ACURA PHARMACEUTICALS, INC
Form 10-Q
November 14, 2016

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20649

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**60067**
(Address of Principal Executive Offices)	*(Zip Code)*

847 705 7709

(Registrant's telephone number, including area code)

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

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

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

Yes þ No ¨

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

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

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

As of October 31, 2016 the registrant had 11,833,801 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

TABLE OF CONTENTS

FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

Part I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited; in thousands except par value)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	$ 4,272	$ 2,485
Marketable securities (Note 7)	-	10,837
Accounts receivable (net of allowances of $5 and $91)	169	83
Accrued investment income	-	37
Inventories, net (Note 8)	424	276
Prepaid expenses and other current assets	411	417
Total current assets	5,276	14,135
Property, plant and equipment, net (Note 9)	979	1,013
Intangible asset (net of accumulated amortization of $517 and $362) (Note 4)	1,483	1,638
Other assets	-	175
Total assets	$ 7,738	$ 16,961
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 403	$ 110
Accrued expenses (Note 10)	736	564
Accrued interest	44	-
Other current liabilities	44	45
Sales returns liability	288	205
Debt - current (Note 11)	2,685	2,320
Total current liabilities	4,200	3,244
Debt – non-current portion (net of discount of $119 and $193, and debt issuance costs of $58 and $97) (Note 11)	3,508	5,430
Accrued interest – non-current portion	519	387

Total liabilities	8,227	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 September 30, 2016 and December 31, 2015, respectively	118	118
Additional paid-in capital	375,625	375,157
Accumulated deficit	(376,232)	(367,310)
Accumulated other comprehensive loss	-	(65)
Total stockholders' (deficit) equity	(489)	7,900
Total liabilities and stockholders' equity	$ 7,738	$ 16,961

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited; in thousands except per share amounts)

	Three months Ended September 30,		Nine months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
License fee revenue	$ -	$ -	$ -	$ 5,250
Collaboration revenue	74	95	307	95
Royalty revenue	39	-	86	-
Product sales, net	105	115	306	563
Total revenues, net	218	210	699	5,908
Cost and expenses:				
Cost of sales (excluding inventory write-downs)	108	132	309	554
Inventory write-downs (Note 8)	-	27	26	334
Research and development	841	432	3,258	1,907
Selling, marketing, general and administrative	1,338	2,024	5,392	6,404
Total costs and expenses	2,287	2,615	8,985	9,199
Operating loss	(2,069)	(2,405)	(8,286)	(3,291)
Non-operating income (expense):				
Investment income	11	39	59	110
Interest expense (Note 11)	(215)	(283)	(697)	(892)
Other income	23	-	2	-
Total other expense, net	(181)	(244)	(636)	(782)
Loss before provision for income taxes	(2,250)	(2,649)	(8,922)	(4,073)
Provision for income taxes	-	-	-	-
Net loss	$ (2,250)	$ (2,649)	$ (8,922)	$ (4,073)
Other comprehensive income (loss):				
Unrealized (losses) gains on securities	(26)	2	65	2
Comprehensive loss	$ (2,276)	$ (2,647)	$ (8,857)	$ (4,071)
Net loss per share of common stock:				
Basic	$ (0.19)	$ (0.23)	$ (0.75)	$ (0.39)
Diluted	$ (0.19)	$ (0.23)	$ (0.75)	$ (0.39)
Weighted average common shares outstanding:				
Basic	11,880	11,677	11,858	10,446
Diluted	11,880	11,677	11,858	10,446

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENT OF STOCKHOLDERS' (DEFICIT) EQUITY

(Unaudited; in thousands)

	Nine months Ended September 30, 2016					
	Common Shares	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at January 1, 2016	11,801	$ 118	$ 375,157	$ (367,310)	$ (65)	$ 7,900
Net loss	-	-	-	(8,922)	-	(8,922)
Other comprehensive income	-	-	-	-	65	65
Share-based compensation	-	-	450	-	-	450
Net distribution of common stock pursuant to restricted stock unit award plan	33	-	18	-	-	18
Balance at September 30, 2016	11,834	$ 118	$ 375,625	$ (376,232)	$ -	$ (489)

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Nine months Ended September 30,	
	2016	2015
Cash Flows from Operating Activities:		
Net loss	$ (8,922)	$ (4,073)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	104	92
Provision to reduce inventory to net realizable value	26	334
Provision for sales returns	83	253
Share-based compensation	450	461
Amortization of debt discount and deferred debt issue costs	113	144
Amortization of bond premium in marketable securities	31	106
Amortization of intangible asset	155	155
(Gain) on sales of marketable securities	(2)	-
Loss on disposal of property, plant and equipment	2	20
Changes in assets and liabilities:		
Accounts receivable, net	(86)	(171)
Accrued investment income	37	15
Inventories	(174)	(104)
Prepaid expenses and other current assets	9	(17)
Other current deferred assets	-	217
Other assets	175	(175)
Accounts payable	293	59
Accrued expenses	170	257
Deferred revenue	-	(353)
Accrued interest – current and long term	176	141
Other current liabilities	17	7
Net cash used in operating activities	(7,343)	(2,632)
Cash Flows from Investing Activities:		
Purchases of marketable securities	-	(3,523)
Proceeds from sales and maturities of marketable securities	10,873	2,811
Proceeds from disposals of property, plant and equipment	-	14
Additions to property, plant and equipment	(72)	(211)
Net cash provided by (used in) investing activities	10,801	(909)
Cash Flows from Financing Activities:		
Proceeds from distribution of restricted stock units	-	1
Proceeds from ATM offering	-	225
Proceeds from Registered Direct offering	-	7,636
Transaction costs from ATM offering	-	(8)

Transaction costs from Registered Direct offering	-	(603)
Principal payments on debt	(1,671)	(1,160)
Net cash (used in) provided by financing activities	(1,671)	6,091
Net increase in cash and cash equivalents	1,787	2,550
Cash and cash equivalents at beginning of year	2,485	774
Cash and cash equivalents at end of period	$ 4,272	$ 3,324
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest on term loan with Oxford Finance LLC	$ 407	$ 606

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

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):

Nine months Ended September 30, 2016

There are no supplemental disclosure activities.

Nine months Ended September 30, 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

SEPTEMBER 30, 2016 AND SEPTEMBER 30, 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 abuse associated with opioid analgesics 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 have completed 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, was 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 and June 8, 2016, we announced that topline interim results from cohorts 1 and 2, respectively, of Study 400 for one test formulation of LTX-04 successfully demonstrated the release of the active opioid ingredient was reduced when three or more 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.

NOTE 2 - LIQUIDITY MATTERS

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. At September 30, 2016, we had unrestricted cash and cash equivalents (after deduction of a $2.5 million compensating balance requirement under our term loan with Oxford Finance LLC) of $1.8 million and an accumulated deficit of $376.2 million. We had a loss from operations of $8.3 million and a net loss of $8.9 million for the nine months ended September 30, 2016.

