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 our first clinical study, Study AP-LTX-400, of our lead Limitx immediate release oral abuse deterrent drug candidate using the opioid hydromorphone HCI (LTX-04). Study AP-LTX-400, or Study 400, is a two cohort, open label, crossover design pharmacokinetic study in healthy adult subjects. The FDA has designated the LTX-04 development program as Fast Track, which is designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. On April 13, 2016 we announced that topline interim results from Cohort 1 of Study 400 for one test formulation of LTX-04 successfully demonstrated the release of the active opioid ingredient was reduced when three intact tablets were ingested, but that additional formulation development will be required for LTX-04 to deliver a sufficient amount of the active ingredient when one or two tablets are administered. We expect compete topline study results from Study 400 to be available in June 2016. We are also developing 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 234 million prescriptions dispensed in 2015. Prescription opioids are also the most widely abused drugs with 11 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 66 tablets or capsules. According to IMS Health, in 2015, sales in the immediate-release opioid product segment were approximately 219 million prescriptions and $2.9 billion, of which approximately 98% was attributable to generic products. Immediate-release oxycodone tablets represent 19.3 million of these prescriptions or almost 1.7 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. We are advised that Egalet has approximately 71 sales representatives promoting Oxaydo to a target group of approximately 11,500 opioid prescribing physicians.

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 2014, the DEA reported 9,339 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.

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, 2015, 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 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 2015 Guidance, we have indefinitely suspended further development of our Aversion Hydrocodone/APAP and reallocated resources to our Limitx development candidates.

Abuse of Prescription Opioid Products and Development of Abuse Deterrent Formulations

Prescription opioids drugs, such as morphine and oxycodone, have a long history of use for the management of pain. Because they are highly effective, they are one of the largest prescribed drug categories in the U.S. However, a side effect of high doses of opioids is euphoria, or "a high". For these reasons, opioids are the most misused or abused prescription drugs in the U.S. Opioids are offered in a variety of dosages including immediate-release tablets (or capsules), extended-release tablets (or capsules), patches and other formats. Abusers will often manipulate or tamper with the formulations to achieve their high, including:

- Oral over-ingestion. Generally recognized as the most prevalent route of administration by abusers, the abuser simply orally ingests more tablets (or capsules) than is recommended for pain relief.

- Oral ingestion of manipulated tablets or patches. Extended-release tablets or patches are sometimes crushed, chewed or otherwise physically or chemically manipulated to defeat the extended-release mechanism and provide an immediate-release of the opioid.

- Nasal snorting. Crushed tablets are insufflated for absorption of the drug through the nasal tissues.

- Injection. The opioid is physically or chemically removed from the dosage and injected into the vein using a syringe.

- Poly-pharmacy. Opioids are sometimes used in conjunction with alcohol or other drugs to accentuate the high.

Abuse deterrent formulations of opioid dosages incorporate physical and/or chemical barriers in the formulations to prevent or discourage an abuser from inappropriately administering the product. The extent and manner in which any of the features of abuse deterrent opioids may be described in the FDA approved label for our pipeline products will be dependent on the results of and the acceptance by the FDA of our and our licensees' studies for each product.

Development of our Limitx and Aversion (if recommenced) product candidates will require one or more abuse deterrent studies 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 our product candidates to currently marketed products. Because our products use known active ingredients in approved dosage strengths, the safety and efficacy of the 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.

Limitx™ Technology

Limitx technology is intended to address abuse by excess oral consumption of multiple tablets and provide a margin of safety during accidental over-ingestion of tablets. Limitx is also expected to exhibit barriers to abuse by snorting and injection

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 (LTX-04) utilizes hydromorphone as its sole active ingredient. We have initiated formulation development of a hydrocodone/APAP product candidate utilizing our Limitx technology (LTX-03). In August 2015, the United States Patent and Trademark Office ("USPTO") issued to us patent 9,101,636 covering, among other things, 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 for Phase I development, which entailed the development of an optimized formulation of LTX-04 suitable for commercial manufacture and human testing. In Phase II, we are performing human pharmacokinetic testing of LTX-04 to characterize the release of drug in vivo. NIDA funding of Phase II development, for which an application has 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 NIDA funds. No assurance can be given that Phase II development funding will be provided by NIDA, but we plan to progress our clinical studies regardless of NIDA funding. We have submitted data on Phase I development of LTX-04 to NIDA for consideration in approving the Phase II grant, of which no assurance can be given of the grant for Phase II.

