As filed with the Securities and Exchange Commission on February 3, 2017

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ACURA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	**2834**	**11-0853640**
(State or other jurisdiction of Incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification No.)*

616 N. North Court
Suite 120
Palatine, Illinois 60067
(847) 705-7709
(Address, including zip code, and telephone number, including area code, of the registrant's principal executive offices)

Peter A. Clemens
Senior Vice President,
Chief Financial Officer and Secretary
Acura Pharmaceuticals, Inc.
616 N. North Court
Suite 120
Palatine, Illinois 60067
(847) 705-7709
(Name, address, including zip code and telephone number, including area code, of agent for service)

Copies to:

John P. Reilly, Esq.
LeClairRyan
1037 Raymond Boulevard, 16th Floor
Newark, NJ 07102
(973) 491-3354

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier registration statement for the same offering. ☐

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee
Common stock, par value $0.01 per share (2)(3)	$	$
Common Stock Purchase Warrants (4)	—	—
Common Stock issuable upon exercise of Common Stock Purchase Warrants (2)(3)(5)	$ 5,000,000	$ 580

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(2) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.
(3) Includes shares and warrants subject to the underwriters' over-allotment option.
(4) No separate fee is payable pursuant to Rule 457(g).
(5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g).

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION** **DATED FEBRUARY 3, 2017**

Shares of Common Stock
Warrants to Purchase Shares of Common Stock

ACURA PHARMACEUTICALS, INC.

We are offering $5,000,000 of shares of our common stock and warrants to purchase shares of our common stock. Each share of common stock is being sold together with **[__]** of a warrant to purchase one share of our common stock. Each warrant will have an exercise price per share not less than 100% of the closing bid price of our common stock immediately preceding the pricing of this offering. The warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The shares of common stock and warrants will be issued separately.

Our common stock is quoted on the Nasdaq Capital Market under the symbol "ACUR". On January 31, 2017, the closing price of our common stock on the Nasdaq Capital Market was $0.54 per share. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

Investing in our securities involves risks. You should carefully read and consider the "Risk Factors" beginning on page 8 of this prospectus before investing.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share and Related Warrant	**Total**
Public offering price	$	$
Underwriting discount (1)	$	$
Proceeds, before expenses, to us (2)	$	$

(1) The underwriters will receive compensation in addition to the underwriting discount listed above. See "Underwriting" beginning on page 98 of this prospectus for a description of the compensation payable to the underwriter.

(2) We estimate the total expenses of this offering payable by us, excluding the underwriting discount, will be approximately $**[_____]**.

In addition to the underwriting discount listed above, we have agreed to reimburse the underwriter for certain of its reasonable out-of-pocket expenses. See "Underwriting" beginning on page 98 for more information on this offering and the underwriting arrangements. All costs associated with the registration will be borne by us.

The underwriters may also purchase up to an additional shares of our common stock at a price of $**[___]** per share and/or additional warrants from us at a price of $**[__]** per warrant to purchase one share of our common stock, within 45 days from the date of this prospectus to cover over-allotments, if any.

The underwriters expect to deliver the shares and warrants against payment therefor on or about _____ ___, 2017.

[_____] **[_____]**

The date of this prospectus is _____ , 2017.

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security registered under the registration statement of which this prospectus is a part.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading "Where You Can Find Additional Information."

As used in this prospectus, unless the context indicates or otherwise requires, "our Company," "the Company," "Acura," "we," "us," and "our" refer to Acura Pharmaceuticals, Inc., a New York corporation, and its consolidated subsidiary.

Acura effected a reverse stock split of its capital stock at the ratio of 1-for-5 on August 27, 2015. Unless the context indicates or otherwise requires, all share numbers and share price data included in this prospectus have been adjusted to give effect to this reverse stock split.

Market, Industry and Other Data

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity, and market size, is based on information from various sources, on assumptions that we have made that are based on those data and other similar sources, and on our knowledge of the markets for our drug candidates. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus. This summary is not complete and may not contain all of the information that you should consider before investing in our securities. You should carefully read the entire prospectus, including our consolidated financial statements and related notes thereto and the information set forth under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in this prospectus before making an investment decision.

ACURA PHARMACEUTICALS, INC.

Our Company

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, or PSE, 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, or collectively Egalet, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is currently approved by the U. S. Food and Drug Administration, or 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, or Bayer, entered into a License and Development Agreement, or 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. On December 14, 2016, we announced that we had received advice from the FDA on the continued development of LTX-04 following the FDA's review of summary data from Study 400. The FDA confirmed our intention to reformulate LTX-04 to provide increased drug levels following an intended 1 or 2 tablet dose, noting that a scientific bridge of bioequivalence to the reference product will support a finding of safety and efficacy. The FDA also recommended that we identify studies to measure the clinical impact on abuser behavior and overdose outcome (such as drug liking and respiratory depression) associated with the reduction in maximum drug concentration, or Cmax, when 3 or more LTX-04 tablets were ingested. We identified a subpopulation of participants in Study 400 that demonstrated increased reductions in Cmax when taking LTX-04, or faster drug absorbers. The FDA noted that to label a product for a particular subpopulation, including faster drug absorbers, prescribers should be able to understand that only a subset of their patients may benefit from use of the product. We intend to advance new formulations of LTX-04 to a second pharmacokinetic study which is expected to commence in late first quarter 2017 after we address certain formulation stability issues. We intend to develop LTX-04 through proof of concept and then rapidly advance a formulation of a product with greater prevalence of oral excessive tablet abuse, or ETA, such as immediate-release hydrocodone with acetaminophen. We are actively seeking a licensing partner for our Limitx product candidates.

Our Strategy

Our goal is to become a leading specialty pharmaceutical company focused on addressing the growing societal problem of pharmaceutical drug abuse by developing a broad portfolio of products with abuse deterrent features and benefits. Specifically, we intend to:

- capitalize on our experience and expertise in the research and development of technologies that address medication abuse and misuse;
- develop a full line of pharmaceutical products that utilize our proprietary technologies;
- commercialize our products with our internal resources or license to strategically focused companies in the United States and other geographic territories;
- maintain an efficient internal cost structure; and
- in-license or acquire technologies and/or products to expand our portfolio of technologies and products.

Our Present Financial Condition

As of September 30, 2016, we had cash and cash equivalents of approximately $4.3 million. Under our term loan with Oxford Finance LLC, or Oxford, we are required to maintain a $2.5 million compensating balance until such time as we raise an additional $6.0 million through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions. We estimate that our current cash reserves (excluding the estimated net proceeds of this offering), will be sufficient to fund our operations and the development and commercialization of our Aversion, Impede and Limitx Technologies and related product candidates only through March 31, 2017 while maintaining compliance with our $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, or 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 31, 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 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's 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. Any extended delay or cessation of the Company's continuing product develop efforts will have a material adverse effect on the Company's financial condition and results of operations.

Corporate Information

We were incorporated in New York in 1935. Our headquarters are located at 616 N. North Court, Suite 120, Palatine, Illinois 60067. Our website address is www.acurapharm.com. We do not incorporate information in, or accessible through, our website into this prospectus, and you should not consider it a part of this prospectus.

We own or have rights to various trademarks, trade names or service marks, including Aversion® Technology, Impede® Technology, Oxaydo®, Nexafed®, Limitx™ and Acura® Pharmaceuticals. The trademarks Dilaudid®, Vicodin®, Lortab®, Lorcet®, OxyContin®, Sudafed®, Zyrtec-D®, and Allegra-D® referred to in this prospectus are the registered trademarks of others.

The Offering

Common Stock offered by us	**[_____]** shares of common stock and warrants to purchase up to an aggregate of **[_____]** shares of common stock (assuming a combined public offering price of $**[___]** per share and related warrant, the closing price of our common stock on the Nasdaq Capital Market on _____ __, 2017).
Common stock outstanding after this offering	**[_____]** shares or **[_____]** shares if the warrants sold in this offering are exercised in full (assuming a combined public offering price of $**[___]** per share and related warrant, the closing price of our common stock on the Nasdaq Capital Market on , 2017) (**[_____]** shares if the underwriters' over-allotment option is exercised in full).
Warrants offered by us	Each share of common stock is being sold together with **[___]** of a warrant to purchase one share of our common stock. Each warrant will have an exercise price per share not less than 100% of the closing price of our common stock immediately preceding the pricing of this offering. The warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The shares of common stock and warrants will be issued separately. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.
Overallotment Option	We have granted the underwriters an option for a period of up to 45 days from the date of this prospectus to purchase up to an aggregate of **[_____]** additional shares of our common stock and/or additional warrants to purchase up to **[_____]** shares of our common stock, assuming a combined public offering price of $**[_____]** per share and related warrant, the closing price of our common stock on the Nasdaq Capital Market on _____ , 2017, less the underwriting discount, solely to cover over-allotments.
Use of proceeds	We intend to use the net proceeds received from this offering to fund the pre-clinical and clinical research and development of our Limitx product candidates, and for working capital and general corporate purposes. See "Use of Proceeds" on page 32 of this prospectus.
Risk factors	See "Risk Factors" beginning on page 8 of this prospectus for a discussion of factors you should carefully consider before investing in our securities.
Nasdaq trading symbol	Our common stock is quoted on the Nasdaq Capital Market under the symbol "ACUR".

The number of shares of our common stock to be outstanding immediately after this offering is based on _____ shares of our common stock outstanding as of January 31, 2017, and excludes:

- **1,397,315** shares of our common stock issuable upon the exercise of options to purchase our common stock outstanding as of January 31, 2017, at a weighted average exercise price of $**13.56** per share;
- **59,560** shares of our common stock issuable upon the exercise of warrants to purchase our common stock outstanding as of January 31, 2017, at a weighted average exercise price of $**2.52** per share;

261,343 shares of our common stock issuable in exchange for restricted stock units granted under our 2014 Restricted Stock Unit Award Plan as of January 31, 2017; and

- **416,478** shares of our common stock reserved for future issuance under our 2016 Stock Option Plan as of January 31, 2017.

Except as otherwise indicated, all information in this prospectus reflects and assumes no exercise by the underwriters of the overallotment option, and no exercise of the warrants offered hereby.

Summary of Consolidated Financial Results

The following tables summarize our consolidated financial data for the periods presented and should be read together with the sections of this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our consolidated financial statements and related notes appearing elsewhere in this prospectus. We derived the summary statement of operations data and balance sheet data for the years ended December 31, 2015 and 2014 from our audited consolidated financial statements and related notes appearing elsewhere in this prospectus. The statement of operations data for the nine months ended September 30, 2016 and 2015 and the balance sheet data as of September 30, 2016 have been derived from our unaudited condensed consolidated financial statements appearing elsewhere in this prospectus. We have prepared the unaudited financial statements on the same basis as the audited financial statements and have included all adjustments, consisting only of normal recurring adjustments, which in our opinion are necessary to state fairly the financial information set forth in those statements. Our historical results are not necessarily indicative of the results we expect in the future.

	Years ended December 31, (audited)		Nine months ended September 30, (unaudited)	
	2015	2014	2016	2015
	(in thousands)			
Operating Results Data:				
Net revenues	$ 8,587	$ 751	$ 699	$ 5,908
Research and development expenses	$ 2,608	$ 4,582	$ 3,258	$ 1,907
Marketing, general and administrative expenses	$ 8,994	$ 7,940	$ 5,392	$ 6,404
Interest expense, net	$ (991)	$ (1,104)	$ (638)	$ (782)
Other income	3	4	2	-
Loss before provision for income taxes	$ (4,989)	$ (13,209)	$ (8,922)	$ (4,073)
Provision for income taxes	-	-	-	-
Net Loss	$ (4,989)	$ (13,209)	$ (8,922)	$ (4,073)
Loss per share:				
Basic	$ (0.46)	$ (1.35)	$ (0.75)	$ (0.39)
Diluted	$ (0.46)	$ (1.35)	$ (0.75)	$ (0.39)
Weighted average common shares outstanding:				
Basic	10,796	9,779	11,858	10,446
Diluted	10,796	9,779	11,858	10,446

	As of December 31, (audited)		As of September 30, 2016 (unaudited)	
	2015	2014	Actual	As Adjusted (1)
	(in thousands)			
Consolidated Balance Sheet Data:				
Cash and cash equivalents	$ 2,485	$ 774	$ 4,272	$
Total assets	$ 16,961	$ 16,033	$ 7,738	
Total liabilities	$ 9,061	$ 10,981	$ 8,227	
Accumulated deficit	$ (367,310)	$ (362,321)	$ (376,232)	
Total stockholders' equity (deficit)	$ 7,900	$ 5,052	$ (489)	

(1) The as adjusted balance sheet data gives effect to the sale of **[_____]** shares of common stock in this offering at an assumed public offering price of $**[___]** per share, the closing price of our common stock as reported by the Nasdaq Capital Market, and the application of the net proceeds as described in "Use of Proceeds," after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described in this prospectus before you decide to invest in our securities. If any of the following risks actually occurs, our business, financial condition, results of operations and/or further growth prospects would be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline and you may lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant rights to our business at this time may adversely affect our business operations.

Risks Related to Our Business and Industry

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

We had a net loss of $8.9 million, $5.0 million and $13.2 million for the nine months ended September 30, 2016 and the years ended December 31, 2015 and 2014, respectively. Our future profitability will depend on several factors, including:

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

We are currently focused primarily on the development of our lead Limitx product candidate, LTX-04, as well as our other Limitx programs, which we believe will result in our continued incurrence of significant research, development and other expenses related to those programs. If preclinical studies or the clinical trials for any of our Limitx drug candidates fail or produce unsuccessful results and those drug candidates do not gain regulatory approval, or if any of our Limitx drug candidates, if approved, fail to achieve market acceptance, we may never become profitable.

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

Even if Egalet succeeds in commercializing Oxaydo, or if we or a licensee succeed in developing and commercializing one or more of our pipeline Limitx or Impede Technology products, we expect to continue using cash reserves for the foreseeable future. Our expenses may increase in the foreseeable future as a result of continued research and development of our product candidates, maintaining and expanding the scope of our intellectual property, commercializing our Nexafed products, and hiring of additional research and development staff.

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

We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.

Our operations to date have consumed substantial amounts of cash. Negative cash flows from our operations are expected to continue over at least the next several years. Our cash utilization amount is highly dependent on the progress of our product development programs, particularly, the results of our preclinical and clinical studies of our Limitx product candidates and the cost, timing and outcomes of regulatory approval for our Limitx product candidates. In addition, the further development of our ongoing clinical trials will depend on upcoming analysis and results of those studies and our financial resources at that time.

We will require future additional capital infusions including public or private financing, strategic partnerships or other arrangements with organizations that have capabilities and/or products that are complementary to our own capabilities and/or products, in order to continue the development of our product candidates. However, there can be no assurances that we will complete any financings, strategic alliances or collaborative development agreements, and the terms of such arrangements may not be advantageous to us. Any additional equity financing will be dilutive to our current stockholders and debt financing, if available, may involve restrictive covenants. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. Our failure to raise capital when needed could materially harm our business, financial condition and results of operations.

Our ongoing capital requirements will depend on numerous factors, including: the progress and results of preclinical testing and clinical trials of our Limitx product candidates under development; the costs of complying with the FDA and other domestic regulatory agency requirements, the progress of our research and development programs and those of our partners; the time and costs expended and required to obtain any necessary or desired regulatory approvals; our ability to enter into licensing arrangements, including any unanticipated licensing arrangements that may be necessary to enable us to continue our development and clinical trial programs; the costs and expenses of filing, prosecuting and, if necessary, enforcing our patent claims, or defending against possible claims of infringement by third-party patent or other technology rights; the cost of commercialization activities and arrangements that we undertake; and the demand for our products, which demand depends in turn on circumstances and uncertainties that cannot be fully known, understood or quantified unless and until the time of approval, including the FDA approved label for any product.

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., or APT, entered into a loan and security agreement with Oxford Finance LLC, or 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, or 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 Oxford were to declare an event of default, it 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. Any declaration of an event of default would significantly harm our business and could cause the price of our common stock to decline.

We are largely dependent on our successful development of our Limitx product candidates and on the commercial success of Oxaydo.