At October 31, 2016, we had unrestricted cash and cash equivalents of $4.2 million (which includes the $3.5 million payment received under our License Agreement with KemPharm, Inc. as discussed in Note 4, and is after the deduction of our $2.5 million compensating balance requirement under our term loan with Oxford Finance LLC). We estimate that our current unrestricted cash and cash equivalents 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 March 2017 while maintaining compliance with the $2.5 million compensating balance requirement under our term loan with Oxford Finance LLC.

In addition to our $2.5 million cash reserve requirement, the term loan agreement with Oxford Finance LLC ("Oxford") contains customary affirmation and negative covenants. One such covenant is that the Company must submit on an annual basis to Oxford, within 120 days after the end of its fiscal year, audited consolidated financial statements, together with an unqualified audit opinion from an independent registered public accounting firm (the "Unqualified Audit Opinion Covenant"). Failure to comply with the Unqualified Audit Opinion Covenant is a breach of the term loan agreement and unless such covenant or breach is waived, Oxford would have the option of accelerating the debt under the term loan agreement and initiating enforcement collection actions, foreclosing on collateral (which includes most assets of the Company) and, among other things, preventing the Company from using any funds in its bank or securities accounts. Per the term loan agreement an audit opinion with an explanatory paragraph noting substantial doubt about the Company's ability to continue in business (the "going concern opinion") is deemed to violate the Unqualified Audit Opinion Covenant. We anticipate that unless the Company raises approximately $10.0 million prior to the completion of the audit of our 2016 financial statements, projected to occur by early March 2017, our auditor's opinion will contain a going concern opinion and absent a waiver from Oxford, we will be in breach of our term loan agreement. There can be no assurance that we will be able to raise such funds. We expect to engage in discussions with Oxford in order to seek a waiver from the Unqualified Audit Opinion Covenant, but there can be no assurance Oxford will grant such a waiver.

To fund further operations and product development activities beyond March 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, there will be substantial doubt about the Company's ability to continue as a going concern and 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

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.

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 our 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 is responsible for the fees and expenses relating to the Oxaydo NDA and product line extensions of Oxaydo, provided that Egalet will pay a substantial majority of the fees and expenses and we will pay for the remaining fees and expense 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. Egalet 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.

KemPharm Agreement

On October 13, 2016, we and KemPharm Inc. (”KemPharm”) entered into a worldwide License Agreement (the “KemPharm Agreement”) pursuant to which we licensed our Aversion® technology to KemPharm for its use in the development and commercialization of three products using 2 of KemPharm’s prodrug candidates. KemPharm has also been granted an option to extend the KemPharm Agreement to cover two additional prodrug candidates. KemPharm is responsible for all development, manufacturing and commercialization activities, although we may provide initial technical assistance.

Upon execution of the KemPharm Agreement, KemPharm paid us an upfront payment of $3.5 million. If KemPharm exercises its option to use our Aversion technology with more than the 2 licensed prodrugs, then KemPharm will pay us up to $1.0 million for each additional prodrug license. In addition, we will receive from KemPharm a low single digit royalty on commercial sales by KemPharm of products developed using our Aversion technology under the KemPharm Agreement. KemPharm’s royalty payment obligations commence on the first commercial sale of a product using our Aversion technology and expire, on a country-by-country basis, upon the expiration of the last to expire patent claim of the Aversion technology covering a product in such country, at which time the license for the particular product and country becomes fully paid and royalty free.

The KemPharm Agreement expires upon the expiration of KemPharm’s royalty payment obligations in all countries. Either party may terminate the KemPharm Agreement in its entirety if the other party materially breaches the KemPharm Agreement, subject to applicable cure periods. Acura or KemPharm may terminate the KemPharm Agreement with respect to the U.S. and other countries if the other party challenges the patents covering the licensed products. KemPharm may terminate the KemPharm Agreement for convenience on ninety (90) days prior written notice. 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 KemPharm Agreement provides for termination of our license grant to KemPharm.

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.

Purdue Pharma

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

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 nine month periods ending September 30, 2016 and 2015, we recognized amortization expense on this intangible asset of $155 thousand. At September 30, 2016 the unamortized portion of the intangible asset was $1.5 million. We also purchased from Pfizer in April 2014 selected raw and packaging material inventories relating to Oxaydo for $260 thousand. During the nine months ended 2015, we recorded a $260 thousand inventory obsolescence expense on 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).

On October 13, 2016, we and KemPharm entered into a Licensed Agreement pursuant to which we licensed to KemPharm our Aversion technology for use in certain KemPharm prodrug candidates. KemPharm paid us $3.5 million upon execution of the KemPharm Agreement. The payment was recognized as revenue when received as we had no further requirements to earn the payment (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 and nine month periods ended September 30, 2016, we recognized collaboration revenue of $74 thousand and $307 thousand, respectively. During each of the three and nine month periods ended September 30, 2015, we recognized collaboration revenue of $95 thousand.

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 $39 thousand and $86 thousand on Oxaydo net sales during the three and nine month periods, respectively, ended September 30, 2016. We did not recognize any royalty revenue during the same periods in 2015. (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. At September 30, 2016 and December 31, 2015, we had a $288 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 nine month periods ended September 30, 2016 and 2015 were not material.

NOTE 6 - RESEARCH AND DEVELOPMENT ACTIVITIES

Research and Development (“R&D”) expenses may include internal R&D activities, external Contract Research Organization (“CRO”) services and their clinical research sites, and other activities. Internal R&D activity expenses may 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 may include preclinical laboratory experiments and clinical trial studies. Other activity expenses may include regulatory services and consulting including our cost sharing expenses of certain clinical studies for product line extensions (additional strengths) of Oxaydo for the United States under the Egalet Agreement and our cost sharing expenses of the FDA required post-marketing study for Oxaydo under the Egalet Agreement, 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 December 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 $46 thousand and $200 thousand of services remained to be performed under this agreement at September 30, 2016 and December 31, 2015, respectively. No service costs were prepaid under this agreement at either September 30, 2016 or December 31, 2015.

NOTE 7 - INVESTMENTS IN MARKETABLE SECURITIES

We had no investments at September 30, 2016. Investments in marketable securities at December 31, 2015 consisted of the following:

	December 31, 2015 (in millions)
Marketable securities:	
Corporate bonds - maturing within 1 year	$ 3.1
Corporate bonds - maturing after 1 year and less than two years	0.4
Exchange-traded funds	7.3
Total marketable securities	$ 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 at December 31, 2015:

	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 at December 31, 2015 consisted of the following:

	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 December 31, 2015 consisted of unrealized losses on securities of $65 thousand.

Fair Value of Other Financial Instruments

The Company's financial instruments consist primarily of cash and cash equivalents, marketable securities, accounts and other receivables, trade accounts payable, accrued expenses and our long-term debt. The carrying amounts of these financial instruments, other than marketable securities and our long-term debt, are representative of their respective fair values due to their relatively short maturities. The Company believes the fair value of long-term debt approximates its carrying value based upon the borrowing rates currently available to the Company for loans with similar terms. As discussed above, marketable securities are recorded at fair value.