NIDA Disclaimer: Phase I and possibly Phase II research on LTX-04 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.

Limitx Technology Products in Development

We have the following products in development utilizing our Limitx technology:

Limitx Technology Product	Status
Immediate-release hydromorphone HCI (LTX-04)	Phase I exploratory pharmacokinetic study in process
Immediate-release hydrocodone bitartrate with acetaminophen (LTX-03)	Formulation development in process
Immediate-release oxycodone HCl (LTX-01) & (LTX-02)	Formulation development in process

In January 2016, our IND for LTX-04, our lead product candidate utilizing our Limitx technology, was allowed to proceed to clinical testing. The initial LTX-04 clinical study, Study AP-LTX-400, or Study 400, is a two cohort, open label, crossover design pharmacokinetic study in healthy adult subjects. Cohort 1 enrolled 30 subjects who were randomized into three subgroups of 10 taking either 1, 2 or 3 tablets. Each subgroup subject orally swallowed the planned number of tablets in a randomized manner taking single doses of two different test formulations of LTX-04 (designated as LTX-04P and LTX-04S and distinguished by their respective acid neutralizing capacity) and Purdue Pharma's marketed drug DILAUDID® as a comparator. All tablets contained 2mg of hydromorphone hydrochloride. The 1, 2 and 3 tablets subgroups in Cohort 1 completed 8, 10 and 8 subjects respectively. All subjects received doses of naltrexone and there was a one week washout between doses. Blood samples are taken at pre-designated time-points after dosing and are subsequently analyzed for the concentration of hydromorphone contained in the sample. All subjects in Cohort 1 have continuous pH (a measure of acid concentration) monitoring of their stomach acid. The objective of Cohort 1 was to determine if adequate active drug entered the blood stream when one or two LIMITX tablets were swallowed and to begin assessing the ability of the LIMIT technology to start retarding the release of active ingredients when three tablets are ingested.

Subjects in Cohort 2, which commenced dosing in late April 2016, is randomized into three subgroups taking four, six or eight tablets. Each Cohort 2 subject will take test formulation of LTX-04P and DILAUDID®. The objective of Cohort 2 will be to further explore the extent the release of the hydromorphone active ingredient from LTX-04 tablets is retarded as the dose level increases to abusive levels. A safety assessment of LIMITX Hydromorphone will be made from both study cohorts.

On April 13, 2016, we announced that topline interim results from Cohort 1 of Study 400 demonstrated LTX-04P, one test formulation of LTX-04, successfully demonstrated the release of the active opioid ingredient was reduced when three intact tablets were ingested, but that additional formulation development will be required for LTX-04 to deliver a sufficient amount of the active ingredient to patients when one or two tablets are administered. Specifically, the topline interim results of Cohort 1 of Study 400 demonstrated:

- Subjects taking 3 tablets of the marketed comparator product, DILAUDID®, had a maximum plasma concentration of the active ingredient, or Cmax, 4.8 times higher than subjects taking 1 tablet. Likewise, the Cmax for LTX-04S was 4.7 times higher for the 3 tablet group compared to the 1 tablet group. Both of these groups had stomach acid pH between 2 and 4 at 15 minutes post-dose. However, the 3 tablet LTX-04P dose achieved an average stomach acid pH of 4.7 at 15 minutes post-dose and the Cmax was only 3.8 times as high as the single tablet dose, an estimated 22% reduction in Cmax than expected. The increase in stomach pH demonstrated with LTX-04P was expected to correlate to a slowing of the release of active ingredient from the tablet's micro-particles resulting in a reduction of Cmax, among other measures. Drug abuse is typically associated with an increase in Cmax.