We anticipate that, for at least fiscal 2017 and 2018, our ability to generate revenues and become profitable will depend in large part on our successful development of our Limitx product candidates and on the commercial success of our only FDA approved product, Oxaydo. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead Limitx product candidate, LTX-04, and other Limitx product candidates in development. We completed our first Phase I clinical study for LTX-04 in mid-2016 and are engaged in formulation development or early preclinical development for our other Limitx product candidates. Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approve and commercialization of our Limitx product candidates, which may never occur. If our clinical studies for LTX-04 are not successful we may determine that further clinical development of LTX-04 or other Limitx product candidates should be discontinued. If clinical studies for these product candidates produce unsuccessful results and we are forced or elect to cease their development, our business and prospects would be substantially harmed. We expect that any revenues from our Limitx product candidates will be derived from upfront payments, milestones payments and royalties under license agreements with one or more pharmaceutical company partners, of which no assurance can be given.

The commercial success of Oxaydo will depend on many factors, including our and our licensee Egalet's ability to:

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

There can be no assurance that Egalet will devote sufficient resources to the marketing and commercialization of Oxaydo. Egalet's marketing of Oxaydo may result in low market acceptance and insufficient demand for, and sales of, the product. If Egalet fails to successfully commercialize Oxaydo and generate and increase sales, we may be unable to generate sufficient revenues to sustain or grow our business and we may never become profitable, and our business, financial condition and results of operations will be materially adversely affected.

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

We commenced the launch and commercial distribution of Nexafed in mid-December 2012 and launched our Nexafed Sinus Pressure + Pain product in February 2015. Our Nexafed products compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in marketing their competing products. Category leading brands are often supported by regional and national advertising and promotional efforts. Our Nexafed products will compete with national brands as well as pharmacy store brands that are offered at a lower price. There can be no assurance that we will succeed in commercializing our Nexafed products, or that the pricing of our Nexafed products will allow us to generate significant revenues or profit. Regulations have been enacted in several state or local jurisdictions requiring a doctor's prescription to obtain pseudoephedrine products. An expansion of such restrictions to other jurisdictions or even nationally will adversely impact our ability to market our Nexafed products as over-the-counter, or OTC, products and generate revenue from Nexafed products sales. Our failure to successfully commercialize our Nexafed® products and to develop and commercialize other Impede Technology products will have a material adverse effect on our business and financial condition.

If Egalet is not successful in commercializing Oxaydo, our revenues and our business will suffer.

Pursuant to our Collaboration and License Agreement with Egalet, or the Egalet Agreement, Egalet is responsible for manufacturing, marketing, pricing, promotion, selling and distribution of Oxaydo. If the Egalet Agreement is terminated in accordance with its terms, including due to a party's failure to perform its obligations or responsibilities under the Agreement, then we would need to commercialize Oxaydo ourselves, for which we currently have no infrastructure, or alternatively enter into a new agreement with another pharmaceutical company, of which no assurance can be given. If we are unable to build the necessary infrastructure to commercialize Oxaydo ourselves, which would substantially increase our expenses and capital requirements, which we are currently unable to fund, or are unable to find a suitable replacement commercialization partner, we would be unable to generate any revenue from Oxaydo. Even if we are successful at replacing the commercialization capabilities of Egalet, our revenues and/or royalties from Oxaydo could be adversely impacted.

Egalet's third party manufacturing facility currently is the sole commercial source of supply of Oxaydo. If Egalet's manufacturing facility fails to obtain sufficient DEA quotas for oxycodone, fails to source adequate quantities of active and inactive ingredients, fails to comply with regulatory requirements, or otherwise experiences disruptions in commercial supply of Oxaydo, product revenue and our royalties could be adversely impacted.

Egalet has various products in development for which Oxaydo will vie for such licensee's development, promotional, marketing, and selling resources. If Egalet fails to commit sufficient promotional, marketing and selling resources to Oxaydo, our expected royalties could be adversely impacted. Additionally, there can be no assurance that Egalet will commit the resources required for the successful commercialization of Oxaydo.

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

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

Our failure to continue the development of our Limitx opioid product candidates including hydromorphone HCI or hydrocodone/acetaminophen, or to successfully establish a license agreement with a pharmaceutical company for the development and commercialization of such products, will adversely impact our ability to develop, market and sell our Limitx technology products and our revenues and business will be materially adversely affected.

We are engaged in the development of product candidates utilizing or Limitx technology, including Phase 1 exploratory pharmacokinetic studies for our hydromorphone HCI lead product candidate. Our plan for developing, manufacturing and commercializing our Limitx opioid products includes entering into an agreement similar to the Egalet Agreement with a strategically focused pharmaceutical company. There can be no assurance, however, that our early-stage development of our Limitx product candidates will be successful, or even if successful, that we will be successful in entering into such an agreement. Pending any such agreement, and subject to available funding, we expect to continue the development of our Limitx product candidates on our own. The continued development of our Limitx product candidates will likely require additional financing, which may not be available on acceptable terms, or at all. In the absence of available financing, or our failure to successfully enter into a license agreement with a pharmaceutical company to develop and commercialize our Limitx products, we may have to limit the size or scope of, or delay or abandon, the development of some or all of our product candidates, which would adversely impact our financial condition and results of operations.

We must rely on current cash reserves, royalties from Egalet on Egalet's sales of Oxaydo, revenues from our Nexafed product sales and payments that may be made under the Bayer Agreement to fund operations.

To fund our continued operations, we expect to rely on our current cash resources, royalty payments under the Egalet Agreement relating to Oxaydo, collaboration reimbursement, milestones and royalty payments that may be made under the Bayer Agreement, and milestones and royalty payments that may be made under future license agreements with other pharmaceutical company partners for our product candidates in development, of which no assurances can be given, and revenues from our commercialization of our Nexafed products. No assurance can be given that current cash reserves and revenues from our Nexafed product sales and royalties from Egalet on Oxaydo net sales and payments under the Bayer agreement will be sufficient to fund continued operations and the development of our product candidates until such time as we generate revenues from any of our products in development. Moreover, no assurance can be given that we will be successful in raising additional financing or, if financing is obtained, that such financing will be sufficient to fund operations until we generate sufficient revenues from Oxaydo, or until product candidates utilizing our Limitx or Impede Technologies may be commercialized. In the event our cash reserves are insufficient to fund continued operations, we may need to suspend some or all of our product development efforts or possibly discontinue operations.

Our and our licensees' ability to market and promote Oxaydo and Limitx technology products by describing the abuse deterrent features of such products will be determined by the FDA approved label for such products.

The commercial success of Oxaydo and our Limitx Technology products in development will depend upon our and our licensees' ability to obtain FDA approved labeling describing such products' abuse deterrent features or benefits. Our or our licensees' failure to achieve FDA approval of product labeling containing such information will prevent or substantially limit our and our licensees' advertising and promotion of such abuse deterrent features in order to differentiate our products from other immediate release opioid products containing the same active ingredients, and would have a material adverse impact on our business and results of operations. 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 2015 FDA 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. We have committed to the FDA to undertake epidemiological studies to assess the actual consequences of abuse of Oxaydo in the market. However, 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 and our licensees' discussions with, and agreement by, the FDA as part of the new drug application, or NDA, review process for each of our product candidates. The outcome of those discussions with the FDA will determine whether we or our licensees will be able to market our products with labeling that sufficiently differentiates them from other products that have comparable therapeutic profiles. While the FDA approved label for Oxaydo includes the results from a clinical study which evaluated the effects of nasally snorting crushed Oxaydo and commercially available oxycodone tablets and limitations on wetting or dissolving Oxaydo, it does not, however, include the results of our laboratory studies intended to evaluate Oxaydo's potential to limit extraction of oxycodone HCl from dissolved Oxaydo Tablets and resist conversion into an injectable, or IV solution. The absence of the results of these extraction and syringe studies in the FDA approved label for Oxaydo may substantially limit our licensee's ability to differentiate Oxaydo from other immediate release oxycodone products, which would have a material adverse effect on market acceptance of Oxaydo and on our business and results of operations.

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

Further, because the FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse deterrent characteristics of our product, as in the case of Oxaydo, the FDA's Office of Prescription Drug Promotion, or OPDP, will continue to review the acceptability of promotional claims and product advertising campaigns for our marketed products. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of Oxaydo from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution, which could harm the commercial success of our product and materially affect our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Egalet Agreement grants Egalet an exclusive worldwide license to develop and commercialize Oxaydo. Our license agreement with KemPharm Inc., or the KemPharm Agreement, grants exclusive worldwide rights to KemPharm to utilize our Aversion technology in certain of KemPharm's prodrug products. We believe that opportunities exist to enter into license agreements similar to the Egalet Agreement and the KemPharm Agreement with other pharmaceutical company partners for the development and commercialization of our Limitx, Impede and Aversion Technologies in the United States and worldwide. However, there can be no assurance that we will be successful in entering into such license agreements in the future. If we are unable to enter into such agreements, our ability to develop and commercialize our product candidates, and our financial condition and results of operations, would be materially adversely affected.

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

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

If we fail to maintain our license agreement with Eaglet, we may have to commercialize Oxaydo on our own.

Our plan for manufacturing and commercializing Oxaydo currently requires us to maintain our license agreement with Egalet. In addition to other customary termination provisions, the Egalet Agreement provides that Egalet may terminate the Egalet Agreement upon certain notice periods. If Egalet elects to terminate the Egalet Agreement, or if we are otherwise unable to maintain our existing relationship with Egalet, we would have to commercialize Oxaydo ourselves for which we currently have no infrastructure, or alternatively enter into a new agreement with another pharmaceutical company, of which no assurance can be given. Our ability to commercialize Oxaydo on our own may require additional financing, which may not be available on acceptable terms, or at all.

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

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

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

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

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

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

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

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

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

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

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

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

In addition the newly elected administration has indicated it intends to replace portions of the Healthcare Reform Law. This could affect reimbursement for our product and introduces numerous uncertainties into the industry's operations.

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

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

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

Because healthcare costs have risen significantly, numerous initiatives and reforms by legislatures, regulators and third-party payers to curb these cost increases have resulted in a trend in the healthcare industry to consolidate product suppliers and purchasers. As the healthcare industry consolidates, competition among suppliers to provide products to purchasers has become more intense. This in turn has resulted, and will likely continue to result, in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, and large single accounts continue to use their market power to influence product pricing and purchasing decisions. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to influence the worldwide healthcare industry, resulting in further business consolidations, which may exert further downward pressure on the prices of our anticipated products. This downward pricing pressure may adversely impact our business, financial condition or results of operations. Under each of the Egalet Agreement and the KemPharm Agreement, our licensees control the price of the licensed products, and we expect that our licensees, if any, of our products in development, will control the price of such products and may provide price discounts and price reductions in its discretion. Such price discounts and reductions will reduce the net sales of our licensed products and, correspondingly, our royalty payments under such license agreements. In addition, if any of our large customers is acquired or merged with another provider of similar products, we may lose that customer's business. For example, for the year ended December 31, 2015 Rite Aid accounted for approximately 54% of our Nexafed revenue. Walgreens is not currently a customer of Nexafed and is in the process of acquiring Rite Aid. Following Walgreens' acquisition of Rite Aid, it is possible that we could lose the Nexafed revenue derived from Rite Aid unless Walgreens elects to purchase Nexafed.

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

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

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

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

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

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

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

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

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

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

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

We are aware of certain United States and international pending patent applications owned by third parties with claims potentially encompassing Oxaydo and our other products. If such patent applications result in valid and enforceable issued patents, containing claims in their current form or otherwise encompassing our products we or our licensees may be required to obtain a license to such patents, should one be available, or alternatively, alter our products so as to avoid infringing such third-party patents. If we or our licensees are unable to obtain a license on commercially reasonable terms, or at all, we or our licensees could be restricted or prevented from commercializing our products. Additionally, any alterations to our products or our technologies could be time consuming and costly and may not result in technologies or products that are non-infringing or commercially viable.

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

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

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

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

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.

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

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

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

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

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

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

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

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

It is possible that other generic manufacturers may also seek to launch a generic version of Oxaydo and challenge our patents. Any determination in any 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.

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

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

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

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

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

We believe potential competitors may be developing opioid abuse deterrent technologies and products. Such potential competitors include, but may not be limited to, Pain Therapeutics, Pfizer Inc., Purdue Pharma, Atlantic Pharmaceuticals, Egalet Corporation, KemPharm, Shionogi, Nektar Therapeutics, Signature Therapeutics, QRx Pharma, Tris Pharma, Pisgah Labs, Teva Pharmaceuticals, Sun Pharmaceuticals and Collegium Pharmaceuticals, Inc. These companies appear to be focusing their development efforts on ER Opioid Products, except for Atlantic Pharmaceuticals, Pisgah Labs, and KemPharm.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Common Stock and this Offering

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

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

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

During the nine months ended September 30, 2016, our stock traded as high as $3.52 per share and as low as $1.40 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors could include:

- results from our pre-clinical and clinical development programs, including our Limitx product candidates;
- FDA actions related to our products in development;
- FDA actions related to any of our potential products;
- announcements regarding the sales of Oxaydo;
- announcements regarding the progress of sales of Oxaydo;
- announcements regarding the progress of our preclinical and clinical programs;
- our success in the commercialization of our Nexafed products;
- announcements regarding the sales of our Nexafed products;
- announcements regarding the execution of license agreements with third parties for our products or product candidates;
- failure of any of our products in development, if approved, to achieve commercial success;
- quarterly variations in our results of operations or those of our competitors;

- our ability to develop and market new and enhanced products on a timely basis;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies;
- additions or departures of key personnel;
- commencement of, or our involvement in, litigation;
- the inability of our contract manufacturers to provide us with adequate commercial supplies of our products;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board or management;
- general economic conditions and slow or negative growth of our market; and
- political instability, natural disasters, war and/or events of terrorism.

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

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

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

Historically, we have not declared and paid any cash dividends on our common stock. In addition, our Loan and Security Agreement with Oxford Finance LLC restricts our ability to pay dividends during the term of such Agreement. We intend to retain all of our earnings for the foreseeable future to finance the operation and expansion of our business. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases.

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

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

As of January 31, 2017, our three largest shareholders owned an aggregate of 5,177,733 shares of our common stock (representing approximately 43.6% of our outstanding shares). All of such shares are available for resale by such stockholders. If some or all of such shares are sold by it may have the effect of depressing the trading price of our common stock. In addition, such sales could make it more difficult for us to raise capital if needed in the future.

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).

At times, our shares of common stock have been thinly traded, so you may be unable to sell at or near ask prices or even at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.

Our common stock is currently traded on The NASDAQ Capital Market and experiences periods when it could be considered "thinly-traded." This situation may be attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days, weeks or months when trading activity in our shares is minimal, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common stock will be sustained, or that current trading levels will be sustained or not diminish.

This offering will cause immediate and substantial dilution in pro forma net tangible book value.

Since the public offering price of the securities offered pursuant to this prospectus is higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. See "Dilution" in this prospectus for a more detailed discussion of the dilution you will incur if you purchase securities in this offering. In the event that you exercise your warrants, you will experience additional dilution to the extent that the exercise price of the warrants is higher than the tangible book value per share of our common stock. In addition, we may have issued restricted stock units to acquire common stock at prices below the expected public offering price of the shares of common stock offered hereby. To the extent outstanding restricted stock units are ultimately converted, or if we issue restricted stock units to our employees under our equity incentive plans, there will be further dilution to investors who purchase shares in this offering.

Our management will have broad discretion over the use of the proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.

Our management will have broad discretion to use the net proceeds received by us from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. We may not apply the net proceeds we receive from this offering in ways that increase the value of your investment. We expect to use the net proceeds we receive from this offering for the development of our Limitx product candidates and for general corporate purposes, including working capital and capital expenditures. We have not allocated these net proceeds for any specific purposes. Our management might not be able to yield a significant return, if any, on any investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use the proceeds.

There is no established market for the warrants to purchase shares of our common stock being offered in this offering.

There is no established trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

The warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay the exercise price specified therefore, prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

We are a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a “smaller reporting company,” meaning that we are not an investment company, an asset- backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than $75 million and annual revenues of less than $50 million during the most recently completed fiscal year. “Smaller reporting companies” are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports and in certain registration statements. Decreased disclosures in our SEC filings due to our status as a “smaller reporting company” may make it harder for investors to analyze our results of operations and financial prospects.

FORWARD LOOKING STATEMENTS

Certain statements in this prospectus 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 labelling 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;
- 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;
- whether the FDA will agree with or accept the results of our studies for our product candidates;
- 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 whether we will be able to promote the features of our abuse discouraging technologies;
- 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; and
- whether we will be able to maintain our listing on the Nasdaq Capital Market.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "indicates," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. We cannot assure you that we have identified all the factors that create uncertainties. Moreover, new risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in this prospectus.

Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, investors in our securities are cautioned not to place undue reliance on such forward-looking statements.