NOTE 8 - INVENTORIES

Inventories consist of raw materials and finished goods on our Nexafed product at September 30, 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. Our purchases of ingredients and other materials required in our development and clinical trial activities are expensed as incurred.

Inventories are summarized as follows:

	September 30, 2016	December 31, 2015
	(in thousands)	
Raw and packaging materials	$ 98	$ -
Finished goods	358	346
Total	456	346
Less: reserve for finished goods	(32)	(70)
Net inventory	$ 424	$ 276

Inventory reserve activity during the nine months ended September 30, 2016 and 2015 was as follows:

	2016	2015
	(in thousands)	
Reserve balance at January 1st,	$ 70	$ -
Reserve expense – raw and packaging materials	-	260
Reserve expense – finished goods	26	47
	96	307
Inventory destruction – raw and packaging materials	-	(260)
Inventory destruction - finished goods	(64)	-
Reserve balance at September 30th,	$ 32	$ 47

NOTE 9 - PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are stated at cost of $2,821 thousand and $2,754 thousand, less accumulated depreciation of $1,842 thousand and $1,741 thousand at September 30, 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 are removed from the respective accounts. 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

Our depreciation expense was $104 thousand and $92 thousand for the nine month periods ended September 30, 2016 and 2015, respectively. Depreciation expense is recorded on a straight-line basis over the estimated useful lives of the related assets.

NOTE 10 - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	September 30, 2016	December 31, 2015
	(in thousands)	
Payroll, payroll taxes, and benefits	$ 86	$ 101
Professional services	198	171
Franchise and property taxes	20	21
Marketing and promotion	35	115
Clinical, non-clinical and regulatory services	44	92
Licensee cost sharing expenses	325	-
Other fees and services	28	64
Total	$ 736	$ 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 September 30, 2016, we have made $3.6 million in principal payments on the Term Loan and the balance of term Loan is $6.4 million. 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 a compensating balance requirement under which we are required 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.

On October 13, 2016, we and Oxford entered into a second amendment to the Loan Agreement (the “Second Amendment”). Pursuant to the Second Amendment, (i) the requirement that we maintain a $2.5 million cash balance reserve until such time as $5 million in principal was repaid under the Term Loan, has been modified so that the $2.5 million cash balance reserve remains in place until we raised an additional $6.0 million (excluding payments received under the KemPharm Agreement) through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions, provided that at least $3.0 million of such amount must be raised through the issuance and sale of our equity securities, and (ii) the Lender consented to the terms of our Agreement with KemPharm.

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 September 30, 2016, we have accrued and accumulated $519 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, warranties and 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. One affirmative covenant is that the Company must submit on an annual basis to Oxford, within 120 days after the end of its fiscal year, audited consolidated financial statements, together with an unqualified audit opinion from an independent registered public accounting firm (the "Unqualified Audit Opinion Covenant"). Failure to comply with the Unqualified Audit Opinion Covenant is a breach of the term loan agreement and unless such covenant or breach is waived, Oxford would have the option of accelerating the debt under the term loan agreement and initiating enforcement collection actions, foreclosing on collateral (which includes most assets of the Company) and, among other things, preventing the Company from using any funds in its bank or securities accounts. Per the term loan agreement an audit opinion with an explanatory paragraph noting substantial doubt about the Company's ability to continue in business (the "going concern opinion") is deemed to violate the Unqualified Audit Opinion Covenant. We anticipate that unless the Company raises approximately $10.0 million prior to the completion of the audit of our 2016 financial statements, projected to occur by early March 2017, our auditor's opinion will contain a going concern opinion and absent a waiver from Oxford, we will be in breach of our term loan agreement. There can be no assurance that we will be able to raise such funds. We expect to engage in discussions with Oxford in order to seek a waiver from the Unqualified Audit Opinion Covenant, but there can be no assurance Oxford will grant such a waiver.

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	(1,670)	-	(1,670)
Classification	2,035	(2,035)	-
Balance at September 30, 2016	$2,685	$ 3,685	$6,370

Debt Discount	Current	Long-term	Total
Balance at Dec 31, 2015	$ -	$ (193)	$(193)
Modification of warrants	-	-	-
Amortization expense	-	74	74
Balance at September 30, 2016	$ -	$ (119)	$(119)

Deferred Debt Issuance Costs	Current	Long-term	Total
Balance at Dec 31, 2015	$-	$ (97)	$(97)
Amortization expense	-	39	39
Balance at September 30, 2016	$-	$ (58)	$(58)
Long-term Debt, net at September 30, 2016	$2,685	$ 3,508	$6,193

Our interest expense for the three and nine months ended September 30, 2016 and 2015 consisted of the following (in thousands):

	Three months Ended September 30,		Nine months Ended September 30,	
	2016	2015	2016	2015
Interest expense:				
Term loan	$ 180	$ 236	$ 584	$ 748
Debt discount	23	31	74	94
Debt issue costs	12	16	39	50
Total interest expense	$ 215	$ 283	$ 697	$ 892

The annual principal payments of the debt at September 30, 2016 are as follows:

Calendar Year	Annual Principal Payments (in thousands)
2016	$ 651
2017	2,741
2018	2,978
Total	$ 6,370

NOTE 12 - EQUITY FINANCING

Our universal shelf registration statement on Form S-3 (File No. 333-210039) 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 “registered direct” offerings, “at the market” offerings and certain other transactions. We expect that the net proceeds from such transactions, if any are completed, 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 nine month periods ended September 30, 2016 and 2015 is shown below (in thousands except price data):

	Nine months Ended September 30,			
	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

17

NOTE 14 - SHARE-BASED COMPENSATION

Share-based Compensation

We have three share-based compensation plans covering stock options and RSUs for our employees and directors.

We measure our compensation cost related to share-based payment transactions based on fair value of the equity or liability instrument issued. For purposes of estimating the fair value of each stock option unit on the date of grant, we utilize the Black-Scholes option-pricing model. 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 September 30,		Nine months Ended September 30,	
	2016	2015	2016	2015
Research and development expense:				
Stock options	$ 43	$ 39	$ 128	$ 117
Restricted stock units	-	-	-	-
Subtotal	$ 43	$ 39	$ 128	$ 117
General and administrative expense:				
Stock options	$ 77	$ 107	$ 232	$ 293
Restricted stock units	30	4	90	51
Subtotal	$ 107	$ 111	$ 322	$ 344
Total	$ 150	$ 150	$ 450	$ 461

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 nine month periods ended September 30, 2016 and 2015 is shown below:

	Nine months Ended September 30,			
	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	-	-	(16)	24.50
Outstanding, ending	1,198	$ 15.67	895	$ 20.66
Options exercisable	1,000	$ 18.37	779	$ 23.21

There was no intrinsic value of option awards which were vested and outstanding at September 30, 2016. The intrinsic value of the option awards which were vested and outstanding at December 31, 2015 was $6 thousand. The total remaining unrecognized compensation cost on unvested option awards outstanding at September 30, 2016 was $351 thousand, and is expected to be recognized in operating expense over the 14 months remaining in the requisite service periods. As of September 30, 2016, 615 thousand shares are available for award under the stock option plans.