- Subjects taking one or two tablets of both LTX-04 formulations had comparable extent of drug absorption (measured by AUC) as the same number of tablets of DILAUDID®. However, these tablets delivered approximately 50% less peak plasma concentration (Cmax) than DILAUDID®. As such, the LTX-04 test formulations were considered to not have achieved equivalent blood levels of drug and will require further development. All study drugs were generally well tolerated and no serious adverse events were observed.

We intend to complete Cohort 2 of Study 400 in which subjects will take 4, 6 and 8 tablets testing the LTX-04P formulation to confirm the abuse deterrent results observed in Cohort 1. We expect compete topline results from Study 400 to be available in late June 2016. We have commenced reformulation work on the LIMITX technology micro-particles to improve the drug delivery with one and two tablets. We intend to discuss with the FDA the Cohort 1 results and the next clinical phase under its Fast Track development designation for LTX-04.

Aversion Technology

Aversion Technology incorporates gelling ingredients and irritants into tablets to discourage abuse by snorting and provide barriers to abuse by injection. Our Aversion Technology and related opioid products, like Oxaydo, are 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.

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. Egalet launched Oxaydo in the United States late in the third quarter of 2015.

The 2015 market for immediate-release oxycodone products was 19.3 million dispensed prescription or 1.7 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.

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 has advised that it has commenced formulation work on a new dosage strength for Oxaydo, and has set a target date for submission of this new dosage strength to the FDA in the second half of 2017. Egalet is also evaluating possible alternatives to enhance Oxaydo's product label.

We are advised that Egalet commenced promoting Oxaydo in September 2015 and has since expanded its target physician group to approximately 11,500 immediate-release opioid prescribing physicians using approximately 71 sales representatives. Commercial shipments of Oxaydo commenced in early October 2015. Egalet has further advised us that they have implemented a co-pay support program in which any non-government insurance covered patient receiving an Oxaydo prescription will be eligible to receive a credit such that their out-of-pocket cost, or co-pay, is limited to $15 per prescription. Egalet is in the early stages of promoting Oxaydo to physicians and addressing the challenges of establishing retail pharmacy stocking of a Schedule II narcotic.

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 a $2.5 million milestone in October 2015 in connection with the launch of Oxaydo. 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 commenced 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 as 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. 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.

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.

Abuse of Pseudoephedrine Products

The chemical structure of pseudoephedrine, or 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 wide range of solvents are amenable to the process.

Impede 1.0 Technology

Our Impede 1.0 Technology, a proprietary mixture of inactive ingredients, prevents the extraction of PSE from tablets using known extraction methods and disrupts the direct conversion of PSE from tablets into methamphetamine.

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 a next generation, or Impede 2.0 Technology to improve the meth-resistance of our technology. We have completed one-pot, direct conversion meth testing performed by our CRO on the following commercially available products and on our Nexafed Impede 2.0 extended-release product, with the following results:

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 have begun a project to integrate Impede 2.0 technology into our commercially available Nexafed 30mg tablet while moving supply to an alternate contract manufacturer.

Nexafed Products

Our Nexafed product line consists of immediate release tablets which currently utilize our patented Impede 1.0 Technology. Nexafed is a 30mg pseudoephedrine tablet and Nexafed Sinus Pressure + Pain is a 30/325mg 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 are 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 13,300 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 56% 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.

We understand that in 2014, a majority pharmacies in West Virginia voluntarily began selling on only meth-resistant products for the single-ingredient immediate-release PSE offerings. In 2015, newspapers reported about 60% of single-ingredient immediate-release PSE sales in West Virginia were for meth-resistant formulations. In March 2016, Indiana enacted legislation, subject to adoption of rule and policy making by the Indiana Board of Pharmacy, to require state pharmacists to use professional discretion when selling PSE-containing cold and allergy products, including encouraging the use of new meth-resistant formulations, in an effort to help reduce local methamphetamine production.