USE OF PROCEEDS

We estimate that the net proceeds of this offering will be approximately $[__] million, or approximately $[__] million if the underwriters exercise the over-allotment option in full, assuming the sale of [_____] shares of our common stock and warrants to purchase [_____] shares of common stock at an assumed combined public offering price of $[_____] per share and related warrant, the closing price of our common stock on the Nasdaq Capital Market on _____, 2017, after deducting the estimated underwriting discount and estimated offering expenses payable by us.

A $0.25 increase (decrease) in the assumed combined public offering price of $[_____] per share and related warrant would increase (decrease) the expected net proceeds of this offering by approximately $[_____] million, assuming the number of shares and warrants offered by us remains the same and after deducting the estimated underwriting discount and estimated offering expenses payable by us. A 100,000 increase (decrease) in the assumed number of shares of our common stock sold in this offering would increase (decrease) the expected net proceeds of this offering by approximately $[_____], assuming the assumed public offering price per share remains the same.

We intend to use the net proceeds received from this offering to fund the continued development of our Limitx product candidates, and for working capital and general corporate purposes. We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, we will retain broad discretion over the use of these proceeds. Pending any use as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

PRICE RANGE OF OUR COMMON STOCK

Our common stock is traded on the Nasdaq Capital Market under the symbol "ACUR". Set forth below for the periods indicated are the high and low sales prices for trading in our common stock as reported by the NASDAQ Capital Market. All stock prices in the table below are adjusted for a 1-for-5 reverse stock split effected on August 27, 2015.

Period	Sale Prices	
	High	Low
2015 Fiscal Year		
First Quarter	$ 5.75	$ 2.25
Second Quarter	6.75	3.70
Third Quarter	4.80	2.27
Fourth Quarter	2.85	1.62
2016 Fiscal Year		
First Quarter	$ 2.83	$ 1.61
Second Quarter	3.52	1.71
Third Quarter	2.18	1.40
Fourth Quarter	1.65	0.71
2017 Fiscal Year		
First Quarter (through January 31, 2017)	$ 0.84	$ 0.54

The NASDAQ Capital Market 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)

On January 31, 2017, the last reported sale price for our common stock on the Nasdaq Capital Market was $0.54 per share. As of January 31, 2017, there were approximately 310 stockholders of record of our common stock, including approximately 91 holders who are nominees for an undetermined number of beneficial owners based upon a review of the securities position listing provided by our transfer agent.

DIVIDEND POLICY

We have not declared or paid any cash dividend on our capital stock in the past and do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business. In addition, our Loan and Security Agreement with Oxford Finance LLC restricts our ability to pay dividends during the term of such Agreement. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2016, as follows:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale of _____shares of our common stock and warrants to purchase __ shares of our common stock by us at an assumed offering price of $_____ per share, after deducting underwriting discounts and commissions and estimated offering expenses.

The information below is not necessarily indicative of what our capitalization would have been had this offering been completed on September 30, 2016. You should read this table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included in this prospectus.

	As of September 30, 2016	
	Actual	As Adjusted
	(unaudited) (in thousands)	
Cash and cash equivalents	$ 4,272	$
Long-term liabilities	$ 4,027	
Stockholders' Equity:		
Common stock, $0.01 par value, 100,000 shares authorized, 11,834 shares issued and outstanding as of September 30, 2016; _____ shares issued and outstanding as adjusted	$ 118	
Additional paid-in capital	$ 375,625	
Accumulated deficit	$ (376,232)	
Total stockholders' (deficit) equity	$ (489)	
Total capitalization	$ 3,538	$

A $0.25 increase (decrease) in the assumed combined public offering price and related warrant would increase (decrease) the expected net proceeds of this offering by approximately $____ million, assuming the number of shares and warrants offered by us remains the same, and after deducting the estimated underwriting discount and estimated offering expenses payable by us. A 100,000 increase (decrease) in the assumed number of shares of our common stock sold in this offering would increase (decrease) the expected net proceeds of this offering by approximately $___ assuming the assumed public offering price per share remains the same. The table above excludes the following shares:

- 1,198,316 shares of our common stock issuable upon the exercise of options to purchase our common stock outstanding as of September 30, 2016, at a weighted average exercise price of $18.37 per share;
- 59,560 shares of our common stock issuable upon the exercise of warrants to purchase our common stock outstanding as of September 30, 2016, at a weighted average exercise price of $2.52 per share;
- 90,555 shares of stock issuable in exchange for restricted stock units granted under our 2014 Restricted Stock Unit Award Plan as of September 30, 2016; and
- 615,478 shares of our common stock reserved for future issuance under our 2008 Stock Option Plan and our 2016 Stock Option Plan as of September 30, 2016.

DILUTION

If you purchase our securities in this offering, you will experience dilution in the net tangible book value per share of the common stock you purchase to the extent of the difference between the combined public offering price per share and related warrant and the net tangible book value per share of our common stock immediately after this offering. The net tangible book value of our common stock on September 30, 2016, was approximately $(1,969), or approximately $(0.166) per share. Net tangible book value per share is equal to the amount of our total tangible assets (total assets less intangible assets), less total liabilities, divided by the aggregate number of shares of our common stock outstanding.

After giving effect to the assumed sale by us of **[_____]** shares of common stock and warrants to purchase **[_____]** shares of common stock in this offering at an assumed combined public offering price of $**[_____]** per share and related warrant (the closing price of our common stock on the Nasdaq Capital Market on _____ ___, 2017), assuming no value is attributed to the warrants, and such warrants are accounted for and classified as equity, and after deducting the estimated underwriting discount and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2016, would have been approximately $**[__]** million, or approximately $**[__]** per share. This represents an immediate increase in net tangible book value of approximately $**[__]** per share to existing stockholders and an immediate dilution of approximately $**[_____]** per share to new investors purchasing shares of our common stock and warrants in this offering. The following table illustrates this per share dilution:

Assumed combined public offering price per share and related warrant		$
Pro forma net tangible book value per share as of September 30, 2016	$	
Increase in net tangible book value per share attributable to this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution in pro forma net tangible book value per share to new investors		$

A $0.25 increase in the assumed combined public offering price of $**[_____]**per share and related warrant would increase our as adjusted net tangible book value after this offering by approximately $**[__]** million, or approximately $**[__]** per share, and increase the dilution to new investors by approximately $**[_____]** per share, assuming that the number of shares of common stock and warrants offered by us, as set forth above, remains the same and after deducting the estimated underwriting discount and estimated offering expenses payable by us. A $0.25 decrease in the assumed combined public offering price of $**[__]** per share and related warrant would decrease our as adjusted net tangible book value after this offering by $**[__]** million, or approximately $**[_____]** per share, and decrease the dilution per share to new investors by approximately $**[_____]** per share, assuming that the number of shares of common stock and warrants offered by us, as set forth above, remains the same and after deducting the estimated underwriting discount and estimated offering expenses payable by us. We may also increase or decrease the number of shares of common stock and warrants we are offering from the assumed number of shares set forth above. An increase (decrease) of 100,000 in the assumed number of shares of common stock sold in this offering would increase (decrease) our as adjusted net tangible book value after this offering by approximately $**[_____]**, or less than $**[_____]** per share, and increase (decrease) the dilution per share to new investors by less than $**[_____]** per share, assuming that the combined public offering price of $**[__]** per share and related warrant remains the same. The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares of common stock and warrants that we offer in this offering, and other terms of this offering determined at pricing.

If the underwriters exercise in full their option to purchase **[_____]** additional shares of common stock and warrants to purchase up to an additional **[_____]** shares of common stock at the assumed combined public offering price of $**[_____]** per share and related warrant, the as adjusted net tangible book value of our common stock after this offering would be $**[_____]** per share, representing an immediate increase in net tangible book value of approximately $**[_____]** per share to existing stockholders and an immediate dilution of $**[____]** per share to the investors in this offering, after deducting the underwriting discount and estimated offering expenses payable by us.

This table does not take into account further dilution to new investors that could occur upon the exercise of the warrants offered hereby or outstanding options and warrants having a per share exercise price less than the public offering price per share in this offering. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes and other financial information appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties as described under the heading "Forward-Looking Statements" elsewhere in this prospectus. You should review the disclosure under the heading "Risk Factors" in this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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, or PSE, 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, or collectively Egalet, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is currently approved by the U. S. Food and Drug Administration, or 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, or Bayer, entered into a License and Development Agreement, or 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. On December 14, 2016, we announced that we had received advice from the FDA on the continued development of LTX-04 following the FDA's review of summary data from Study 400. The FDA confirmed our intention to reformulate LTX-04 to provide increased drug levels following an intended 1 or 2 tablet dose, noting that a scientific bridge of bioequivalence to the reference product will support a finding of safety and efficacy. The FDA also recommended that we identify studies to measure the clinical impact on abuser behavior and overdose outcome (such as drug liking and respiratory depression) associated with the reduction in maximum drug concentration, or Cmax, when 3 or more LTX-04 tablets were ingested. We identified a subpopulation of participants in Study 400 that demonstrated increased reductions in Cmax when taking LTX-04, or faster drug absorbers. The FDA noted that to label a product for a particular subpopulation, including faster drug absorbers, prescribers should be able to understand that only a subset of their patients may benefit from use of the product. We intend to advance new formulations of LTX-04 to a second pharmacokinetic study which is expected to commence in late first quarter 2017 after we address certain formulation stability issues. We intend to develop LTX-04 through proof of concept and then rapidly advance a formulation of a product with greater prevalence of oral excessive tablet abuse, or ETA, such as immediate-release hydrocodone with acetaminophen. We are actively seeking a licensing partner for our Limitx product candidates.

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, 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 January 31, 2017, our unrestricted cash and cash equivalents was $2.2 million (which is after the deduction of the $2.5 million compensating balance requirement under our term loan with Oxford).

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

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 and 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)	
Revenues:	$000's			Percent
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 entered into the Egalet 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 we 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 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 or 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 consisted 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)	
Revenues:	$000's			Percent
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

Egalet paid us an upfront payment of $5.0 million upon signing the Egalet Agreement.

We 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 periods.

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.

Results of Operations for the Years Ended December 31, 2015 and 2014.

	December 31			
	2015	2014	Change	
Revenues:	$000's		$000's	Percent
License fee revenue	$ 5,250	$ 500	$ 4,750	950%
Milestone revenue	2,500	-	2,500	-
Collaboration revenue	170	-	170	-
Royalty revenue	5	4	1	25
Product sales, net	662	247	415	168
Total revenues, net	8,587	751	7,836	1,044
Operating expenses:				
Cost of sales	986	428	558	189
Research and development	2,608	4,582	(1,974)	(43)
Selling, marketing, general and administrative	8,994	7,940	1,054	13
Total operating expenses	12,588	12,950	(362)	(3)
Operating loss	(4,001)	(12,199)	(8,198)	(67)
Non-Operating income (expense):				
Investment income	166	198	(32)	(16)
Interest expense	(1,157)	(1,212)	(55)	(5)
Other income	3	4	(1)	(25)
Total other income (expense), net	(988)	(1,010)	(22)	(2)
Loss before income taxes	(4,989)	(13,209)	(8,220)	(62)
Provision for income taxes	-	-	-	-
Net loss	$ (4,989)	$ (13,209)	$ (8,220)	(62)%

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.

In December 2014, we entered into an agreement with Purdue Pharma 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 into an agreement whereby Acura conceded Purdue'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 relating to the December 2014 agreement.

Milestone Revenue

Milestone revenue is contingent upon the achievement of certain pre-defined events in the development agreements. Milestone payments are recognized as revenue upon achievement of the "at risk" milestone events, which represent the culmination of the earnings process related to that milestone. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones are substantially at risk at the inception of an agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment. Each milestone payment is non-refundable and non-creditable when made. In October 2015, Egalet paid us a $2.5 million milestone payment in connection with the first commercial sale of Oxaydo.

Collaboration Revenue

Collaboration revenue is derived from reimbursement of development expenses and are recognized when costs are incurred pursuant to the collaboration agreement. We recognized $170 thousand of collaboration revenue during the year ended 2015.

Royalties

In connection with our Collaboration and License Agreement with Egalet to commercialize Oxaydo tablets we receive a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on Oxaydo net sales during such year (excluding net sales resulting from our co-promotion efforts). Egalet's first commercial sale of Oxaydo occurred in October 2015 and we have recorded royalties of $5 thousand on net sales through December 31, 2015.

In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer Inc. (the "Pfizer Agreement"), we began earning royalties on Oxecta starting in February 2013. We recorded royalties of approximately $4 thousand for the year ended December 31, 2014. Effective April 9, 2014, the Pfizer Agreement was terminated and the rights to Oxecta were returned to us after making a one-time payment of $2.0 million to Pfizer.

Product Sales

Nexafed® was launched in December 2012. Nexafed® Sinus Pressure + Pain was launched in February 2015. The Company sells the Nexafed® product line in the United States to wholesale pharmaceutical distributors 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. As of December 31, 2015 both products had a shelf life of twenty-four months from the date of manufacture which was subsequently extended to 36 months on product acquired from one manufacturer.

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.

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 years ended 2015 and 2014, cost of sales was $986 thousand and $428 thousand, respectively.

Included in cost of sales for the years ended 2015 and 2014, is $330 thousand and $201 thousand, respectively, of inventory reserve expense. The expense in 2015 was for $260 thousand of raw and package materials purchased from Pfizer at the time we reacquired Oxaydo from Pfizer and for $70 thousand of finished goods held for distribution and sale on our Nexafed® product line. The expense in 2014 was for $201 thousand of finished goods for distribution and sale on Nexafed®.

Research and Development

Research and development expense (R&D) for the years ended 2015 and 2014 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 2015 and 2014 yearly results are non-cash share-based compensation expenses of approximately $160 thousand and $220 thousand, respectively. Excluding the share-based compensation expense, our R&D expenses decreased approximately $1.9 million between reporting periods primarily from a reduction in development expenses on various product candidates. During 2015 we indefinitely suspended further development of our Aversion Hydrocodone/APAP product and began development of our Limitx technology, which is being supported by a $300 thousand grant by the National Institute on Drug Abuse of the National Institutes of Health, all of which has been received. We have reallocated our resources to our Limitx development candidates. During 2015 we demonstrated in a pilot clinical study the bioequivalence of a formulation of our Nexafed extended release tablets utilizing our Impede 2.0 technology to Sudafed® 12-hour Tablets. We have begun a project to integrate Impede 2.0 technology into our commercially available Nexafed 30mg tablet while moving supply to an alternate contract manufacturer.

General, Administrative, Selling and Marketing

Selling and marketing expenses for the years ended 2015 and 2014 was primarily of advertising and marketing activities on the Nexafed product line. Our Nexafed advertising and marketing activities will continue in 2016. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the 2015 and 2014 yearly results are non-cash share-based compensation expenses of approximately $480 thousand and $700 thousand, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses increased by $1.2 million between reporting periods, resulting primarily from increases in advertising and marketing activities and our patent legal litigation expenses with Purdue Pharma.

Non-Operating Income (Expense)

During the years ended 2015 and 2014, non-operating expense consisted principally of interest expense on our term loan from Oxford, which originated on December 27, 2013, less investment income derived from our investments.

Income Taxes

Our results for 2015 and 2014 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, we are required to maintain a $2.5 million compensating balance. As of January 31, 2017, our unrestricted cash and cash equivalents was $2.2 million (which 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 (excluding the net proceeds of this offering), together with milestone and royalty payments, if any, that may be made under the Egalet Agreement, the KemPharm Agreement, and the Bayer Agreement, and revenues from our commercialization of our Nexafed Products will be sufficient to fund our continuing operations through March 31, 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 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, or 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 31, 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.

Term Loan with Oxford Finance

On December 27, 2013, we and our subsidiary, Acura Pharmaceutical Technologies, Inc. entered into a Loan and Security Agreement, or the Loan Agreement, with Oxford Finance LLC, or Oxford, as collateral agent and as a lender, pursuant to which the Oxford made a term loan to us in the principal amount of $10.0 million, or the Term Loan, subject to the terms and conditions set forth in the Loan Agreement. We are using the proceeds of the Loan Agreement for general working capital and to fund our business requirements.

The full principal amount of the Term Loan was funded on December 27, 2013. The Term Loan accrues interest at a fixed rate of 8.35% per annum (with a default rate of 13.35% per annum). We were required to make monthly interest−only payments until April 1, 2015 and starting on April 1, 2015, we are required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through the maturity date of December 1, 2018. As of September 30, 2016, the outstanding principal balance of the Term Loan was $6.37 million. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on December 1, 2018. As security for our obligations under the Loan Agreement, we granted Oxford a security interest in substantially all of our existing and after−acquired assets, exclusive of intellectual property assets. Pursuant to the Loan Agreement, we are not allowed to pledge our intellectual property assets to others.