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:

	Nine months Ended September 30,			
	2016		2015	
	(in thousands)			
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	45	45	29	29
Granted	88	-	42	-
Distributed	(42)	(42)	(26)	(26)
Vested	-	66	-	32
Forfeited or expired	-	-	-	-
Outstanding, ending	91	69	45	35

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 September 30, 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 portion of the RSU awards which are subject to cash settlement are also subject to marked-to market accounting and the liability recorded in the Company's balance sheet as an estimate for such cash settlement was $45 thousand at December 31, 2015. Distributions of stock under the January 2, 2015 award could not 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 portion of the RSU awards which are subject to cash settlement are also subject to marked-to market accounting and the liability recorded in the Company's balance sheet as an estimate for such cash settlement was $44 thousand at September 30, 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 September 30, 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 and 2015 as the Company reported a net loss for both the nine month and three month periods ending September 30 and including the effects of 1.3 million and 1.0 million common stock equivalents from those periods in the diluted EPS calculations would have been antidilutive.

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

	Three months Ended September 30,	Nine months Ended September 30,

	2016	2015	2016	2015
EPS – basic and diluted				
Numerator: net loss	$(2,250)	$(2,649)	$(8,922)	$(4,073)
Denominator (weighted):				
Common shares	11,834	11,653	11,833	10,432
Vested RSUs	46	24	25	14
Basic and diluted weighted average shares outstanding	11,880	11,677	11,858	10,446
EPS – basic and diluted	$(0.19)	$(0.23)	$(0.75)	$(0.39)
Excluded securities (non-weighted):				
Common shares issuable:				
Stock options	1,198	895	1,198	895
Nonvested RSUs	22	10	22	10
Common stock warrants	60	60	60	60
Total excluded common shares	1,280	965	1,280	965

NOTE 17 - COMMITMENTS AND CONTINGENCIES

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 expects that voluntary stipulations of dismissal of the vast majority, if not all, of these cases will be filed and approved by the trial court before the close of the 2016 calendar year. Acura is optimistic that any remaining 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. On May 24, 2016, the Court entered an Order approving a stipulation which stays the individual cases against Acura and provides for an agreed upon dismissal protocol for all cases where is a lack of product identification. To date, 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 September 30, 2016 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

Purdue Pharma Settlement

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"). 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 actions regarding the 007 Patent and the 171 Patent are collectively referred to as the "Actions". On April 6, 2016, we filed a petition for Inter Partes Review (the "IPR Review") with the U.S. Patent and Trademark Office ("USPTO") seeking to invalidate Purdue's 007 Patent.

On May 20, 2016, Purdue on behalf of themselves and certain affiliates, Egalet Corporation, on behalf of itself and its affiliates and we, on behalf of ourselves and our affiliates entered into a settlement agreement (the "Settlement Agreement") to settle the Actions and the IPR Review. Under the Settlement Agreement the parties dismissed or withdrew the Actions, requested that the USPTO terminate the IPR Review and exchanged mutual releases. No payments were made under the Settlement Agreement.

The Settlement Agreement also provides that Purdue will not, in the future, assert certain Purdue U.S. patents, including the 007 Patent, the 171 Patent and related technologies (the "Purdue Patents") against any Acura Settlement

Product or Egalet Settlement Product (except generally in an action or interference by Acura or Egalet challenging a Purdue Patent). Acura Settlement Products and Egalet Settlement Products are certain immediate-release and extended-release products, including Oxaydo. In addition, the Settlement Agreement provides that Purdue will not challenge, with certain exceptions, the Acura/Egalet Patents with respect to the Purdue Settlement Products (as defined below) and that Purdue provides Acura and/or Egalet certain waivers of non-patent marketing exclusivity with respect to Purdue Settlement Products.

The Settlement Agreement also provides that Acura and Egalet will not, in the future, assert certain Acura and/or Egalet U.S. patents (the "Acura/Egalet Patents"), including Acura's Aversion® Technology patents, against any Purdue Settlement Products (except generally in an action or interference by Purdue challenging an Acura/Egalet Patent). Purdue Settlement Products are certain immediate-release and extended-release products. In addition, the Settlement Agreement provides that Acura and Egalet will not challenge, with certain exceptions, the Purdue Patents with respect to the Acura Settlement Products and Egalet Settlement Products and that Acura and Egalet provide Purdue certain waivers of non-patent marketing exclusivity with respect to the Acura Settlement Products and Egalet Settlement Products. In addition, Purdue has certain rights to negotiate to exclusively distribute an authorized generic version of certain Egalet Settlement Products, including, in some circumstances, Oxaydo® and other products using Acura's Aversion® Technology if licensed to Egalet.

The Settlement Agreement specifically excludes our patents related to our Impede® and Limitx™ technologies from the scope of the Acura/Egalet Patents under the Settlement Agreement.

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.

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 our 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 is responsible for the fees and expenses relating to the Oxaydo NDA and product line extensions of Oxaydo, provided that Egalet will pay a substantial majority of the expenses and we will pay for the remaining fees and 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. Egalet 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. At September 30, 2016, we have accrued approximately $200 thousand of cost sharing expenses of certain clinical studies for product line extensions (additional strengths) of Oxaydo for the United States under the Egalet Agreement and approximately $100 thousand of cost sharing expenses of the FDA required post-marketing study for Oxaydo under the Egalet Agreement.

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;
- our ability to remain in compliance with our obligations under our term loan with Oxford Finance LLC, or to obtain a waiver from Oxford Finance LLC for our failure to comply with our covenants contained in such term loan agreement;

- 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 we will be able to reformulate LTX-04 to improve its abuse deterrent performance;
- whether the extent to which products formulated with the Limitx Technology deter abuse will be determined sufficient by the FDA to support approval or labeling describing abuse deterrent features;
- whether our Limitx Technology can be expanded into extended-release formulations;
- 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," "expe "plans," "anticipates," "believes," "indicates," "estimates," "projects," "predicts," "potential" and similar expressions intended identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue

reliance on these forward-looking statements. We discuss many of these risks in greater detail in our 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 abuse associated with opioid analgesics 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 have completed 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, was 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 and June 8, 2016 we announced that topline interim results from cohorts 1 and 2, respectively, of Study 400 for one test formulation of LTX-04 successfully demonstrated the release of the active opioid ingredient was reduced when three or more 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. In July 2016, we submitted the topline results of Study 400 to the FDA under our LTX-04 Fast Track designation and are awaiting comments from the FDA. 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 21% 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. In October 2016, we received FDA recommendations on our meth-resistant testing protocols for our Nexafed extended release tablets which utilizes 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. We can now scale-up our manufacture batch size at a contract manufacturer which allow us to submit an IND to the FDA for our Nexafed extended release tablets, however, we have not yet committed to that level of development.