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
Nexafed 30mg with Impede 2.0 Technology	Transferring to alternate supplier and scaling-up to commercial supply
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. Pre-IND meeting held with the FDA
Extended – release combination products	Formulations being considered
Methamphetamine resistant pseudoephedrine – containing product	In development pursuant to Bayer Agreement

In July 2015, we had a pre-IND meeting with the FDA to discuss the results from our pharmacokinetic and meth-resistance testing studies to determine the development path for our extended-release development product. The FDA acknowledged the potential value of the development of risk-mitigating strategies for new formulations of pseudoephedrine products while also recognizing an approved "meth-deterrent" extended release pseudoephedrine product would be novel in the over-the-counter (OTC) setting. The FDA did not make a formal determination whether "meth-resistant" claims would be appropriate but is open to consider such an appropriately worded, evidence-based claim directed to the consumer and/or retailer. As recommended by the FDA, we intend to submit additional "meth-resistant" testing information to the FDA for review prior to submitting an IND.

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 $4.39 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.

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.

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 233 million tablet and capsule prescriptions dispensed in 2015 of which approximately 219 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 2015, sales in the IR opioid product segment were approximately $2.9 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 2015 is provided below:

IR Opioid Products[1]	2015 US Prescriptions (Millions)[2]	% of Total
Hydrocodone	97	44%
Oxycodone	57	26%
Tramadol	44	20%
Codeine	16	8%
3 Others	5	2%
Total	219	100%

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

[2] IMS Health, 2015

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®.

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 patent covering, among other things, our Limitx technology:

Patent No. (Jurisdiction)	Subject matter	Issued	Expires
9,101,636 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	August 2015	Nov. 2033
9,320,796 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	April 2016	Nov. 2033
2,892,908 (CAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Allowed; not yet issued	
(JAPAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Allowed; not yet issued	

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

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
7,201,920 (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
2,004,294,953 (AUS)	Abuse deterrent pharmaceuticals	Apr. 2010	Nov. 2024
2,010,200,979 (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
175,863 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
221,018 (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
2010300641 (AUS)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Allowed, not yet issued	
2,775,890 (CAN)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Allowed, not yet issued	
2,488,029 (EUR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Mar. 2016	Sept. 2030
218533 (ISR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Allowed, not yet issued	

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 October 2014, we ceded priority of the 630 patent to a patent application filed by Purdue Pharma and expect this patent to be rescinded**.**

In addition to our issued patents listed above and additional unlisted issued 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 and the Bayer 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 ANDAs 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 our Annual Report on Form 10-K under the caption "Item 1A. Risk Factors – Generic manufacturers are using litigation and regulatory means to seek approval for generic versions of Oxaydo, which could cause Egalet's sales to suffer and adversely impact our royalty revenue" for a discussion of the settlements and license grants relating to such patent litigation. 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.

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. In January 2016, the District Court issued a claim construction order in the patent infringement action. The order stated that the term polyvinylpyrrolidone as that term is defined in the claims of the Purdue patent covers all polymeric forms of vinylpyrrolidone, including crospovidone used in Oxaydo. We deny the allegations in the complaint, believe they are without merit and are defending the action vigorously.

In April 2016, Purdue commenced a second patent infringement lawsuit against us and Egalet in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's newly issued U.S. Patent No. 9,308,171 (the " 171 Patent"). 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 will defend the action vigorously.

As is the case with patent litigation, there is a risk that the Court may enjoin the making, using, selling and offering for sale Oxaydo and/or may find that Oxaydo infringes the 007 patent and/or the 171 patent. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to the Purdue infringement matters as of March 31, 2016.