On January 7, 2015, we and Oxford entered into an amendment, or the First Amendment, to the Loan Agreement. Pursuant to the First Amendment, (i) the exercise price of the warrants issued to Oxford on the date of funding the Term Loan to purchase 59,561 shares of our Common Stock was lowered from $7.98 to $2.52 per share (such reduced amount being equal to the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the First Amendment and after giving effect to our one-for-five reverse stock split), (ii) we agreed to maintain a $2.5 million cash balance until such time as we have repaid $5.0 million in principal of the Term Loan, and (iii) Oxford 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, or 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) Oxford consented to the terms of our Agreement with KemPharm.

We 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, we must pay Oxford an additional one-time interest payment of $795 thousand.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, limits or restrictions on our ability to incur liens, incur indebtedness, pay dividends, redeem stock, and merge or consolidate and dispose of assets. In addition to our $2.5 million cash reserve covenant, we 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, or the Unqualified Audit Opinion Covenant. Failure to comply with the Unqualified Audit Opinion Covenant is a breach of the Loan Agreement and unless such covenant or breach is waived, Oxford would have the option of accelerating our indebtedness under the 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 the 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.

The Loan Agreement contains customary events of default (some of which are subject to applicable grace or cure periods) that entitle Oxford to cause our indebtedness under the Loan Agreement to become immediately due and payable. These include, among others, non−payment defaults, covenant defaults, a material adverse change affecting us or our operations, bankruptcy and insolvency defaults and material judgment defaults.

The warrants to purchase 59,561 shares of our common stock we issued to Oxford in connection with the Term Loan, having an exercise price of $2.52 per share (as adjusted pursuant to the First Amendment and after giving effect to our one-for-five reverse stock split), are immediately exercisable for cash or by net exercise and will expire December 27, 2020.

Off-Balance Sheet Arrangements

We do not engage in transactions or arrangements with unconsolidated or other special purpose entities.

Critical Accounting Policies

The preparation of our financial statements in accordance with United States generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses in our financial statements and accompanying notes. We evaluate our estimates on an ongoing basis, including those estimates related to contract agreements, research collaborations and investments. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The following items in our financial statements require significant estimates and judgments:

Revenue Recognition

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

Nexafed was launched in mid-December 2012 and Nexafed Sinus Pressure + Pain was launched in February 2015. We sell our Nexafed products in the United States to wholesale pharmaceutical distributors as well as directly to chain drug stores. Our Nexafed products are sold subject to the right of return 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 and accordingly we had deferred the recognition of revenue of $353 thousand of Nexafed® shipments at December 31, 2014 until the right of return no longer exists or adequate history and information becomes available to estimate product returns. During the first quarter of 2015 we determined we had obtained sufficient sales returns history to reasonably estimate future returns from those customers. As a result of this change, 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 recorded cost of sales of $255 thousand. At December 31, 2015, we had a $205 thousand sales returns liability which will be reviewed against sales returns activity each calendar quarter for adjustment. Revenue and cost of sales are being recognized at the time the Nexafed products are shipped to customers.

Research and Development

Research and Development ("R&D") expenses include internal R&D activities, external activity expenses of Contract Research Organizations ("CRO") and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. We make payments to the CRO's based on agreed upon terms and may include payments in advance of the study starting date. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely upon 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. At December 31, 2015, we were entered into a cancelable arrangement for contract manufacturing services of approximately $0.2 million on a project to integrate Impede 2.0 technology into our commercially available Nexafed 30mg tablet while moving supply to an alternate contract manufacturer. At December 31, 2014, we were entered into several cancelable CRO arrangements and our obligations under these arrangements were approximately $0.1 million for services to be incurred as subjects are enrolled and progress through the studies.

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 measured 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 against deferred income tax assets is required 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. Because we realized taxable income in 2011 we were able to utilize a portion of our net operating loss carryforwards. At December 31, 2015, 100% of the remaining deferred income tax assets are offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that 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 a benefit from income taxes in such period would be recognized.

Stock Compensation

Compensation cost related to stock-based payment transactions is measured 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 utilized the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of our common stock (as determined by reviewing its historical public market closing prices). Our accounting for stock-based compensation for restricted stock units, or RSUs, is based on the fair-value method. The fair value of the RSUs is the market price of our common stock on the date of grant, less its exercise cost.

Capital Expenditures

Our capital expenditures during the nine months ended September 30, 2016 and fiscal years 2015 and 2014 were $72 thousand, $214 thousand and $135 thousand, respectively. Capital expenditures in each such year were primarily attributable to the purchase of scientific equipment.

Impact of Inflation

We believe that inflation did not have a material impact on our operations for the periods reported.

Quantitative and Qualitative Disclosures About Market Risk

Some of the securities that we invest in may be subject to market risk. Our primary objective in our cash management activities is to preserve principal while at the same time maximizing income we receive from our investments. A change in the prevailing interest rates may cause the principal amount of our investments to fluctuate. We have no holdings of derivative financial and commodity instruments. As of September 30, 2016, our investments consisted of corporate bonds and exchange-traded funds.

BUSINESS

Our Company

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, or PSE, 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, or collectively Egalet, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is currently approved by the U. S. Food and Drug Administration, or 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, or Bayer, entered into a License and Development Agreement, or 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, or Study 4000, of our lead Limitx immediate release oral abuse deterrent drug candidate using the opioid hydromorphone HCI (LTX-04). 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. On December 14, 2016, we announced that we had received advice from the FDA on the continued development of LTX-04 following the FDA's review of summary data from Study 400. The FDA confirmed our intention to reformulate LTX-04 to provide increased drug levels following an intended 1 or 2 tablet dose, noting that a scientific bridge of bioequivalence to the reference product will support a finding of safety and efficacy. The FDA also recommended that we identify studies to measure the clinical impact on abuser behavior and overdose outcome (such as drug liking and respiratory depression) associated with the reduction in maximum drug concentration, or Cmax, when three or more LTX-04 tablets were ingested. We identified a subpopulation of participants in Study 400 that demonstrated increased reductions in Cmax when taking LTX-04, or faster drug absorbers. The FDA noted that to label a product for a particular subpopulation, including faster drug absorbers, prescribers should be able to understand that only a subset of their patients may benefit from use of the product. We intend to advance new formulations of LTX-04 to a second pharmacokinetic study which is expected to commence in late first quarter 2017 after we address certain formulation stability issues. We intend to develop LTX-04 through proof of concept and then rapidly advance a formulation of a product with greater prevalence of oral excessive tablet abuse, or ETA, such as immediate-release hydrocodone with acetaminophen.

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 will 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.

We conduct research, development, laboratory, manufacturing, and warehousing activities at our operations facility in Culver, Indiana and lease an administrative office in Palatine, Illinois. In addition to internal capabilities and activities, we engage numerous clinical research organizations, or CROs, with expertise in regulatory affairs, clinical trial design and monitoring, clinical data management, biostatistics, medical writing, laboratory testing and related services. We have also contracted with two third-party pharmaceutical product manufacturers and packagers to supply our commercial requirements for our Nexafed and Nexafed Sinus Pressure + Pain products.

Our Strategy

Our goal is to become a leading specialty pharmaceutical company focused on addressing the growing societal problem of pharmaceutical drug abuse by developing a broad portfolio of products with abuse deterrent features and benefits. Specifically, we intend to:

- *Capitalize on our experience and expertise in the research and development of technologies that address medication abuse and misuse*. We have one FDA approved product containing our Aversion Technology commercially launched in the United States by our licensee, and two products commercially launched containing our Impede Technology. We continue to invest in improvements in these technologies and innovate new technologies, including our Limitx technology, to address medication abuse and misuse.

- *Leverage our technologies by developing a full line of pharmaceutical products which utilize our proprietary technologies*. Medication abuse and misuse is not limited to single drugs but often pervades entire drug categories. We intend to develop or collaborate with strategically focused pharmaceutical companies to develop multiple products in the prescription opioid and OTC cold/allergy markets with our technologies, and are seeking licensing partners for products in development utilizing our Limitx technology.

- *Commercialize our products with our internal resources or license to strategically focused companies in the United States and other geographic territories*. We have developed a small infrastructure to commercialize our OTC products that utilize the Impede Technology. We have licensed our Oxaydo product to Egalet for commercialization, have licensed our Aversion technology to KemPharm for use in certain of its prodrug products, and we are seeking licensing partners for our products in development utilizing our Limitx, Aversion and Impede technologies.

- *Maintain an efficient internal cost structure*. Our internal cost structure is focused on discovering new technologies and developing product formulations using those technologies. We also have a small, focused OTC marketing and sales team. We outsource many high cost elements of development and commercialization, such as clinical trials and commercial manufacturing that minimize required fixed overhead and capital investment and thereby reduces our business risk.

- *In-license or acquire technologies and/or products to expand our portfolio of technologies and products*. We intend to pursue the in-license or acquisition of product candidates and technologies that will allow us to expand our portfolio of products. Such in-licensing or acquisition transactions, if successfully completed, of which no assurance can be given, may include product candidates or technologies for pain relief, addiction, and other drugs.

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 Investigational New Drug application, or 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 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, or 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, 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	2x	1.9x	2.2x	15%
3 Tablet Group	3x	4.8x	3.8x	-22%
4 Tablet Group	4x	6.4x	4.8x	-25%
6 Tablet Group	6x	6.2x	5.2x	-15%
8 Tablet Group	8x	8.4x	6.8x	-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

On December 14, 2016, we announced that we had received advice from the FDA on the continued development of LTX-04 following the FDA's review of summary data from Study 400. The FDA confirmed our intention to reformulate LTX-04 to provide increased drug levels following an intended 1 or 2 tablet dose, noting that a scientific bridge of bioequivalence to the reference product will support a finding of safety and efficacy. The FDA also recommended that we identify studies to measure the clinical impact on abuser behavior and overdose outcome (such as drug liking and respiratory depression) associated with the reduction in Cmax when three or more LTX-04 tablets were ingested. We identified a subpopulation of participants in Study 400 that demonstrated increased reductions in Cmax when taking LTX-04, or faster drug absorbers. The FDA noted that to label a product for a particular subpopulation, including faster drug absorbers, prescribers should be able to understand that only a subset of their patients may benefit from use of the product. The FDA's advice also identified longer term studies necessary for submitting a NDA for LTX-04, including in vitro extraction studies, drug interaction studies, additional pharmacokinetic studies assessing the impact of food and beverages, and a category 3 abuse liability study.

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 tablet dosing. We intend to advance these new formulations of LTX-04 to a second pharmacokinetic study which is expected to commence in late first quarter 2017. 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 such clinical study. We intend to develop LTX-04 through proof of concept and then rapidly advance a formulation of a product with greater prevalence of oral ETA, such as immediate-release hydrocodone with acetaminophen.

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 has also advised that late in the fourth quarter of 2016 it filed a supplemental NDA for Oxaydo with the FDA to support an abuse-deterrent label claim for the intravenous route of abuse.

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, or Egalet, entered into a Collaboration and License Agreement, or 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, or 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., or KemPharm, entered into a worldwide License Agreement, or 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 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, in order to focus our time and available resources on the development of our Limitx technology product candidates. We currently have 6 additional opioids at various stages of formulation development using the Aversion Technology which are not being actively developed.

Abuse of Pseudoephedrine Products

The chemical structure of pseudoephedrine, or PSE, is very similar to methamphetamine, facilitating a straight-forward chemical conversion to methamphetamine. OTC PSE products are sometimes purchased and used for this conversion. There are multiple known processes to convert PSE to methamphetamine, all of which are not complex and do not require specialized equipment; however, many do require readily available but uncommon ingredients. Two of the three most popular processes follow two general processing steps: (1) dissolving the PSE tablets in a solvent to isolate, by filtration, purified PSE and (2) a chemical reduction of the PSE into methamphetamine for drying into crystals. The third method, or the "one-pot" method, involves the direct chemical reduction of the PSE to methamphetamine in the presence of the tablet's inactive ingredients. All the solvents used are ultimately dried off or otherwise removed, so a wide range of solvents are amenable to the process.

Impede 1.0 Technology

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

Studies sponsored by us at an international, independent laboratory demonstrated our Impede 1.0 Technology prevents the extraction of PSE from tablets for conversion into methamphetamine using what we believe are the two most common extraction methods, each requiring extraction of PSE as an initial step. Laboratory tests conducted on our behalf by an independent Clinical Research Organization, or CRO, using the "one-pot" method demonstrated that our Impede Technology disrupted the direct conversion of PSE from the tablets into methamphetamine. The study compared the amount of pure methamphetamine hydrochloride produced from Nexafed and Johnson & Johnson's Sudafed® tablets. Using one hundred 30 mg tablets of both products, multiple one-pot tests and a variety of commonly used solvents, the study demonstrated an average of 38% of the maximum 2.7 grams of pure methamphetamine hydrochloride was recovered from Nexafed. Comparatively, approximately twice as much pure methamphetamine hydrochloride was recovered from Sudafed tablets. Both products yielded a substantial amount of additional solids such that the purity of the total powder provided contained approximately 65% methamphetamine hydrochloride.

Impede 2.0 Technology

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

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

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

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

We have demonstrated in a pilot clinical study the bioequivalence of a formulation of our Nexafed extended release tablets utilizing our Impede 2.0 Technology to Sudafed® 12-hour Tablets. We have 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 14,100 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 55% 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 of pharmacies in West Virginia voluntarily began selling 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 a geographic region 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 allows 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, or 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. The Bayer 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 $7.95 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, or 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 U.S. Drug Enforcement Administration, or 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 relating to our Aversion Technology:

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
7,476,402 (US)	Pharmaceutical compositions of certain combinations of kappa and mu opioid receptor agonists and other ingredients intended to deter opioid analgesic product misuse and abuse	Jan. 2009	Nov. 2023
8,822,489 (US)	Pharmaceutical compositions of certain abuse deterrent products that contain polymers, surfactant and polysorb 80	Jul. 2014	Nov. 2023
2,004,294,953 (AUS)	Abuse deterrent pharmaceuticals	Apr. 2010	Nov. 2024
2,010,200,979 (AUS)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,547,334 (CAN)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,647,360 (CAN)	Abuse deterrent pharmaceuticals	May 2012	Apr. 2027
175,863 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
221,018 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024

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

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
8,901,113 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Dec. 2014	Feb. 2032
2010300641 (AUS)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sept. 2030
2,775,890 (CAN)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sept. 2030
2,488,029 (EUR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Mar. 2016	Sept. 2030
218533 (ISR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jan. 2016	Sept. 2030

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, the KemPharm Agreement, the Bayer Agreement and in the patent infringement settlement agreements described below, 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 the Risk Factor section of this prospectus under the caption "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., or collectively Purdue, commenced a patent infringement lawsuit against us and our Oxaydo product licensee Egalet 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, or 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, or 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, or 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 the discussion under caption "Legal Proceedings" below for a summary of the settlement agreement with Purdue. 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 this prospectus 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.

Research and Manufacturing

We conduct research, development, manufacture of laboratory clinical trial supplies, and warehousing activities at our operations facility in Culver, Indiana and lease an administrative office in Palatine, Illinois. The 25,000 square foot Culver facility is registered with DEA to perform research, development and manufacture of certain DEA-scheduled active pharmaceutical ingredients and finished dosage form products. We have obtained quotas for supply of DEA-scheduled active pharmaceutical ingredients from the DEA and develop finished dosage forms in our Culver facility. We manufacture clinical trial supplies of drug products in our Culver facility. In addition to internal capabilities and activities, we engage numerous clinical research organizations, or CROs, with expertise in regulatory affairs, clinical trial design and monitoring, clinical data management, biostatistics, medical writing, laboratory testing and related services. Egalet is responsible for commercial manufacture of Oxaydo under the Egalet Agreement. We expect that future opioid product candidates developed and licensed by us will be commercially manufactured by our licensees or other qualified third party contract manufacturers.

We rely on two contract manufacturers to manufacture, package and supply our commercial quantities of Nexafed and Nexafed Sinus Pressure + Pain products. Although we believe there are alternate sources of supply that can satisfy our commercial requirements, replacing or adding a contract manufacture will result in additional costs.