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 Excessive Tablet Abuse (ETA). 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 Manipulated Tablet Abuse (MTA). 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 for oral ingestion.

- 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 or functionality 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. A product candidate that does not achieve satisfactory pharmacokinetic results may require a phase III clinical pain study.

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 an oral ETA or accidental 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 was 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.

NIDA Disclaimer: 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.

The LTX-04 development program is also designated as Fast Track by the FDA for its potential to address an unmet medical need.

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 completed

Immediate-release hydrocodone bitartrate with acetaminophen (LTX-03)	Formulation development in process
Immediate-release oxycodone HCl (LTX-01) & (LTX-02)	Formulation development in process

The initial LTX-04 clinical study, Study AP-LTX-400, or Study 400, was a two cohort, open label, crossover design pharmacokinetic study in healthy adult subjects. Study 400 measured the rate and extent of absorption of the active drug ingredient into the bloodstream with the maximum concentration, or Cmax, typically associated with an increase in drug abuse. 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. The 1, 2 and 3 tablets subgroups in Cohort 1 completed 8, 10 and 8 subjects, respectively.

Cohort 2 enrolled 30 subjects who were randomized into three subgroups of 10 taking either 4, 6 or 8 tablets. Each subgroup subject orally swallowed the planned number of tablets in a randomized manner taking single doses of LTX-04P and the marketed drug Dilaudid as a comparator. The 4, 6 and 8 tablets subgroups in Cohort 2 completed 8, 9 and 8 subjects, respectively.

All tablets contained 2mg of hydromorphone hydrochloride. All subjects received doses of naltrexone and there was a one week washout between doses. Blood samples were taken at pre-designated time-points after dosing and were subsequently analyzed for the concentration of hydromorphone contained in the sample. All subjects in Cohort 1 had continuous pH (a measure of acid concentration) monitoring of their gastric fluid. 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 Limitx Technology to start retarding the release of active ingredients when three tablets are ingested. The objective of Cohort 2 was to further explore the extent the release of the hydromorphone active ingredient from LTX-04P tablets is retarded as the dose level increases to abusive levels. A safety assessment of Limitx Hydromorphone will be made from both study cohorts.

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

- Subjects in Study 400 had an average 22% reduction in relative Cmax when 3 or more tablets were ingested as shown in the table below.

Study 400 – Mean Ratio of Cmax (ng/mL) by Dosing Group
Compared to the 1 Tablet Group for the Same Formulation

	Dosing in mg		DILAUDID		LTX-04P		Change	
2 Tablet Group	2	x	1.9	x	2.2	x	15	%
3 Tablet Group	3	x	4.8	x	3.8	x	-22	%
4 Tablet Group	4	x	6.4	x	4.8	x	-25	%
6 Tablet Group	6	x	6.2	x	5.2	x	-15	%
8 Tablet Group	8	x	8.4	x	6.8	x	-18	%
Average 3-8							-22	%

- All Subjects in cohort 2 had extent of drug absorption (measured by AUC) for LTX-04P comparable to Dilaudid when the same number of tablets were ingested. Likewise, the time to maximum plasma concentration, or Tmax, was comparable at all doses to Dilaudid.

- Subjects taking one or two tablets of both LTX-04 test 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.

Further analysis of the 3, 4, 6 and 8 tablet subgroups in Study 400 identified a subpopulation of patients in which LTX-04P appeared to demonstrate enhanced reduction in drug absorption as compared to Dilaudid. This subpopulation is characterized by their propensity to absorb the opioid in Dilaudid quickly, reaching maximum drug concentration in the blood in 30 minutes or less, while, on average, having maximum blood levels of drug 1.8 times that of the slower drug absorbing subjects. This subpopulation may represent a more vulnerable abuse population as speed of drug absorption and higher peak drug levels in the blood are typically associated with more drug abuse and possibly addiction.

In the faster absorbing subpopulation of subjects, assuming each subject should have an expected Cmax for LTX-04P consistent with the average seen in the 1 and 2 tablets subgroups of 53% of Dilaudid, the subpopulations demonstrated:

- 82% of subjects had an estimated reduction in Cmax associated with Limitx
- 38% average estimated reduction in Cmax associated with Limitx
- 66% maximum reduction in estimated Cmax observed in two of 17 subjects
- 1.6x average increase in Tmax associated with Limitx

In July 2016, we submitted the topline results of Study 400 to the FDA under our LTX-04 Fast Track designation and are awaiting comments from the FDA.

We have completed reformulation work on the Limitx Technology micro-particles and have two candidates which we believe will improve the drug delivery with one and two tablets. We intend to study these new micro-particle formulation in the next clinical study. Subsequent to the completion of Study 400, we observed discoloration of the LTX-04 tablets. We will need to eliminate this discoloration effect in our tablets prior to initiating dosing in the next clinical study.

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. On September 15, 2016, Egalet announced that a new 15 mg strength of Oxaydo that they are developing achieved bioequivalence to a reference dose in support of a potential NDA supplement filing.

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 us that it has commenced formulation work on a 15mg dosage strength for Oxaydo, has achieved bioequivalence of this new strength to a reference formulation, 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.

KemPharm Agreement Covering Opioid Prodrugs

On October 13, 2016, we and KemPharm Inc. ("KemPharm") entered into a worldwide License Agreement (the "Agreement") pursuant to which we licensed our Aversion® technology to KemPharm for its use in the development and commercialization of three products using 2 of KemPharm's prodrug candidates. KemPharm has also been granted an option to extend the KemPharm Agreement to cover two additional prodrug candidates. KemPharm is responsible for all development, manufacturing and commercialization activities, although we may provide initial technical assistance.

Upon execution of the KemPharm Agreement, KemPharm paid us an upfront payment of $3.5 million. If KemPharm exercises its option to use our Aversion technology with more than the 2 prodrugs licensed, then KemPharm will pay us up to $1.0 million for each additional prodrug license. In addition, we will receive from KemPharm a low single digit royalty on commercial sales by KemPharm of products developed using our Aversion technology under the KemPharm Agreement. KemPharm's royalty payment obligations commence on the first commercial sale of a product using our Aversion technology and expire, on a country-by-country basis, upon the expiration of the last to expire patent claim of the Aversion technology covering a product in such country, at which time the license for the particular product and country becomes fully paid and royalty free.

The KemPharm Agreement expires upon the expiration of KemPharm's royalty payment obligations in all countries. Either party may terminate the KemPharm Agreement in its entirety if the other party materially breaches the KemPharm Agreement, subject to applicable cure periods. Acura or KemPharm may terminate the KemPharm Agreement with respect to the U.S. and other countries if the other party challenges the patents covering the licensed products. KemPharm may terminate the KemPharm Agreement for convenience on ninety (90) days prior written notice. 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 KemPharm Agreement provides for termination of our license grant to KemPharm.