Reference is made to the Risk Factors contained in our Annual Report on Form 10-K for the year ended December 31, 2015 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 March 31, 2016, we had cash, cash equivalents and marketable securities of $11.0 million compared to $13.3 million of cash, cash equivalents and marketable securities at December 31, 2015. We have a $2.5 million compensating balance requirement at March 31, 2016 under our term loan from Oxford Finance LLC. Excluding the compensating balance requirement, the Company had unrestricted working capital of 4.7 million at March 31, 2016 compared to unrestricted working capital of $8.4 million at December 31, 2015. We had an accumulated deficit of approximately $370.7 million and $367.3 million at March 31, 2016 and December 31, 2015, respectively. We had a loss from operations of $3.1 million and a net loss of $3.4 million for the three months ended March 31, 2016, compared to income from operations of $1.5 million and net income of $1.2 million for the three months ended March 31, 2015. As of April 30, 2016, our unrestricted cash, cash equivalents and marketable (after deduction of a $2.5 million compensating balance requirement under our term loan with Oxford) was $7.7 million.

We estimate that our unrestricted cash, cash equivalents and marketable securities, milestone and royalty payments, if any, that may be made under the Egalet Agreement and the Bayer Agreement, and revenues from our commercialization of our Nexafed products will be sufficient to fund our continuing operations through the first quarter of 2017. Moreover, 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, thereby accelerating the date at which we may exhaust our funding resources. To fund further operations and product development activities beyond the first quarter of 2017, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

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 March 31, 2016 Compared to Three months Ended March 31, 2015

	March 31			
	2016	2015	Increase (decrease)	
	$000's		Percent	
Revenues				
License fee revenue	$ -	$ 5,000	$ (5,000)	(100)%
Collaboration revenue	100	-	100	-
Royalty revenue	17	-	17	-
Product sales, net	107	357	(250)	(70)
Total revenues, net	224	5,357	(5,133)	(96)
Cost and expenses				
Cost of sales (excluding inventory write-down)	102	324	(222)	(68)
Inventory write-down	-	260	(260)	(100)
Research and development	1,014	964	50	5
Sales, marketing, general and administrative	2,246	2,297	(51)	(2)
Total operating expenses	3,362	3,845	(483)	(13)
Operating loss (income)	(3,138)	1,512	(4,650)	(308)
Non-operating income (expense)				
Investment income	27	35	(8)	(23)
Interest expense	(249)	(308)	(59)	(19)
Other expense	(24)	-	24	-
Total other expense, net	(246)	(273)	(27)	(10)
(Loss) income before provision for income taxes	(3,384)	1,239	(4,623)	(373)
Provision for income taxes	-	-	-	-
Net (loss) income	$ (3,384)	$ 1,239	$ (4,623)	(373)%

Revenue and Cost of Sales

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 to commercialize Oxaydo tablets (formerly known as Oxecta) utilizing our Aversion® Technology. Egalet paid us an upfront payment of $5.0 million upon signing the agreement.

Collaboration Revenue

Collaboration revenue is derived from reimbursement of development expenses under various development agreements, such as the collaboration agreement with Bayer, and are recognized when costs are incurred pursuant to the collaboration agreement. We recognized $100 thousand of collaboration revenue during the three months ended March 31, 2016.

Royalties

In connection with our Collaboration and License Agreement with Egalet to commercialize Oxaydo tablets we receive 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). Egalet's first commercial sale of Oxaydo occurred in October 2015 and we have recorded royalties of $17 thousand on net sales for the three month period ended March 31, 2016.

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 usually 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. Our net product sales for the three months ended March 31, 2016 and 2015 were $107 thousand and $357 thousand, respectively.

Cost and Expenses

Cost of Sales

Cost of sales includes third-party acquisition costs, third-party warehousing and product distribution charges and inventory reserve expense 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 March 31, 2016 and 2015, cost of sales was $102 thousand and $324 thousand, respectively.

Included in cost and expenses for the three months ended March 31, 2015 is $260 thousand of inventory reserve expense on raw and package materials purchased from Pfizer at the time we reacquired Oxaydo from Pfizer.