Competition

Our products and technologies will, if marketed, compete to varying degrees against both brand and generic products offering similar therapeutic benefits and being developed and marketed by small and large pharmaceutical (for prescription products) and consumer packaged goods (for OTC products) companies. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in research, development and commercialization of their competitive technologies and products. Prescription generic products and OTC store brand products will offer cost savings to third party payers and/or consumers that will create pricing pressure on our products. Also, these competitors may have a substantial sales volume advantage over our products, which may result in our costs of manufacturing being higher than our competitors' costs.

We believe potential competitors may be developing opioid abuse deterrent technologies and products. Such potential competitors include, but may not be limited to, Pain Therapeutics, Pfizer Inc., Purdue Pharma, Atlantic Pharmaceuticals, Egalet Corporation, KemPharm, Shionogi, Nektar Therapeutics, Signature Therapeutics, QRx Pharma, Tris Pharma, Pisgah Labs, Teva Pharmaceuticals, Sun Pharmaceuticals, Ensysce Biopharma, and Collegium Pharmaceuticals. Egalet, our partner for Oxaydo, is also developing other analgesic products, all of which will compete for development and commercialization resources for Oxaydo, which may adversely impact the sales of Oxaydo. In August 2014, Purdue Pharma announced the submission of an NDA for an immediate-release oxycodone HCl product with reported abuse deterrent properties which subsequently received a vote against approval by an FDA Advisory Committee which requested reformulation of the product.

Our Impede Technology products containing PSE will compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Some of our competitors will have multiple consumer product offerings both within and outside the cold, allergy and sinus category providing them with substantial leverage in dealing with a highly consolidated pharmacy distribution network. The competing products may have well established brand names and may be supported by national or regional advertising. Nexafed will compete primarily with Johnson & Johnson's Sudafed® brand and Nexafed Sinus Pressure + Pain with Pfizer's Advil® Cold and Sinus, as well as generic/store brand formulations of such products manufactured by Perrigo Company and others. A competing product from Perrigo is being marketed with claims of methamphetamine-resistance.

We are also aware that some large pharmaceutical companies in the past have sought to develop PSE technologies or products that resist conversion into methamphetamine.

We may consider licensing our Impede Technology or products utilizing such technology for commercialization.

Government Regulation

All pharmaceutical firms, including us, are subject to extensive regulation by the federal government, principally by the FDA under the Federal Food, Drug and Cosmetic Act, or the FD&C Act, and, to a lesser extent, by state and local governments. Before our prescription products and some OTC products may be marketed in the U.S., they must be approved by the FDA for commercial distribution. Certain OTC products must comply with applicable FDA regulations, known as OTC Monographs, in order to be marketed, but do not require FDA review and approval before marketing. Additionally, we are subject to extensive regulation by the DEA under the Controlled Substances Act, the Combat Methamphetamine Act of 2005, and related laws and regulations for research, development, manufacturing, marketing and distribution of controlled substances and certain other pharmaceutical active ingredients that are regulated as Listed Chemicals. Extensive FDA, DEA, and state regulation of our products and commercial operations continues after drug product approvals, and the requirements for our continued marketing of our products may change even after initial approval. We are also subject to regulation under federal, state and local laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, state, federal and foreign regulations, including possible future regulations of the pharmaceutical industry. We cannot predict the extent to which we may be affected by legislative and other regulatory developments concerning our products and the healthcare industry in general.

The FD&C Act, the Controlled Substances Act and other federal statutes and regulations govern the testing, manufacture, quality control, export and import, labeling, storage, record keeping, approval, pricing, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements both before and after approval, can subject us, our third party manufacturers and other collaborative partners to administrative and judicial sanctions, such as, among other things, warning letters, fines and other monetary payments, recall or seizure of products, criminal proceedings, suspension or withdrawal of regulatory approvals, interruption or cessation of clinical trials, total or partial suspension of production or distribution, injunctions, limitations on or the limitation of claims we can make for our products, and refusal of the government to enter into supply contracts for distribution directly by governmental agencies, or delay in approving or refusal to approve new drug applications. The FDA also has the authority to revoke or withhold approvals of new drug applications.

FDA approval is required before any "new drug," can be marketed. A "new drug" is one not generally recognized, by experts qualified by scientific training and experience, as safe and effective for its intended use. Our products not subject to and in compliance with an OTC Monograph are new drugs and require prior FDA approval. Such approval must be based on extensive information and data submitted in a NDA, including but not limited to adequate and well controlled laboratory and clinical investigations to demonstrate the safety and effectiveness of the drug product for its intended use(s). In addition to providing required safety and effectiveness data for FDA approval, a drug manufacturer's practices and procedures must comply with current Good Manufacturing Practices, or cGMPs, which apply to manufacturing, receiving, holding and shipping. Accordingly, manufacturers must continue to expend time, money and effort in all applicable areas relating to quality assurance and regulatory compliance, including production and quality control to comply with cGMPs. Failure to so comply risks delays in approval of drug products and possible FDA enforcement actions, such as an injunction against shipment of products, the seizure of non-complying products, criminal prosecution and/or any of the other possible consequences described above. We are subject to periodic inspection by the FDA and DEA, which inspections may or may not be announced in advance.

The FDA Drug Approval Process

The process of drug development is complex and lengthy. The activities undertaken before a new pharmaceutical product may be marketed in the U.S. generally include, but are not limited to, preclinical studies; submission to the FDA of an Investigational New Drug application, or IND, which must become active before human clinical trials may commence; adequate and well-controlled human clinical trials to establish the safety and efficacy of the product; submission to the FDA of an NDA; acceptance for filing of the NDA by FDA; satisfactory completion of an FDA pre-approval inspection of the clinical trial sites and manufacturing facility or facilities at which both the active ingredients and finished drug product are produced to assess compliance with, among other things, patient informed consent requirements, the clinical trial protocols, current Good Clinical Practices, or GCP, and cGMPs; and FDA review and approval of the NDA prior to any commercial sale and distribution of the product in the U.S.

Preclinical studies include laboratory evaluation of product chemistry and formulation, and in some cases, animal studies and other studies to preliminarily assess the potential safety and efficacy of the product candidate. The results of preclinical studies together with manufacturing information, analytical data, and detailed information including protocols for proposed human clinical trials are then submitted to the FDA as a part of an IND. An IND must become effective, and approval must be obtained from an Institutional Review Board, or IRB, prior to the commencement of human clinical trials. The IND becomes effective 30 days following its receipt by the FDA unless the FDA objects to, or otherwise raises concerns or questions and imposes a clinical hold. We, the FDA or the IRB may suspend or terminate a clinical trial at any time after it has commenced due to safety or efficacy concerns or for commercial reasons. In the event that FDA objects to the IND and imposes a clinical hold, the IND sponsor must address any outstanding FDA concerns or questions to the satisfaction of the FDA before clinical trials can proceed or resume. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials.

Human clinical trials are typically conducted in three phases that may sometimes overlap or be combined:

Phase 1: This phase is typically the first involving human participants, and involves the smallest number of human participants (typically, 20-50). The investigational drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In addition, it is sometimes possible to gain a preliminary indication of efficacy.

Phase 2: Once the preliminary safety and tolerability of the drug in humans is confirmed during phase 1, phase 2 involves studies in a somewhat larger group of study subjects. Unlike phase 1 studies, which typically involve healthy subjects, participants in phase 2 studies may be affected by the disease or condition for which the product candidate is being developed. Phase 2 studies are intended to identify possible adverse effects and safety risks, to evaluate the efficacy of the product for specific targeted diseases, and to determine appropriate dosage and tolerance.

Phase 3: Phase 3 trials typically involve a large numbers of patients affected by the disease or condition for which the product candidate is being developed. Phase 3 clinical trials are undertaken to evaluate clinical efficacy and safety under conditions resembling those for which the product will be used in actual clinical practice after FDA approval of the NDA. Phase 3 trials are typically the most costly and time-consuming of the clinical phases.

Phase 4 or Post-Marketing Requirements: Phase 4 trials may be required by FDA after the approval of the NDA for the product, as a condition of the approval, or may be undertaken voluntarily by the sponsor of the trial. The purpose of phase 4 trials is to continue to evaluate the safety and efficacy of the drug on a long-term basis and in a much larger and more diverse patient population than was included in the prior phases of clinical investigation.

After clinical trials have been completed, and if they were considered successful, the sponsor may submit a NDA or Abbreviated New Drug Application, or ANDA, to the FDA including the results of the preclinical and clinical testing, together with, among other things, detailed information on the chemistry, manufacturing, quality controls, and proposed product labeling. There are two types of NDAs; a 505(b)(1) NDA and a 505(b)(2) NDA. A 505(b)(1) NDA is also known as a "full NDA" and is described by section 505(b)(1) of the FD&C Act as an application containing full reports of investigations of safety and effectiveness, in addition to other information. The data in a full NDA is either owned by the applicant or are data for which the applicant has obtained a right of reference. A 505(b)(2) application is one described under section 505(b)(2) of the FD&C Act as an application for which information, or one or more of the investigations relied upon by the applicant for approval, "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted". This provision permits the FDA to rely for approval of an NDA on data not developed by the applicant, such as published literature or the FDA's finding of safety and effectiveness of a previously approved drug. 505(b)(2) applications are submitted under section 505(b)(1) of the FD&C Act and are therefore subject to the same statutory provisions that govern 505(b)(1) applications that require among other things, "full reports" of safety and effectiveness.

505(b)(2) NDAs must include one of several different types of patent certifications to each patent that is listed in the FDA publication known as the Orange Book in connection with any previously approved drug, the approval of which is relied upon for approval of the 505(b)(2) NDA. Depending on the type of certification made, the approval of the 505(b)(2) NDA may be delayed until the relevant patent(s) expire, or in the case of a Paragraph IV Certification may lead to patent litigation against the applicant and a potential automatic approval delay of 30 months or more.

Each NDA requires payment of a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, as periodically amended. According to FDA’s fee schedule, effective on October 1, 2016, for the 2017 fiscal year, the user fee for an application fee requiring clinical data, such as an NDA is $2,038,100. The FDA adjusts PDUFA user fees on an annual basis. PDUFA also imposes annual product and facility fees. A written request can be submitted for a waiver of the application fee for the first human drug application that is filed by a small business, but no waivers for product or establishment fees are available. Where we are subject to these fees, they are significant expenditures that may be incurred in the future and must be paid at the time of submission of each application to FDA.

After an NDA is submitted by an applicant, and if it is accepted for filing by the FDA, the FDA will then review the NDA and, if and when it determines that the data submitted are adequate to show that the product is safe and effective for its intended use, the FDA will approve the product for commercial distribution in the U.S. There can be no assurance that any of our products in development will receive FDA approval or that even if approved, they will be approved with labeling that includes descriptions of its abuse deterrent features. Moreover, even if our products in development are approved with labeling that includes descriptions of the abuse deterrent features of our products, advertising and promotion for the products will be limited to the specific claims and descriptions in the FDA approved product labeling.

The FDA requires drug manufacturers to establish and maintain quality control procedures for manufacturing, processing and holding drugs and investigational products, and products must be manufactured in accordance with defined specifications. Before approving an NDA, the FDA usually will inspect the facility(ies) at which the active pharmaceutical ingredients and finished drug product is manufactured, and will not approve the product unless it finds that cGMP compliance at those facility(ies) are satisfactory. If the FDA determines the NDA is not acceptable, the FDA may outline the deficiencies in the NDA and often will request additional information, thus delaying the approval of a product. Notwithstanding the submission of any requested additional testing or information, the FDA ultimately may decide that the application does not satisfy the criteria for approval. After a product is approved, changes to the approved product, such as adding new indications, manufacturing changes, or changes in or additions to the approved labeling for the product, may require submission of a new NDA or, in some instances, an NDA amendment, for further FDA review. Post-approval marketing of products in larger or different patient populations than those that were studied during development can lead to new findings about the safety or efficacy of the products. This information can lead to a product sponsor's requesting approval for and/or the FDA requiring changes in the labeling of the product or even the withdrawal of the product from the market.

The Best Pharmaceuticals for Children Act, or BPCA, became law in 2002 and was subsequently reauthorized and amended by FDAAA. The reauthorization of BPCA provides an additional six months of market exclusivity beyond the expiration date of existing market exclusivities or eligible patents to NDA applicants that conduct acceptable pediatric studies of new and currently-marketed drug products for which pediatric information would be beneficial, as identified by FDA in a Pediatric Written Request. The FD&C Act, as amended by the Pediatric Research Equity Act, or PREA, requires that most applications for drugs and biologics include a pediatric assessment (unless waived or deferred) to ensure the drugs' and biologics' safety and effectiveness in children. Such pediatric assessment must contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective. The pediatric assessments can only be deferred provided there is a timeline for the completion of such studies. FDA may waive (partially or fully) the pediatric assessment requirement for several reasons, including if the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed. The FDA has indicated our Oxaydo product is exempt from the pediatric studies requirement of the PREA.

The terms of approval of any NDA for our product candidates, including the indication and product labeling (and, consequently permissible advertising and promotional claims we can make) may be more restrictive than what is sought in the NDA or what is desired by us. Additionally, the FDA conditioned approval of our Oxaydo product on our commitment to conduct Phase 4 epidemiological studies to assess the actual abuse levels of Oxaydo in the market. The testing and FDA approval process for our product candidates requires substantial time, effort, and financial resources, and we cannot be sure that any approval will be granted on a timely basis, if at all.

Further, drug products approved by FDA may be subject to continuing obligations intended to assure safe use of the products. Specifically, under the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007, or FDAAA, FDA may require Risk Evaluation and Mitigation Strategies, or REMS, to manage known or potential serious risks associated with drugs or biological products. If FDA finds, at the time of approval or afterward, that a REMS is necessary to ensure that the benefits of our products outweigh the risks associated with the products, FDA will require a REMS and, consequently, that we take additional measures to ensure safe use of the product. Components of a REMS may include, but are not limited to, a Medication Guide and/or Patient Package Insert, a marketing and sales communication plan for patients or healthcare providers concerning the drug, Elements To Assure Safe Use, or ETASUs such as, but not limited to, patient, prescriber, and pharmacy registries, and restrictions on the extent or methods of distribution, a REMS implementation system, and a timetable for assessment of the effectiveness of the REMS. Currently, all extended-release or long-acting (ERLA) opioid products approved by the FDA are subject to a class-wide REMS program. FDA is in the process of incorporating immediate-release opioids into this class-wide REMS program.

In addition, we, our suppliers and our licensees are required to comply with extensive FDA requirements both before and after approval. For example, we or our licensees are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning the advertising and promotion of our products, which, as discussed above, may significantly affect the extent to which we can include statements or claims referencing our abuse deterrent technology in product labeling and advertising. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to avoid the product being rendered misbranded and/or adulterated under the FD&C Act as a result of manufacturing problems. In addition, discovery of any material safety issues may result in changes to product labeling or restrictions on a product manufacturer, potentially including removal of the product from the market.

Whether or not FDA NDA approval in the U.S. has been obtained, approvals from comparable governmental regulatory authorities in foreign countries must be obtained prior to the commencement of commercialization of our drug products in those countries. The approval procedure varies in complexity from country to country, and the time required may be longer or shorter than that required for FDA approval.

FDA's OTC Monograph Process

The FDA regulates certain non-prescription drugs using an OTC Monograph which, when final, is published in the Code of Federal Regulations at 21 C.F.R. Parts 330-358. For example, 21 C.F.R. Part 341 sets forth the products, such as pseudoephedrine hydrochloride, that may be marketed as an OTC cold, cough, allergy, bronchodilator, or antiasthmatic drug product in a form suitable for oral, inhalant, or topical administration and is generally recognized as safe and effective and is not misbranded. Such products that meet each of the conditions established in the OTC Monograph regulations and the other applicable regulations may be marketed without prior approval by the FDA.

The general conditions set forth for OTC Monograph products include, among other things:

- the product is manufactured at FDA registered establishments and in accordance with cGMPs;
- the product label meets applicable format and content requirements including permissible "Indications" and all required dosing instructions and limitations, warnings, precautions and contraindications that have been established in an applicable OTC Monograph;
- the product contains only permissible active ingredients in permissible strengths and dosage forms;
- the product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation; and
- the product container and container components meet FDA's requirements.

The advertising for OTC drug products is regulated by the Federal Trade Commission, or FTC, which generally requires that advertising claims be truthful, not misleading, and substantiated by adequate and reliable scientific evidence. False, misleading, or unsubstantiated OTC drug advertising may be subject to FTC enforcement action and may also be challenged in court by competitors or others under the federal Lanham Act or similar state laws. Penalties for false or misleading advertising may include monetary fines or judgments as well as injunctions against further dissemination of such advertising claims.