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.

On November 15, 2016, we expect the USPTO to issue to us patent number 9,492,443 in connection with our Aversion Technology.

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 completed a project to integrate Impede 2.0 Technology into our commercially available Nexafed 30mg tablet while moving supply to an alternate contract manufacturer. We expect to perform process validation on this new formulation in the first half of 2017 and introduce the new formulation into the market.

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 13,900 pharmacies or about approximately 21% 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. According to media reports, Rite Aid pharmacies and many independent pharmacies in small geography in Maine have, at the request of local authorities and community leaders, removed all traditional pseudoephedrine-containing products from their shelves and stock only meth-resistant formulations such as Nexafed.

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 have submitted additional “meth-resistant” testing information to the FDA for review prior to submitting an IND. In October 2016, we received FDA recommendations on our meth-resistant testing protocols for our Nexafed extended release tablets. We can now scale-up our manufacture batch size at a contract manufacturer which allow us to submit an IND to the FDA for our Nexafed extended release tablets, however, we have not yet committed to that level of development.

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. Egalet has committed to the FDA to undertake epidemiological studies to assess the actual consequences of abuse of Oxaydo in the market. Under the terms of the Egalet Agreement, we share a minority portion of the fees and expenses relating to such FDA required epidemiological studies. 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	Aug. 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	Apr. 2016	Nov. 2033
2,892,908 (CAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Apr. 2016	Nov. 2033
5,922,851 (JAPAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Apr. 2016	Nov. 2033

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
9,492,443 (US)	Pharmaceutical compositions of immediate-release abuse deterrent opioid products	Nov. 2016	Nov. 2023

We have the following additional issued patents related to our Aversion Technology:

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
7,476,402 (US) 8,822,489 (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

	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	Jun. 2016	Sep. 2030
2,488,029 (EUR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Mar. 2016	Sep. 2030
218533 (ISR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jan. 2016	

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 "007 Patent"). 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 actions regarding the 007 Patent and the 171 Patent are collectively referred to as the "Actions". On April 6, 2016, we filed a petition for Inter Parties Review (the "IPR Review") with the USPTO seeking to invalidate Purdue's 007 Patent.

On May 20, 2016, we, Purdue and Egalet entered into a settlement agreement to settle the Actions and the IPR Review. Under the Settlement Agreement the parties dismissed or withdrew the Actions, requested that the USPTO terminate the IPR Review and exchanged mutual releases. No payments were made by the parties under the Settlement Agreement. See Note 17 – Commitments and Contingencies, for a summary discussion of the Settlement Agreement. The Settlement Agreement specifically excludes our patents related to our Impede and Limitx technologies from the scope of our patents subject to the Settlement Agreement.

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 September 30, 2016, we had cash and cash equivalents of $4.3 million compared to $13.3 million of cash, cash equivalents and marketable securities at December 31, 2015. Under our term loan with Oxford Finance LLC ("Oxford"), we are required to maintain a $2.5 million compensating balance until such time as we raise an additional $6.0 million (excluding payments under our KemPharm Agreement) through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions. We had an accumulated deficit of approximately $376.2 million and $367.3 million at September 30, 2016 and December 31, 2015, respectively. We had a loss from operations of $8.3 million and a net loss of $8.9 million for the nine months ended September 30, 2016, compared to a net loss from operations of $3.3 million and net loss of $4.1 million for the nine months ended September 30, 2015. As of October 31, 2016, our unrestricted cash and cash equivalents was $4.2 million (which includes the $3.5 million payment received under the KemPharm Agreement and is after the deduction of the $2.5 million compensating balance requirement under our term loan with Oxford).

We estimate that our unrestricted cash and cash equivalents, milestone and royalty payments, if any, that may be made under the Egalet Agreement, the Bayer Agreement and the KemPharm Agreement and revenues from our commercialization of our Nexafed products will be sufficient to fund our continuing operations through March 2017 while maintaining compliance with the $2.5 million compensating balance requirement under our term loan with Oxford. 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.

In addition to our $2.5 million cash reserve requirement, our term loan agreement with Oxford contains customary affirmative and negative covenants. One such covenant is that the Company must submit on an annual basis to

Oxford, within 120 days after the end of its fiscal year, audited consolidated financial statements, together with an unqualified audit opinion from an independent registered public accounting firm (the "Unqualified Audit Opinion Covenant"). Failure to comply with the Unqualified Audit Opinion Covenant is a breach of the term loan agreement and unless such covenant or breach is waived, Oxford would have the option of accelerating the debt under the term loan agreement and initiating enforcement collection actions, foreclosing on collateral (which includes most assets of the Company) and, among other things, preventing the Company from using any funds in its bank or securities accounts. Per the term loan agreement an audit opinion with an explanatory paragraph noting substantial doubt about the Company's ability to continue in business (the "going concern opinion") is deemed to violate the Unqualified Audit Opinion Covenant. We anticipate that unless the Company raises approximately $10.0 million prior to the completion of the audit of our 2016 financial statements, projected to occur by early March 2017, our auditor's opinion will contain a going concern opinion and absent a waiver from Oxford, we will be in breach of our term loan agreement. There can be no assurance that we will be able to raise such funds. We expect to engage in discussions with Oxford in order to seek a waiver from the Unqualified Audit Opinion Covenant, but there can be no assurance Oxford will grant such a waiver.

To fund further operations and product development activities beyond March 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, there will be substantial doubt about the Company's ability to continue as a going concern and 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 sales, marketing 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 as well as cost sharing expenses of line extension studies as well as cost sharing expense of post-marketing studies under the Egalet Agreement. Sales and marketing expenses include costs associated with the Nexafed product line advertising .Salaries and other personnel-related costs include the stock-based compensation associated with stock options and restricted stock units granted to employees and non-employee directors.

Three months Ended September 30, 2016 Compared to Three months Ended September 30, 2015

	September 30			
	2016	2015	Increase (decrease)	
	$000's			Percent
Revenues:				
License fee revenue	$-	$-	$ -	-%
Collaboration revenue	74	95	(21)	(22)
Royalty revenue	39	-	39	-
Product sales, net	105	115	(10)	(9)
Total revenues, net	218	210	8	4
Cost and expenses:				
Cost of sales (excluding inventory write-downs)	108	132	(24)	(18)
Inventory write-downs	-	27	(27)	(100)
Research and development	841	432	409	95
Sales, marketing, general and administrative	1,338	2,024	(686)	(34)
Total costs and expenses	2,287	2,615	(328)	(13)
Operating loss	(2,069)	(2,405)	(336)	(14)
Non-operating income (expense):				
Investment income	11	39	(28)	(72)
Interest expense	(215)	(283)	(68)	(24)
Other income	23	-	23	-
Total other expense, net	(181)	(244)	(63)	(26)
Loss before provision for income taxes	(2,250)	(2,649)	(399)	(15)
Provision for income taxes	-	-	-	-
Net loss	$(2,250)	$(2,649)	$ (399)	(15)%

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.