Research and Development

Research and development expense (R&D) for the three months ended 2016 was primarily for our Limitx and 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. The initial LTX-04 clinical study, Study AP-LTX-400, or Study 400, was ongoing during the first quarter 2016. R&D expense for the three months ended 2015 was primarily for our Aversion and 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 2016 and 2015 quarterly results are non-cash share-based compensation expenses of approximately $43 thousand and $39 thousand, respectively. Excluding the share-based compensation expense, our R&D expenses increased approximately $46 thousand between reporting.

General, Administrative, Selling and Marketing

Selling and marketing expenses for the three months ended 2016 was primarily of advertising and marketing activities on the Nexafed product line. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the 2016 and 2015 quarterly results are non-cash share-based compensation expenses of approximately $107 thousand and $112 thousand, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased by $46 thousand between reporting periods, resulting primarily from decreases in advertising and marketing activities and offset by increases in our patent legal and litigation expenses with Purdue Pharma.

Non-Operating Income (Expense)

During the three months ended March 31, 2016 and 2015, non-operating expense consisted principally of interest expense on our term loan from Oxford, which originated on December 27, 2013, less investment income derived from our investments.

Income Taxes

Our results for 2016 and 2015 include no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Liquidity and Capital Resources

At March 31, 2016, we had cash, cash equivalents and marketable securities $11.0 million compared to $13.3 million at December 31, 2015. 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 $4.7 million at March 31, 2016 compared to $8.4 million at December 31, 2015. We estimate that such unrestricted working capital, together with milestone and royalty payments, if any, that may be made under the Egalet Agreement and the Bayer Agreement, and revenues from our commercialization of our Nexafed Products will be sufficient to fund our continuing operations through the first quarter of 2017.

To fund further operations and product development activities, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company’s continuing product development efforts will have a material adverse effect on the Company’s financial condition and results of operations.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company’s accompanying balance sheets is dependent upon continued operations of the Company, which in turn is dependent upon the Company’s ability to meet its financing requirements on a continuous basis, to maintain existing financing and to succeed in its future operations. The Company’s financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

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 Limitx products in development with other pharmaceutical company partners, for which there can be no assurance, and from the commercialization of our Nexafed products.

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

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company’s 2015 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 2015 Annual Report are also applicable to 2016.

Item 4. Controls and Procedures

(a) *Disclosure Controls and Procedures*. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined on Rules 13a – 13(e) and 15(d) – 15(e) under the Exchange Act) as of the end of the period covered by this Report. The Company's disclosure controls and procedures are designed to provide reasonable assurance that information is recorded, processed, summarized and reported accurately and on a timely basis in the Company's periodic reports filed with the SEC. Based upon such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures are effective to provide reasonable assurance. Notwithstanding the foregoing, a control system, no matter how well designed and operated, can provide only reasonable, not absolute assurance that it will detect or uncover failures within the Company to disclose material information otherwise require to be set forth in the Company's periodic reports.

(b) *Changes in Internal Controls over Financial Reporting.* There were no changes in our internal controls over financial reporting during the first fiscal quarter of 2016 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 17, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

Item 6. Exhibits

The exhibits required by this Item are listed below.

31.1	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
31.2	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
32.1	Certification of Periodic Report by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

May 2, 2016

ACURA PHARMACEUTICALS, INC.

/s/ Robert B. Jones

Robert B. Jones
Chief Executive Officer

/s/ Peter A. Clemens

Peter A. Clemens
Senior VP & Chief Financial Officer

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

May 2, 2016

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

Exhibit 31.2

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

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

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

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

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

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

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

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

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

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

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

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

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

May 2, 2016

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

Exhibit 32.1

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

In connection with the Quarterly Report of Acura Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert B. Jones, the Chief Executive Officer of the Company, and Peter A. Clemens, Chief Financial Officer certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

May 2, 2016

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

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