A product marketed pursuant to an OTC Monograph must be registered with the FDA and have a National Drug Code listing which is required for all marketed drug products. After marketing, the FDA may test the product or otherwise investigate the manufacturing and development of the product to ensure compliance with the OTC Monograph. Should the FDA determine that a product is not marketed in compliance with the OTC Monograph or is advertised outside of its regulations, the FDA may require corrective action up to and including market withdrawal and recall.

DEA Regulation

Our Oxaydo product and several of our products in development, if approved and marketed, will be regulated as "controlled substances" as defined in the CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the loss and diversion of potentially abused drugs into illicit channels of commerce and closely monitors and regulates handlers of controlled substances, and the equipment and raw materials used in their manufacture and packaging.

The DEA designates controlled substances as Schedule I, II, III, IV or V or as List I Chemicals. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. List I Chemicals are used to regulate potentially abused raw materials, such as pseudoephedrine HCl. We believe all of our products will receive DEA Scheduling consistent with current DEA Scheduling standards. For example, Oxaydo Tablets are listed as a Schedule II controlled substances under the CSA, the same as all other oxycodone HCl products. Consequently, their manufacture, shipment, storage, sale and use will be subject to a high degree of regulation. For example, generally, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Annual DEA registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance or List I Chemical. Except for certain DEA defined co-incidental activities, each registration is specific to a particular location and activity. For example, separate registrations are needed for import and manufacturing, and each registration must specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and, thereafter, on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include, among other things, background checks on employees and physical control of inventory through measures such as vaults, cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances and List I Chemicals, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or significant losses of any controlled substance and List I Chemicals, and to obtain authorization to destroy any controlled substance and List I Chemicals. In addition, special authorization, notification and permit requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II and List I Chemicals. Distributions of any Schedule I or II controlled substance must also be accomplished using special order forms, with copies provided to the DEA. Because Oxaydo Tablets are Schedule II they are subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much oxycodone active ingredient may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of oxycodone that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We or our licensees must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance and List I Chemicals. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our or our licensees' quota of an active ingredient may not be sufficient to meet commercial demand or complete the manufacture or purchase of material required for clinical trials. Any delay or refusal by the DEA in establishing our or our licensees' quota for controlled substances or List I Chemicals could delay or stop our clinical trials or product launches, or interrupt commercial sales of our products which could have a material adverse effect on our business, financial position and results of operations.

The DEA also regulates Listed Chemicals, which are chemicals that may be susceptible to abuse, diversion, and use in the illicit manufacture of controlled substances. Some Listed Chemicals, including pseudoephedrine, are used in various prescription and OTC drug products. DEA and state laws and regulations impose extensive recordkeeping, security, distribution, and reporting requirements for companies that handle, manufacture, or distribute Listed Chemicals, including lawful drug products containing Listed Chemicals. In particular, OTC drug products containing certain Listed Chemicals, including pseudoephedrine, are required to be secured behind the pharmacy counter and dispensed to customers directly by a pharmacist only in limited quantities. Pharmacists must obtain proof of identity from customers, and must keep detailed records and make reports to the DEA regarding sales of such products. Individual states may, and in some cases have, imposed stricter requirements on the sale of drug products containing Listed Chemicals, including requiring a doctor's prescription prior to dispensing such products to a customer.

The DEA conducts periodic inspections of registered establishments that handle controlled substances and Listed Chemicals. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Individual states also regulate controlled substances and List I Chemicals, and we or our licensees are subject to such regulation by several states with respect to the manufacture and future distribution of these products.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States, the commercial success of our product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payers at the federal, state and private levels. Government payer programs, including Medicare and Medicaid, private health care insurance companies and managed care plans may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy is not medically appropriate or necessary. Also, third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The United States Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among other cost containment measures, the Healthcare Reform Law establishes:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- A new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period (the “donut hole”); and
- A new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

Many of the Healthcare Reform Law’s most significant reforms were implemented in 2014, with others thereafter, and their details will be shaped significantly by implementing regulations, some of which have yet to be finalized. If such reforms result in an increase in the proportion of uninsured patients who are prescribed products resulting from our proprietary or partnered programs, this could adversely impact future sales of our products and our business and results of operations. Where patients receive insurance coverage under any of the new options made available through the Healthcare Reform Law, the possibility exists that manufacturers may be required to pay Medicaid rebates on that resulting drug utilization, a decision that could impact manufacturer revenues. In addition, the Administration has also announced delays in the implementation of key provisions of the Healthcare Reform Law. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under government programs, and may also increase our or our licensees’ regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payer interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. In addition to the Healthcare Reform Law, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to keep healthcare costs down while expanding individual healthcare benefits. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products. Certain of these changes could limit the prices that can be charged for drugs we develop or the amounts of reimbursement available for these products from governmental agencies or third-party payers, or may increase the tax obligations on pharmaceutical companies, or may facilitate the introduction of generic competition with respect to products we are able to commercialize. In short, our or our licensees’ results of operations could be adversely affected by current and future healthcare reforms.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payers, that an adequate level of coverage or payment will be available so that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably.

Other Healthcare Laws and Compliance Requirements

We and our licensees that commercialize our products are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The reach of the Anti-Kickback Statute was broadened by the Health Care Reform Law, which, among other things, amends the intent requirement of the statute so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. The Healthcare Reform Law also provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. The civil False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The "qui tam" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. Violations of these laws or any other federal or state fraud and abuse laws may subject our licensees to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs, which could harm the commercial success of our products and materially affect our business, financial condition and results of operations.

Legal Proceedings

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, we were 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 us. 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 us with prejudice.

In Pennsylvania, and California, Generic Defendants, including us, 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 us, where there is no case-specific product identification. **[**We expect 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.**]** We expect that any remaining Philadelphia cases will eventually be dismissed in our favor 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 our 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, we 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 us 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 us. 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 us 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 January 31, 2017 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., or 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, or 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, or 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, or IPR Review, with the U.S. Patent and Trademark Office, or 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, or 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, or collectively 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, or collectively 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, we 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 we 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, we received an additional $250 thousand payment from Purdue Pharma relating to the December 2014 agreement.

Segment Reporting

We operate in one business segment; the research, development and manufacture of innovative abuse deterrent, orally administered pharmaceutical products.

Environmental Compliance

We are subject to regulation under federal, state and local environmental laws and believe we are in material compliance with such laws. We incur the usual waste disposal cost associated with a pharmaceutical research, development and manufacturing operation.

Employees

We have 15 full-time employees, 9 of whom are engaged in the research, development and manufacture of product candidates utilizing our proprietary Aversion, Impede, and Limitx Technologies. The remaining employees are engaged in administrative legal, accounting, finance, marketing, market research, and business development activities. All of our senior management and most of our other employees have had prior experience in pharmaceutical or biotechnology companies. None of our employees are covered by collective bargaining agreements. We believe that our relations with our employees are good.

MANAGEMENT

The name, age and position of our directors, executive officers and key employees as of January 31, 2016 are as follows:

Name	Age	Position
Robert B. Jones	58	President, Chief Executive Officer and Director
Peter A. Clemens	64	Senior Vice President, Chief Financial Officer and Secretary
Albert W. Brzeczko, Ph.D.	60	Vice President, Technical Affairs
Robert A. Seiser	53	Vice President, Treasurer, and Corporate Controller
James F. Emigh	61	Vice President of Corporate Development
J. Bradley Rivet	63	Vice President of Marketing
Bruce F. Wesson[1] [2] [3]	74	Director
William G. Skelly[1][2] [3]	66	Director
Immanuel Thangaraj[2]	46	Director
George K. Ross[1] [3]	75	Director

(1) Member of audit committee.
(2) Member of compensation committee.
(3) Member of strategic transaction committee.

Robert B. Jones has been our President and Chief Executive Officer since July 7, 2011. From April 2011 through July 6, 2011, Mr. Jones was our Interim President and Chief Executive Officer. Mr. Jones was our Senior Vice President and Chief Operating Officer from April 2008 to April 2011. From May, 2003 to March, 2008, Mr. Jones served first as the Vice President, Finance and then as Vice President, Strategy and Business Analysis of Adolor Corporation. From November 2000 to May 2003 he served as Vice President, Finance and then as Chief Operating Officer of Opt-E-Script, Inc., a privately held personalized medicine company where Mr. Jones was responsible for all commercialization activities. Prior to that, Mr. Jones was Vice President, Sales and Marketing for Purepac Pharmaceutical Company. Mr. Jones received his M.B.A. from the University of North Carolina and a B.S. from Cornell University. Mr. Jones was appointed a director of the Company in July 2011.

Peter A. Clemens has been Senior Vice President, Chief Financial Officer and Secretary since April 2004. Mr. Clemens was our Vice President, Chief Financial Officer and Secretary from February 1998 to March 2004 and a member of our Board of Directors from June, 1998 to August, 2004. Mr. Clemens is a Certified Public Accountant and earned a Bachelor of Business Administration degree from the University of Notre Dame and a Masters of Business Administration from Indiana University.

Albert W. Brzeczko, Ph.D., has been Vice President, Technical Affairs of Acura Pharmaceutical Technologies, Inc. since February 2009. From 1999 through 2009, Dr. Brzeczko was Vice President, Global Pharma New Product Development and Pharma Technologies for International Specialty Products, Inc., a contract services group specializing in the development of technologies for the bioenhancement of poorly soluble drugs. Prior to 1999, Dr. Brzeczko held various positions of increasing responsibility in pharmaceutical product development with UPM Pharmaceuticals, Banner Pharmacaps, Mylan Laboratories, and DuPont Merck. Dr. Brzeczko received a Bachelor of Science degree in biochemistry and a Ph.D. in pharmaceutical sciences from the University of Maryland.

Robert A. Seiser has been a Vice President, Treasurer and Corporate Controller since April 2004. Mr. Seiser joined us in March 1998 as our Treasurer and Corporate Controller. Mr. Seiser is a Certified Public Accountant and earned a Bachelor of Business Administration degree from Loyola University of Chicago.

James F. Emigh has been Vice President of Corporate Development since October 2011. From April 2004 to October 2011, Mr. Emigh was our Vice President of Marketing and Administration. Prior to such time, Mr. Emigh was our Vice President of Sales and Marketing. Mr. Emigh joined us in May, 1998, serving first as Executive Director of Customer Relations and then as Vice President of Operations. Mr. Emigh holds a Bachelor of Pharmacy degree from Washington State University and a Masters of Business Administration from George Mason University.

J. Bradley Rivet has been Vice President of Marketing since October 2011. Prior to such time, Mr. Rivet was Vice President of Effcon Laboratories Inc. Mr. Rivet has also held various management positions with aaiPharma Inc. and Burroughs Welcome Co. Mr. Rivet received his Bachelor of Science degree from Louisiana State University.

Bruce F. Wesson has been a member of our Board of Directors since March 1998. From January 1991 until June 30, 2011, Mr. Wesson was a Partner of Galen Associates, a health care venture firm, and a General Partner of Galen Partners III, L.P. Prior to January 1991, he was Senior Vice President and Managing Director of Smith Barney, Harris Upham & Co. Inc., an investment banking firm. He currently serves on the Boards of Derma Sciences, Inc., and as Vice Chairman of the Board of MedAssets, Inc., each a publicly traded company**.** Mr. Wesson earned a Bachelor of Arts degree from Colgate University and a Masters of Business Administration from Columbia University.

William G. Skelly has been a member of our Board of Directors since May 1996 and served as our Chairman from October 1996 through June 2000. Since 1990, Mr. Skelly has served as Chairman, President and Chief Executive Officer of Central Biomedia, Inc. and its subsidiary SERA, Inc. From 1985 to 1990, Mr. Skelly served as President of Martec Pharmaceutical, Inc. Mr. Skelly earned a Bachelor of Arts degree from Michigan State University and a Masters of Business Administration from the University of Missouri-Kansas City.

Immanuel Thangaraj has been a member of our Board of Directors since December, 2002. Mr. Thangaraj has been a Managing Director of Essex Woodlands Health Ventures, a venture capital firm specializing in the healthcare industry, since 1997. Prior to joining Essex Woodlands Health Ventures, he helped establish a telecommunication services company, for which he served as its CEO. Mr. Thangaraj holds a Bachelor of Arts and a Masters of Business Administration from the University of Chicago.

George K. Ross has been a member of our Board of Directors since January, 2008. Since April 2002, Mr. Ross has been a consultant to early stage businesses and a financial investor. Since April 1, 2015 Mr. Ross has been an advisor to GP Shopper LLC, a provider of mobile solutions for retail and brands. From July 2005 through December 2010 he served as Executive Director, Foundations and Partnerships for World Vision U.S. in New York City. His business career has included senior financial officer and board member positions with both public and private companies in diverse industries. Mr. Ross was Executive Vice President and Chief Financial Officer and a board member of Tier Technologies Inc. from February 1997 to January 2000, which became a public company during this period. Mr. Ross is a Certified Public Accountant and earned a Bachelor of Arts degree from Ohio Wesleyan University and a Masters of Business Administration from Ohio State University.

The term of office of each director will continue until the next annual meeting of shareholders and until such person's successor has been elected and qualified. Officers are appointed by the Board of Directors and serve at the discretion of the Board, although the employment of Robert B. Jones, our President and Chief Executive Officer and Peter A. Clemens, our Senior Vice President and Chief Financial Officer are subject to the provisions of their respective Employment Agreements.

Director Independence

Our shares of common stock are listed on The Nasdaq Capital Market. Under the rules of The Nasdaq Stock Market, independent directors must comprise a majority of our Board of Directors. In addition, the rules of The Nasdaq Stock Market require that, subject to specified exceptions, each member of the Audit and Compensation Committees of our Board of Directors be independent. Audit Committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or Exchange Act. Under the rules of The Nasdaq Stock Market, a director will only qualify as an “independent director” if, in the opinion of our Board of Directors, that person does have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered to be independent for purposes of Rule 10A-3, a member of the Audit Committee of our Board of Directors may not, other than in his or her capacity as a member of the Audit Committee, the Board of Directors or any other committee of our Board of Directors:

- accept, directly or indirectly, any consulting, advisory, or other compensatory fee from us or any of our subsidiaries; or

- be an affiliated person of us or any of our subsidiaries.

Our Board of Directors has undertaken a review of its composition, the composition of its committees and the independence of each director. In connection with this review, our Board of Directors determined that each of Messrs. Wesson, Skelly, Thangaraj and Ross, representing four of our five directors, satisfies the independence requirements of The NASDAQ Stock Market and Rule 10A-3 of the Exchange Act. In making this determination, our Board of Directors considered the relationships that each non-employee director has with us and all other facts and circumstances our Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our share capital by each non-employee director and their affiliates. In addition, our Board of Directors considered information that was provided by each director concerning his or her background, employment and affiliations, including relationships with our stockholders.

Corporate Governance

Our Board of Directors has established an Audit Committee, a Compensation Committee and a Strategic Transaction Committee. Currently, our entire Board serves as our Nominating Committee. Our Audit Committee and our Compensation Committee operate under written charters approved by our Board of Directors, copies of which are available on our website and will be made available in print to any shareholder who requests it. A brief description of these committees is provided below.

Audit Committee

The Audit Committee is composed of George K. Ross, Chairman, Bruce F. Wesson and William G. Skelly. The Audit Committee is responsible for selecting the Company's registered independent public accounting firm, approving the audit fee payable to the auditors, working with independent auditors and other corporate officials, reviewing the scope and results of the audit by, and the recommendations of, our independent auditors, approving the services provided by the auditors, reviewing our financial statements and reporting on the results of the audits to the Board, reviewing our insurance coverage, financial controls and filings with the SEC, including, meeting quarterly prior to the filing of our quarterly and annual reports containing financial statements filed with the SEC, and submitting to the Board its recommendations relating to our financial reporting, accounting practices and policies and financial, accounting and operational controls.

In assessing the independence of the Audit Committee in 2016, our Board reviewed and analyzed the standards for independence provided in NASDAQ Marketplace Rule 5605 and applicable SEC regulations. Based on this analysis, our Board has determined that each of Messrs. Ross, Wesson and Skelly satisfies such standards for independence. Our Board also determined that Mr. Ross is a "financial expert" as provided in NASDAQ Marketplace Rule 5605(c)(3) and SEC regulations.

Compensation Committee

The Compensation Committee is composed of William Skelly, Chairman, Bruce F. Wesson and Immanuel Thangaraj. This committee is responsible for consulting with and making recommendations to the Board of Directors about executive and director compensation and compensation of employees. In 2016 the Compensation Committee retained the Hay Group, an independent compensation consulting firm, to assist in evaluating stock option and other incentives for our executive officers and other employees. The retention of the Hay Group was not recommended by management.