Collaboration Revenue

Collaboration revenue is derived from reimbursement of development expenses under various development agreements, such as the collaboration agreement with Bayer, and is recognized when costs are incurred pursuant to the collaboration agreement. We recognized $74 thousand and $95 thousand of collaboration revenue during the three months ended September 30, 2016 and 2015, respectively.

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 any of our co-promotion efforts). Egalet's first commercial sale of Oxaydo occurred in October 2015 and received a $2.5 million product launch milestone payment. We began to earn royalties on Oxaydo net sales in the fourth quarter of 2015. We have recorded royalties of $39 thousand on net sales for the three month period ended September 30, 2016.

Net Product Sales

Nexafed® was launched by us in December 2012. Nexafed® Sinus Pressure + Pain was launched by us 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 had an initial shelf life of twenty-four months from the date of manufacture, which shelf life has been extended to thirty-six months for Nexafed product supplied from one of the Company's contract manufacturers. Revenue is being recognized at the time the product is sold to a customer. Our net product sales for the three months ended September 30, 2016 and 2015 were $105 thousand and $115 thousand, respectively.

Cost and Expenses

Cost of Sales

Cost of sales includes third-party acquisition costs, third-party warehousing, third-party distribution charges and inventory reserve expenses for the Nexafed product line. For the three months ended September 30, 2016 and 2015, cost of sales was $108 thousand and $132 thousand, respectively.

Included in cost and expenses for the three months ended September 30, 2016 and 2015, is $0 thousand and $27 thousand of inventory reserve expenses on finished goods, respectively.

Research and Development

Research and development expense (R&D) for the three months ended September 30, 2016 was primarily for our Limitx Technology 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. During the third quarter 2016, we did not incur additional cost sharing expenses associated with clinical studies for product line extensions (additional strengths) of Oxaydo for the United States under the Egalet Agreement nor cost sharing expenses of the FDA required post-marketing study for Oxaydo under the Egalet Agreement. The initial LTX-04 clinical study, Study AP-LTX-400, or Study 400, was completed during the third quarter 2016 for expenses of approximately $237 thousand. R&D expense for the three months ended September 30, 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 third quarter 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 $0.4 million between reporting periods.

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. 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 third quarter results are non-cash share-based compensation expenses of approximately $0.1 million. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased by approximately $0.7 million between reporting periods, resulting primarily from decreases in advertising and marketing activities.

Non-Operating Income (Expense)

During the three months ended September 30, 2016 and 2015, non-operating expense consisted principally of interest expense on our term loan from Oxford Finance LLC, 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.

Nine months Ended September 30, 2016 Compared to Nine months Ended September 30, 2015

	September 30			
	2016	2015	Increase (decrease)	
	$000's			Percent
Revenues:				
License fee revenue	$-	$5,250	$ (5,250)	(100)%
Collaboration revenue	307	95	212	223
Royalty revenue	86	-	86	-
Product sales, net	306	563	(257)	(46)
Total revenues, net	699	5,908	(5,209)	(88)
Cost and expenses:				
Cost of sales (excluding inventory write-down)	309	554	(245)	(44)

Inventory write-downs	26	334	(308)	(92)
Research and development	3,258	1,907	1,351	71
Sales, marketing, general and administrative	5,392	6,404	(1,012)	(16
Total costs and expenses	8,985	9,199	(214)	(2)
Operating loss	(8,286)	(3,291)	4,995	152
Non-operating income (expense):				
Investment income	59	110	(51)	(46
Interest expense	(697)	(892)	(195)	(22)
Other income	2	-	2	-
Total other expense, net	(636)	(782)	(146)	(19)
Loss before provision for income taxes	(8,922)	(4,073)	4,849	119
Provision for income taxes	-	-	-	-
Net loss	$(8,922)	$(4,073)	$ 4,849	119 %

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.

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

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 $307 thousand and $95 thousand of collaboration revenue during the nine months ended September 30, 2016 and 2015, respectively.

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 any of our co-promotion efforts). Egalet's first commercial sale of Oxaydo occurred in October 2015 where we received a $2.5 million milestone payment and accordingly, we began to earn royalties in the fourth quarter of 2015. We have recorded royalties of $86 thousand on net sales for the nine month period ended September 30, 2016.

Net Product Sales

Nexafed® was launched by us in December 2012. Nexafed® Sinus Pressure + Pain was launched by us 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 had an initial shelf life of twenty-four months from the date of manufacture, which shelf life has been extended to thirty-six months for Nexafed product supplied from one of the Company's contract manufacturers.

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 nine months ended September 30, 2016 and 2015 were $306 thousand and $563 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 nine months ended September 30, 2016 and 2015, cost of sales was $309 thousand and $554 thousand, respectively.

Included in cost and expenses for the nine months ended September 30, 2016 and 2015, is $26 thousand and $74 thousand of inventory reserve expense on finished goods, respectively. During the nine months ended September 30, 2015, we recorded reserves and wrote off against these reserves, $260 thousand of raw and packaging material inventories we purchased from Pfizer for the Oxaydo product we reacquired from Pfizer.

Research and Development

Research and development expense (R&D) for the nine 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 as well as approximately $200 thousand of cost sharing expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States under the Egalet Agreement and approximately $100 thousand of cost sharing expenses of the FDA required post-marketing study for Oxaydo under the Egalet Agreement. The initial LTX-04 clinical study, Study AP-LTX-400, or Study 400, was ongoing and completed during the first nine months of 2016 for expenses of approximately $1.0 million. R&D expense for the nine 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 nine month results are non-cash share-based compensation expenses of approximately $0.1 million. Excluding the share-based compensation expense, our R&D expenses increased approximately $1.3 million between reporting.

General, Administrative, Selling and Marketing

Selling and marketing expenses for the nine months ended 2016 was primarily of advertising and marketing activities on the Nexafed product. 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 nine month results are non-cash share-based compensation expenses of approximately $0.3 million. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased by approximately $1.0 million 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 and the cost sharing expenses under the Egalet Agreement. On May 20, 2016, a settlement agreement was entered into between Purdue Pharma on behalf of themselves and certain affiliates, Egalet Corporation, on behalf of itself and its affiliates and we, on behalf of ourselves and our affiliates.

Non-Operating Income (Expense)

During the nine months ended September 30, 2016 and 2015, non-operating expense consisted principally of interest expense on our term loan from Oxford Finance LLC, 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 September 30, 2016, we had cash and cash equivalents of $4.3 million compared to cash, cash equivalents, and marketable securities of $13.3 million at December 31, 2015. Under our term loan with Oxford Finance LLC ("Oxford"), we are required to maintain a $2.5 million compensating balance. As of October 31, 2016, our unrestricted cash and cash equivalents was $4.2 million (which includes the $3.5 million payment received under the KemPharm Agreement and is after the deduction of the $2.5 million compensating balance requirement under our term loan with Oxford). We estimate that our 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 March 2017 while maintaining compliance with the $2.5 million compensating balance requirement under our term with Oxford.

In addition to our $2.5 million cash reserve requirement, our term loan agreement with Oxford Finance LLC contains customary affirmative and negative covenants. One such covenant is that the Company must submit on an annual basis to Oxford, within 120 days after the end of its fiscal year, audited consolidated financial statements, together with an unqualified audit opinion from an independent registered public accounting firm (the "Unqualified Audit Opinion Covenant"). Failure to comply with the Unqualified Audit Opinion Covenant is a breach of the term loan agreement and unless such covenant or breach is waived, Oxford would have the option of accelerating the debt under the term loan agreement and initiating enforcement collection actions, foreclosing on collateral (which includes most assets of the Company) and, among other things, preventing the Company from using any funds in its bank or securities accounts. Per the term loan agreement an audit opinion with an explanatory paragraph noting substantial doubt about the Company's ability to continue in business (the "going concern opinion") is deemed to violate the Unqualified Audit Opinion Covenant. We anticipate that unless the Company raises approximately $10.0 million prior to the completion of the audit of our 2016 financial statements, projected to occur by early March 2017, our auditor's opinion will contain a going concern opinion and absent a waiver from Oxford, we will be in breach of our term loan agreement. There can be no assurance that we will be able to raise such funds. We expect to engage in discussions with Oxford in order to seek a waiver from the Unqualified Audit Opinion Covenant, but there can be no assurance Oxford will grant such a waiver.

To fund further operations and product development activities beyond March 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, there will be substantial doubt about the Company's ability to continue as a going concern and 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, the KemPharm 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 third 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 14, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

Item 1A. Risk Factors

Investors in our common stock should consider the following risk factor, in addition to those risk factors set forth in our 2015 Annual Report on Form 10-K:

We require additional funding

We anticipate that we will require additional financing or entry into license or collaborative agreements with third parties providing for net proceeds to us in order to continue to fund operations. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaborative agreements will provide for funding or payments to us sufficient to continue to fund operations. Under our term loan with Oxford Finance LLC, we are required to maintain a $2.5 million compensating balance until we raise an additional $6.0 million (excluding any payments under our License Agreement with KemPharm) through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions, provided that at least $3.0 million must be through the sale of our equity securities. Giving effect to our term loan compensating balance requirement, we believe we have unrestricted cash and cash equivalents sufficient to fund operations through March 2017 while maintaining the compensating balance requirement. In the absence of the receipt of additional financing or payments under third-party license or collaborative agreements prior to such time there will be substantial doubt about the Company's ability to continue as a going concern and we will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. Even assuming we are successful in securing additional sources of financing to fund continued operations, there can be no assurance that the proceeds of such financing will

be sufficient to fund operations until such time, if at all, that we generate sufficient revenue from our products and product candidates to sustain and grow our operations.

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

In December 2013, we (including our wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc. ("APT")) entered into a loan and security agreement with Oxford Finance LLC ("Oxford") pursuant to which we borrowed $10 million from Oxford. Our loan and security agreement with Oxford was amended on January 7, 2015 in connection with our collaboration and license agreement with Egalet and again on October 13, 2016 in connection with our license agreement with KemPharm. Under the Oxford loan agreement, as amended, we are subject to a variety of affirmative and negative covenants, including required financial reporting, providing an unqualified auditor's opinion together with our annual financial statements within 120 days of the end of our fiscal year (the "Unqualified Audit Opinion Covenant"), limitations on certain dispositions and licensing of assets, limitations on the incurrence of additional debt, and the requirement to maintain at least $2.5 million in cash reserves until we raise an additional $6.0 million following the execution of our license agreement with KemPharm through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions, provided that at least $3.0 million of such amount must be through the issuance and sale of our equity securities. To secure our performance of our obligations under this loan and security agreement, we granted Oxford a security interest in substantially all of our assets, other than intellectual property assets, and pledged to Oxford the stock of APT. Our failure to comply with the terms of the loan and security agreement, including the Unqualified Audit Opinion Covenant, the occurrence of a material adverse change in our business, operations or condition (financial or otherwise) or prospects, the material impairment in our prospect of repayment, a material impairment in the perfection or priority of the Oxford's lien on our assets or the value of Oxford's collateral, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our loan, coupled with prepayment penalties, an additional interest payment of $795,000, potential foreclosure on our assets, and other adverse results.

We anticipate that unless the Company raises approximately $10.0 million prior to the completion of the audit of our 2016 financial statements, projected to occur by early March 2017, our auditor's opinion will contain a going concern opinion and absent a waiver from Oxford, we will be in breach of the Unqualified Audit Opinion Covenant. If such breach were to occur, Oxford would have the option, among other things, of accelerating the debt under our loan and security agreement and foreclosing on the Company's assets pledged as collateral for the term loan. There can be no assurance that we will be able to raise the funds needed to allow for compliance with the Unqualified Audit Opinion Covenant. We expect to engage in discussions with Oxford in order to seek a waiver from the Unqualified Audit Opinion Covenant, but there can be no assurance Oxford will grant such a waiver.

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

Our common stock is listed on the NASDAQ Capital Market, a national securities exchange, which imposes continued listing requirements with respect to listed shares. Such continued listing requirements include, for example, NASDAQ Listing Rule 5450(a)(1), which requires that the closing bid price of our common stock shall not fall below $1.00 for thirty consecutive business days and NASDAQ Listing Rule 5550(b)(1), which requires that we maintain $2.5 million in stockholders' equity for continued listing (or meet the alternatives of market value of listed securities of $35 million or net income from continuing operations). Failure to comply with NASDAQ's continued listing standards will result in the issuance of a non-compliance letter and/or initiation of delisting proceedings by NASDAQ.

On August 16, 2016, we received a letter from the Listing Qualifications Staff of the NASDAQ Stock Market notifying us that because our Form 10-Q for the period ended June 30, 2016 reported stockholders' equity of $1,637,000 and we did meet the alternative tests of market value of listed securities or net income, we no longer complied with Listing Rule 5550(b)(1). We had 45 days to submit a plan of compliance which we submitted on September 29, 2016 and which detailed our plan to regain compliance with NASDAQ's $2.5 million minimum stockholders' equity requirement, and in which we requested an extension of time to regain compliance. On October 6, 2017 NASDAQ granted us a grace period of 180 days from the date of Nasdaq's initial letter, or until February 10, 2017, to regain compliance with Listing Rule 5550(b)(1). If we fail to successfully meet NASDAQ's minimum stockholders' equity requirement by such date, or if met, fail to continue to meet such requirement following February 10, 2017, of which no assurance can be given, our common stock will be subject to delisting from the NASDAQ Capital Market.

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

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

Item 6. Exhibits

The exhibits required by this Item are listed below.

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

Signatures

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

November 14, 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

48