The listing standards of the NASDAQ Capital Market specify that the compensation of our executive officers must be determined, or recommended to the Board, either by a majority of independent directors or a compensation committee comprised solely of independent directors. Our Board determined that each of Messrs. Skelly, Wesson and Thangaraj were independent directors under the Nasdaq Marketplace Rules. The Board has also determined that each of Messrs. Skelly, Thangaraj and Wesson meet the more stringent independence standards for compensation committees imposed under NASDAQ Rule 5605(d)(2)(A).

Strategic Transaction Committee

The Strategic Transaction Committee is composed of George K. Ross, Bruce F. Wesson and William G. Skelly. The Strategic Transaction Committee reviews, evaluates and recommends to the Board, for the Board's evaluation and determination, potential acquisitions, divestitures, capital raising transactions, joint ventures and strategic alliances, and licensing and collaboration transactions. All members of this Committee are considered by our Board as independent directors. The Strategic Transaction Committee does not have a Chair.

Nominating Committee

Currently our entire Board of Directors functions as our nominating committee. As needed, the Board will perform the functions typical of a nominating committee, including the identification, recruitment and selection of nominees for election to our Board. Our Board determined that all members of the Board were independent other than Mr. Jones, our CEO. We believe that a nominating committee separate from the Board is not necessary at this time given our relative size, the size of our Board, and our opinion that an additional committee of the Board would not add to the effectiveness of the evaluation and nomination process. The Board's process for recruiting and selecting nominees for Board members, if required, would be to identify individuals who are thought to have the business background and experience, industry specific knowledge and general reputation and expertise allowing them to contribute as effective directors to our governance, and who would be willing to serve as directors of a public company. To date, we have not engaged any third party to assist in identifying or evaluating potential nominees. If a possible candidate is identified, the individual will meet with each member of the Board and be sounded out concerning his/her possible interest and willingness to serve, and Board members would discuss amongst themselves the individual's potential to be an effective Board member. If the discussions and evaluation are positive, the individual would be invited to serve on the Board. To date, no shareholder has presented any candidate for Board membership for consideration, and we do not have a specific policy on shareholder-recommended director candidates. The Board believes its process for evaluation of nominees proposed by shareholders would be no different than the process of evaluating any other candidate, and therefore the Board believes it is appropriate to not have a policy on shareholder-recommended director candidates. The Board of Directors does not have a policy regarding diversity in identifying nominees for director.

The experience, qualifications, attributes or skills that led the Board to conclude that the current board members should serve are: (i) their pharmaceutical industry and senior level management experience in the case of Messrs. Jones, Skelly, and Wesson; (ii) financial and senior level management expertise in the case of Mr. Ross, and (iii) their experience in overseeing management as principals of private equity firms in the case of Messrs. Wesson, and Thangaraj. In addition, pursuant to the Voting Agreement, as amended, described in "Certain Relationships and Related Transactions" we are required to elect one designee of Galen Partners III, L.P. ("Galen"), one designee of Care Capital Investments II, LP ("Care Capital") and one designee of Essex Woodlands Health Ventures V, L.P. ("Essex"), as long as they held the requisite amount of equity. Mr. Thangaraj serves as the designee of Essex. Care Capital is no longer entitled to designate a director, as it no longer holds the requisite amount of our equity, a right which it has not, in any event, recently exercised since the resignation of its designee. As of January 31, 2017, Galen had not nominated a Board designee to replace its designee who had previously resigned.

Compensation Committee Interlocks and Insider Participation

No member of the Compensation Committee was or currently is, an officer or employee of the Company, and no member of the Compensation Committee had any relationship with us requiring disclosure under Item 404 of SEC Regulation S-K. None of our executive officers has served on the Board of Directors or Compensation Committee of any other entity that has or had one or more executive officers who served as a member of our Board of Directors.

Code of Ethics

Our Code of Ethics applicable to our principal executive officer, principal financial officer, principal accounting officer and all of our other employees is available on our website, *www.acurapharm.com*, under the menu item "Code of Ethics" appearing under the "Corporate" tab.

Director Compensation

The following table sets forth a summary of the compensation paid by us to our Directors (other than Robert Jones, whose compensation, is reflected in the Summary Compensation Table) for services rendered in all capacities to us during the fiscal year ended December 31, 2016:

2016 DIRECTOR COMPENSATION

Director	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Option Awards ($)[2]	Total ($)
William G. Skelly	$ 48,750	$ 50,000	—	$ 98,750
Bruce F. Wesson	$ 43,750	$ 50,000	—	$ 93,750
Immanuel Thangaraj	$ 30,000[3] [4]	$ 50,000	—	$ 81,250
George K. Ross	$ 53,500	$ 50,000	—	$ 103,500

(1) Represents the grant date fair value of restricted stock units, or RSUs with respect to the 22,026 RSUs granted to Messrs. Skelly, Wesson, Thangaraj and Ross under our 2014 RSU Plan based on a closing price of $2.27 on January 4, 2016.

Each director realized $15,582 on March 31, 2016, $10,186 on June 30, 2016, $8,810 on September 30, 2016 and $4,240 on December 31, 2016 as a result of the vesting of 5,506 RSUs on each of such dates (based on closing prices of our common stock of $2.83 on March 31, 2016, $1.85 on June 30, 2016, $1.60 on September 30, 2016 and $0.77 on December 30, 2016).

Additionally, in January 2016, Mr. Skelly exchanged 8,247 RSUS and $0.01 par value per share issued under the 2014 RSU plan, for 8,247 shares of Common Stock and 2,062 RSUs for $5,134 in cash. In January 2016, Mr. Wesson exchanged 10,309 RSUs and $0.01 par value per share issued under the 2014 RSU plan, for 10,309 shares of Common Stock. In January 2016, Mr. Thangaraj exchanged 6,185 shares of Common Stock and 4,124 RSUs for $10,269 in cash. In January 2016, Mr. Ross exchanged 8,074 RSUS and $0.01 par value per share issued under the 2014 RSU plan, for 8,074 shares of Common Stock and 3,460 RSUs for $8,615 in cash.

As of December 31, 2016, Messrs. Skelly and Wesson, Thangaraj each held 22,026 fully vested RSUs and Mr. Ross held 24,477 fully vested RSUs.

(2) Each of Messrs. Skelly, Wesson, Thangaraj and Ross held vested options with respect to 18,000 underlying shares as of December 31, 2016.

(3) Committee and board meeting attendance fees waived.

(4) Directors fees paid to Mr. Thangaraj are remitted to Essex Woodlands.

Our Director compensation program is as follows:

- the annual retainer for each non-employee director of $30,000;
- there are no separate Board meeting fees;
- an additional retainer for the Chairman of the Board (unfilled at present) of $20,000;
- Audit Committee members receive a retainer of $7,500 per year (with no separate per meeting fee);
- Audit Committee Chairperson receives an additional annual retainer of $10,000 (in addition to the $7,500 retainer as an Audit Committee member);
- Compensation Committee members receive an annual retainer of $5,000 with no separate per meeting fee;
- Compensation Committee Chairperson receives a $5,000 annual retainer (in addition to the $5,000 retainer for Compensation Committee members); and
- Strategic Transaction Committee Members receive a $250 per meeting fee.

The annual retainer fees are payable in four equal installments at the end of each calendar quarter during the year.

In addition, commencing in 2014 Directors receive annual equity awards valued at $50,000 in the form of stock options or RSUs. For RSUs this is determined by dividing $50,000 by the (i) greater of the Company's closing stock price on the date of grant, and (ii) the minimum stock price (if any) imposed by the Board. For the 2014 and 2016 award there was no minimum stock price. For the 2015 award the minimum stock price was set at $4.85, and as a result Directors received less than $50,000 of value. For the 2017 award, in which each director received 59,523 RSUs, the minimum stock price was set at $0.83, but as the closing price of the stock on the date of grant was higher, and the directors received the full $50,000 of value. The Board monitors the stock so that a minimum can be established in the event of exaggerated fluctuations. Directors who are also our employees receive no additional or special remuneration for their services as Directors. We also reimburse Directors for travel and lodging expenses, if any, incurred in connection with attendance at Board meetings.

EXECUTIVE COMPENSATION

Summary Compensation Table and Discussion of Employment and Incentive Arrangements

The following table sets forth a summary of the compensation paid by us for services rendered in all capacities to us during each of the two fiscal years ended December 31, 2016, to our Chief Executive Officer, and the two most highly compensated executive officers other than the Chief Executive Officer who were serving as executive officers at the end of the last completed fiscal year (collectively, the "2016 named executive officers") whose total annual compensation for 2016 exceeded $100,000:

Name and Principal Position	Year	Base Salary ($)	Bonus ($)	Option Awards[1] ($)	Non-equity incentive plan compensation ($)	Total ($)
Robert B. Jones,	2015	392,000	—	120,680	215,600	728,280
President and CEO	2016	393,000	—	36,237	—	429,237
Peter A. Clemens	2015	285,000	—	86,200	109,700	480,900
SVP & CFO	2016	286,000	—	26,214	—	312,214
Albert W. Brzeczko	2015	290,000	—	86,200	68,500	444,700
VP, Technical Affairs of Acura Pharmaceutical Technologies, Inc.	2016	291,000	—	26,985	—	317,985

(1) The 2015 entries reflect the grant date fair value of options with respect to 70,000, 50,000 and 50,000, underlying shares issued to Messrs. Jones, Clemens and Brzeczko, respectively. The 2016 entries reflect the grant date fair value of options with respect to 47,000, 34,000, and 35,000 underlying shares to Messrs. Jones, Clemens and Brzeczko, respectively. Grant date fair values are computed in accordance with FASB ASC Topic 718. To calculate grant date fair value, we consider an assumed risk free interest rate and a historical volatility percentage for our Common Stock, with an expected divided yield of 0% and an expected term of 10 years. For options issued in 2015 we used a risk free interest rate of 2.22% and historical volatility of 89.04%. For options issued in 2016 we used a risk free interest rate of 2.34% and historical volatility of 85.27%. In all cases we excluded the possibility of forfeiture and calculated values based on 10 year option terms.

Other Compensatory Arrangements

Our executive officers participate in medical, dental, life and disability insurance plans provided to all of our employees.

Bonus/Non-Equity Incentive Plan

Each of Messrs. Jones, Clemens and Brzeczko are eligible for annual bonuses. Each of Mr. Jones' and Mr. Clemens' bonuses are weighted 100% to achievement of organizational goals, while the bonuses for other employees, including for Dr. Brzeczko are weighted 50% to the achievement of organizational goals and 50% to the achievement of individual goals. Amounts paid are reflected in the "Non-equity Incentive Compensation" column of the Summary Compensation Table.

The organizational goals for 2015 were the licensing of our Oxaydo® product, progress toward submitting a New Drug Application for our hydrocodone with acetaminophen product with the FDA, the success of Nexafed on the U.S. market, developing a next generation of our Impede Technology, licensing additional products utilizing our Aversion and Impede technologies, progression of our research and development programs, compliance with the Sarbanes – Oxley Act of 2002, or SOX, meeting year-end cash targets and the execution of transactions to further build our business. In 2015, we licensed the Oxaydo product to Egalet Corporation and affiliates, we entered into a license agreement with Bayer Healthcare LLC with respect to our Impede Technology and advanced our Limitx™ and Impede research programs. We also raised net proceeds of approximately $7.1 million in a registered direct offering to enable us to meet year end cash targets. In sum and as a result of the foregoing, the Compensation Committee determined that 55% of the organizational goals were met in 2015.

Material organizational goals for 2016 were advancing the success of Nexafed on the U.S. market, developing Impede Technology products, the continued development of our Limitx technology product candidates, executing partnerships around our Aversion or Impede technologies, executing partnerships/transactions around our Limitx technology, compliance with SOX, successfully managing our intellectual property, the execution of transactions to further build our cash, and meeting year-end cash targets. The Compensation Committee determined that 20% of the organizational goals were met in 2016. However because of our desire to preserve cash, no bonuses were paid in 2016 to Messrs. Jones, Clemens or Brzeczko.

No compensation will be earned with respect to a performance measure unless a performance "floor" for that measure is exceeded; the incentive opportunity with respect to a measure will be earned if the target is achieved; achievement between the floor and the target results in a lower amount of award with respect to that performance measure. An amount larger than the incentive opportunity for each performance measure can be earned, up to and possibly exceeding a specified limit, for exceeding the target for that measure. Depending on market conditions and other circumstances, performance criteria may be modified during the course of the year, and other performance criteria reweighted.

In ascertaining the achieved level of performance against the targets, the effects of certain extraordinary events, as determined by the Compensation Committee, such as (i) major acquisitions and divestitures, (ii) significant one-time charges, and (iii) changes in accounting principles required by the Financial Accounting Standards Board, are "compensation neutral" for the year in which they occurred; that is, they are not taken into account in determining the degree to which the targets are met in that year.

The Compensation Committee may, after a review of an executive's performance, recommend to the Board that a bonus award be made to such executives based upon other non-enumerated performance targets (whether or not they are parties to employment agreements). This could result in the award of salary increases or bonuses above a targeted range amount.

Employment Agreements

Robert B. Jones commenced employment with us on April 7, 2008 pursuant to an Employment Agreement dated March 18, 2008 as our Senior Vice President and Chief Operating Officer. On April 28, 2011, Mr. Jones was appointed our Interim President and Chief Executive Officer. On July 7, 2011, Mr. Jones was named President and Chief Executive Officer. Mr. Jones' salary was increased from $392,000 to $393,000 commencing January 1, 2016. The term of the Employment Agreement is currently scheduled to expire December 31, 2017, and provides for automatic one (1) year renewals in the absence of written notice to the contrary from us (which would give Mr. Jones the right to terminate his employment for Good Reason) or Mr. Jones at least ninety (90) days prior to the expiration of the initial term or any subsequent renewal period. Pursuant to the Employment Agreement Mr. Jones is eligible for annual bonuses of up to 100% of his base salary on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. In 2016, Mr. Jones did not receive a bonus. See "—Bonus/Non-Equity Incentive Plan." On December 12, 2013, December 11, 2014, December 10, 2015 and December 8, 2016 we granted Mr. Jones stock options to purchase 27,500 shares, 50,400 shares, 70,000 and 47,000 shares of our Common Stock, respectively, in each case exercisable at the fair market value of our Common Stock at the date of grant and vesting in equal installments over 24 months (subject to earlier exercisability as set forth in the table below entitled "Events Affecting Stock Option Vesting and Exercise"). The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause. In the event that we terminate the Employment Agreement without Cause or Mr. Jones terminates the Employment Agreement for Good Reason, we are required to pay Mr. Jones an amount equal to the bonus for such year, calculated on a pro-rata basis assuming full achievement of the bonus criteria for such year (to the extent it has not already been paid), as well as Mr. Jones' base salary for one year (such salary amount being the "Severance Pay"). Pursuant to an amendment to Mr. Jones' Employment Agreement entered into in 2012, in case of termination without Cause and for Good Reason or for voluntary termination more than two years after a Change of Control, such Severance Pay and bonus is payable in equal monthly installments over a period of twelve (12) months, with the first six installments payable six months and one day after termination, if mandated by applicable law, which requires certain payments to certain officers of a public company ("specified employees") to be made commencing six months after termination. However, if such termination is without Cause, for Good Reason or for voluntary termination within two years of a qualifying Change of Control, then the Severance Pay and bonus is payable in a lump sum six months and one day after termination (unless a six month delay is not required by applicable law in which case it is payable 31 days after termination). In addition, upon a termination without Cause or for Good Reason or voluntarily after a Change of Control, any shares remaining unvested under stock options and restricted stock units granted to Mr. Jones will vest in full and Mr. Jones will be entitled to continued coverage under our then-existing benefit plans, including medical and life insurance, for twelve (12) months from the date of termination.

The Employment Agreement restricts Mr. Jones from disclosing, disseminating or using for his personal benefit or for the benefit of others, confidential or proprietary information (as defined in the Employment Agreement) and, provided we have not breached the terms of the Employment Agreement, from competing with us at any time prior to one year after the termination of his employment with us. In addition, Mr. Jones has agreed not to (and not to cause or direct any person to) hire or solicit for employment any of our employees or those of our subsidiaries or affiliates (i) for six (6) months following the termination of his employment by us without Cause or by him for Good Reason, prior to a Change of Control, (ii) for twelve (12) months following the termination of his employment for Cause, prior to a Change of Control, or (iii) twenty-four (24) months following a Change of Control. The table entitled "Events Affecting Stock Option Vesting and Exercise," below, summarizes the vesting and exercisability of Mr. Jones' options following a number of termination scenarios or a Change of Control.

Peter A. Clemens is employed pursuant to an Employment Agreement effective as of March 10, 1998, as amended, which provides that Mr. Clemens will serve as our Senior Vice President and Chief Financial Officer for a term currently scheduled to expire December 31, 2017, and provides for automatic one (1) year renewals in the absence of written notice to the contrary from the Company or Mr. Clemens at least ninety (90) days prior to the expiration of any renewal period. Pursuant to a 2008 amendment to the Employment Agreement, our non-renewal of the Employment Agreement is considered as a termination without Cause for all purposes under the Employment Agreement. Mr. Clemens current base salary under the Employment Agreement is $286,000 (increased from $285,000 effective January 1, 2016). His maximum bonus is 70% of base salary. Mr. Clemens' bonus is based on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. See "—Bonus/Non-Equity Incentive Plan. In 2016, Mr. Clemens was not awarded a bonus. On December 12, 2013, December 11, 2014, December 10, 2015 and December 8, 2016 we granted Mr. Clemens options to purchase 15,000 shares, 36,000 shares, 50,000 shares and 34,000 shares of our Common Stock, respectively, in each case at an exercise price equal to the fair market value of our Common Stock at the date of grant and vesting in equal installments over 24 months (subject to earlier exercisability as set forth in the table below entitled "Events Affecting Stock Option Vesting and Exercise"). The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause. In the event the Employment Agreement is terminated by us without Cause or by Mr. Clemens for Good Reason, we are required to pay Mr. Clemens an amount equal to twice his then base salary, payable in the case of termination without Cause or for Good Reason six months and one day after termination (unless he is not a specified employee at termination in which case payment is in a lump sum within 30 days following termination) and to continue to provide Mr. Clemens coverage under our then existing benefit plans, including medical and life insurance, for a term of 24 months. The Employment Agreement permits Mr. Clemens to terminate the Employment Agreement in the event of a Change in Control (as defined in the Employment Agreement), in which case he would receive the same payments on the same schedule as on a termination for Good Reason. In addition, Mr. Clemens' estate is entitled to six month's salary upon his death as well as a pro rata bonus for the number of months he worked in the year of his death. The Employment Agreement also restricts Mr. Clemens from disclosing, disseminating or using for his personal benefit or for the benefit of others confidential or proprietary information (as defined in the Employment Agreement) and, provided we have not breached the terms of the Employment Agreement, from competing with us at any time prior to two years after the earlier to occur of the expiration of the term and the termination of his employment. In addition, for a period of two (2) years from and after the effective date of the termination of his employment with us (for any reason whatsoever), (i) induce or attempt to influence any employee of the Corporation or any of its subsidiaries or affiliates to leave its employ, or (ii) aid any person, business, or firm, including a supplier, a competitor, licensor or customer of or our manufacturer for the Corporation, in any attempt to hire any person who shall have been employed by us or any of our subsidiaries or affiliates within the period of one (1) year of the date of any such requested aid. The table entitled "Events Affecting Stock Option Vesting and Exercise," below, summarizes the vesting and exercisability of Mr. Clemens' options following a number of termination scenarios or a Change of Control.

For purposes of Mr. Jones and Mr. Clemens severance pay, a Change of Control is generally defined, with certain exceptions, as

- acquisition by a person or group of more than 50% of our outstanding shares
- a merger, reorganization, consolidation of exchange, other than one in which current holders of our voting securities hold more than 50% of our voting securities
- a merger in which we are not the surviving corporation
- a sale or license of substantially all of our assets
- Acura going private (i.e. no longer files reports under the Exchange Act), in a transaction not involving the relevant employee (e.g., Jones, in the case of Jones' severance and Clemens in the case of Clemens' severance)

Events Affecting Stock Option Vesting and Exercise (For Messrs. Jones and Clemens)

Event	Vesting of All Options (Options are exercisable upon vesting)	Exercisability of Options
Termination due to Death	Options vest for one month after death; after that no additional vesting	Vested options immediately exercisable for one year following termination
Termination by Company Without Cause or by Employee for Good Reason or termination by Employee following Change of Control	All options fully vest.	Vested options immediately exercisable for one year following termination Vested options exercisable for 12 months for Mr. Jones (twenty four months in the case of Mr. Clemens)
Termination due to Disability	No additional vesting	Vested options immediately exercisable for one year following termination
Termination by the Company for Cause or by executive other than for Good Reason	No additional vesting	Vested options immediately exercisable for 40 days following termination
Change of Control	Options fully vest for Mr. Jones, and options issued in 2015 and 2016 vest for Mr. Clemens.	Vested options immediately exercisable

Dr. Brzeczko is not party to an employment agreement. Dr. Brzeczko was hired pursuant to an offer letter pursuant to which he received a $40,000 signing bonus and commencing 2016 is eligible for annual bonuses of up to 50% of his base salary (increased from 35% in effect during 2015). In addition for 2016 he was eligible for an additional bonus of up to 15% of base salary in 2016 (for a total of 65% of base salary). Dr. Brzeczko's bonus is based on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. See "—Bonus/Non-Equity Incentive Plan." In 2016 he received no bonus. Upon commencement of his employment on February 9, 2009, he received 4,800 RSUs vesting in equal installments over 24 months, and stock options exercisable for 19,200 shares of Common Stock vesting in equal installments over 24 months. Dr. Brzeczko's annual salary is $291,000 (increased from $290,000 effective January 1, 2016). Dr. Brzeczko is eligible for and over the years of his employment, Dr. Brzeczko has received annual option grants. On December 8, 2016, Dr. Brzeczko was granted stock options exercisable at the fair market value on date of grant for 35,000 shares of Common Stock, vesting in equal installments over 24 months. If a change of control occurs (which constitutes a change of control under the stock option agreements) previously unvested options vest and become exercisable with respect to all underlying shares held by Dr. Brzeczko.

Stock Option Plans

We maintain three stock option plans adopted in 1998, 2008 and 2016, respectively. Our option plans are administered by the Board of Directors. The Board of Directors selects the employees, directors and consultants to be granted options under the plans and, subject to the provisions of each plan, determines the terms and conditions and number of shares subject to each option. Any of our employees or employees of our subsidiary are eligible to receive incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, or the Code ("ISOs"). Non-qualified stock options may be granted to employees as well as non-employee directors and consultants under the plans as determined by the Board. Any person who has been granted an option may, if he is otherwise eligible, be granted an additional option or options.

Each grant of an option is evidenced by an option agreement, and each option agreement specifies whether the option is an ISO or a non-qualified stock option and incorporates such other terms and conditions as the Board of Directors acting in its absolute discretion deems consistent with the terms of the plan, including, without limitation, a restriction on the number of shares of Common Stock subject to the option which first become exercisable during any calendar year.

To the extent that the aggregate fair market value of the Common Stock of the Company underlying a grant of ISOs (determined as of the date such an ISO is granted), which first become exercisable in any calendar year, exceeds $100,000, such Options shall be treated as non-qualified stock options. This $100,000 limitation shall be administered in accordance with the rules under Section 422(d) of the Code.

Upon the grant of an option to an employee, director or consultant the Board will fix the number of shares of Common Stock that the optionee may purchase upon exercise of the option and the price at which the shares may be purchased. The option exercise price for ISOs shall not be less than the fair market value of the Common Stock at the time the option is granted, except that the option exercise price shall be at least 110% of the fair market value where the option is granted to an employee who owns more than 10% of the voting power of all of our classes of stock or any parent or subsidiary. The option exercise price for non-qualified stock options granted under the plans may be less than the fair market value of our Common Stock ("Discounted Options"). "Fair market value" is the closing price of the common stock as reported by the Nasdaq Capital Market (or alternate methodologies if our common stock is not listed on NASDAQ.).

All options available to be granted under each plan must be granted with ten years after shareholder approval. The Board will determine the actual term of the options but no option will be exercisable after the expiration of 10 years from the date of grant. No ISO granted to an employee who owns more than 10% of the combined voting power of all of our outstanding classes of stock may be exercised after five years from the date of grant. Historically, our grants to employees generally vest 1/24th each month, although under plans any vesting schedule is permissible. Our grants to director generally vest ¼ each calendar quarter. Since 2015 our option agreements include vesting upon a change of control (as defined in the 2016 Stock Option Plan). In addition, the plans provide options may be accelerated by the Board of Directors in their discretion, including, upon a change of control, a proposed dissolution or liquidation of the Company, in the event of a proposed sale of all or substantially all of the assets of the Company, or the merger of the Company.

All of our option plans at the election of the participant, allow the participant to be able to exercise options on a net exercise basis by allowing shares subject to the option to be withheld by the Company in satisfaction of the option exercise price and the participant's withholding tax payment obligations relating to the option exercise.

Options granted to employees, directors or consultants under the plans may be exercised during the optionee's lifetime only by the optionee during his employment or service with us or for a period not exceeding one year if the optionee ceased employment or service as a director or consultant because of permanent or total disability within the meaning of Section 22(e)(3) of the Code. Options may be exercised by the optionee's estate, or by any person who acquired the right to exercise such option by bequest or inheritance from the optionee for a period of twelve months from the date of the optionee's death. If such option shall by its terms expire sooner, such option shall not be extended as a result of the optionee's death.

The 1998 Stock Option Plan

The 1998 Stock Option Plan was adopted by the Board of Directors in April, 1998 and approved by our shareholders in June, 1998. The 1998 Stock Option Plan, as amended, provided for the grant of stock options to purchase up to 400,000 shares of our Common Stock. As of December 31, 2016, stock options to purchase 18,000 shares of Common Stock had been granted under the 1998 Stock Option Plan. Of such option grants, 4,630 are ISO's and 13,370 are non-qualified options. No exercise price of an ISO was set at less than 100% of the fair market value of the underlying Common Stock.

In April, 2008 the 1998 Stock Option Plan expired and the remaining 4,382 unissued shares allocated to the Plan were terminated. The average per share exercise price for all outstanding options under the 1998 Stock Option Plan is $36.07.

The 2008 Stock Option Plan

The 2008 Stock Option Plan was adopted by the Board of Directors on March 14, 2008 and approved by our shareholders on April 30, 2008. On June 25, 2009, the 2008 Stock Option Plan was amended to allow participants to require us to withhold Common Stock upon exercise of options for payment of exercise price and statutory minimum withholding taxes. The 2008 Stock Option Plan permits the grant of ISO's and non-qualified stock options to purchase in the aggregate up to 1,200,000 shares of our Common Stock. As of December 31, 2016, stock options to purchase 1,195,795 shares of Common Stock had been granted under the 2008 Stock Option Plan. Of such option grants, 788,831 are ISOs and 406,964 are non-qualified options. The average per share exercise price for all outstanding options under the 2008 Stock Option Plan is $15.17.

The 2016 Stock Option Plan

The 2016 Stock Option Plan, as amended was adopted by the Board of Directors on or about April 12, 2016 and approved by our shareholders on April 28, 2016. The 2016 Stock Option Plan permits the grant of ISO's and non-qualified stock options to purchase in the aggregate up to 600,000 shares of our Common Stock. As of December 31, 2016, stock options to purchase 183,522 shares of Common Stock had been granted under the 2016 Stock Option Plan. Of such option grants, 181,564 are ISOs and 1,958 are non-qualified options. Up to 60,000 shares underlying options may be granted to any participant in a calendar year under the 2016 Stock Option Plan. The average per share exercise price for all outstanding options under the 2016 Stock Option Plan is $0.915.

Restricted Stock Unit Award Plan

The 2014 Restricted Stock Unit Award Plan

The Company's 2014 Restricted Stock Unit Award Plan (the "2014 RSU Plan") was approved by the Company's Board of Directors on February 27, 2014 and by stockholders on May 1, 2014. Under the 2014 RSU Plan, a Restricted Stock Unit ("RSU") represents the right to receive (upon payment of $0.01 par value per share) a share of the Company's Common Stock (or under certain circumstances, cash in lieu thereof ("Cash Settled RSUs")) at a designated time or upon designated events.

The maximum aggregate number of shares which may be subject to RSUs granted under the 2014 RSU Plan is 400,000 shares of authorized, but unissued or reacquired Common Stock. Payment of Cash Settled RSUs will reduce such limit. If an RSU should expire or become forfeited for any reason without the underlying shares of Common Stock or cash subject to such RSU having been distributed, the underlying shares shall, unless the 2014 RSU Plan shall have been terminated, become available for further grant under the 2014 RSU Plan. Unless terminated earlier by the Board of Directors, the RSUs may be distributed under the 2014 RSU Plan until April 30, 2024. The 2014 RSU Plan allows for amendment by the Board of Directors, provide shareholder approval for the amendment is not required under NASDAQ rules or applicable law.

The 2014 RSU Plan is intended to assist the Company in securing and retaining key employees, consultants and directors by allowing them to participate in the ownership and growth of the Company through the RSUs. The granting of RSUs serves as partial consideration for and gives key employees, directors and consultants an additional inducement to, remain in the service of the Company and will provide them with an increased incentive to work for the Company's success. Cash Settled RSUs give non-employee directors the ability to pay tax on their other RSUs distributed simultaneously therewith.

The 2014 RSU Plan is administered by the Company's Board of Directors, or, except with respect to matters involving non-employee Directors ("Non-Employee Directors"), the Compensation Committee, provided it is comprised of not less than two members of the Board, each of whom must be Non-Employee Directors as that term is defined in Rule 16b-3(b)(3)(i) of the Exchange Act (the "Committee").

The Board/Committee has the authority, subject to the provisions of the 2014 RSU Plan, to establish, adopt and revise such rules, regulations and forms and agreements and to interpret the 2014 RSU Plan and make all determinations relating to the 2014 RSU Plan as it may deem necessary or advisable. The Board/Committee also has the authority, subject to the provisions of the 2014 RSU Plan, to delegate ministerial, day-to-day administrative details and non-discretionary duties and functions to officers and employees of the Company. In the administration of the 2014 RSU Plan with respect to Non-Employee Directors, the Board has all of the authority and discretion otherwise granted to the Committee with respect to the administration of the 2014 RSU Plan.

All decisions, determinations and interpretations of the Board/Committee are binding and conclusive on participants in the 2014 RSU Plan and on their legal representatives and beneficiaries.

RSUs may be granted to any of the Company's Non-Employee Directors, any of the Company's employees or consultants, or any employees or consultants of any of the Company's subsidiary corporations, including officers (collectively, "Eligible Participants"). As of January 31, 2017 all of the Company's 15 full-time employees and four Non-Employee Directors of the Company are eligible participants ("Participants") in the 2014 RSU Plan. Any Eligible Participant who has been granted an RSU may be granted additional RSUs.

The RSU Plan does not confer any rights upon any Participant with respect to continuation of employment or service as an employee, consultant or a Non-Employee Director.

Each RSU granted under the 2014 RSU Plan is evidenced by a written award agreement ("RSU Award Agreement"), which contains the terms and conditions of the specific RSU granted.

RSUs generally vest as set forth in the RSU Award Agreement.

In addition, unless expressly provided otherwise in the RSU Award Agreement or an employment or consulting agreement, each RSU immediately vests and is nonforfeitable to the Participant upon the occurrence of any of the following events:

(1) a Participant's service as an employee of the Company is terminated by the Company without Cause (as defined) or due to the Participant's death or disability (as defined), or in the case of a Non-Employee Director, upon the Participant's death or Disability or if the Participant is not renominated as a director (other than for "Cause" or refusal to stand for re-election) or is not elected by the Company's stockholders, if nominated; or

(2) a Change in Control (as defined in the RSU Plan)

Accelerated vesting does not directly translate into accelerated distribution of shares, subject to an RSU Award. For instance if the Company terminates an employee's employment without cause, such employee's RSUs will immediately vest (unless otherwise provided in the RSU Award Agreement) but, absent a Change in Control, he will not commence to receive the shares underlying his RSU award until the scheduled distribution date.

RSU awards are generally distributed on the first business day of the year after they vest. For example, if an award vests quarterly during 2017, it will be distributed on the first business day of 2018. Non-Employee Directors may irrevocably elect to defer distributions to a specified date or dates and to take payment in cash instead of stock for up to 40% of the RSUs in an award (rendering such RSUs as Cash Settled RSUs). The cash payment election may be made at anytime before distribution, but any such cash payment is subject to any limits on redemption under any loan or other financing agreement. The deferral election must be made by the December 31 of the year before the grant, except that in the case of a grant in 2014, the deferral election may be made within 30 days of the date of the Non-Employee Director's eligibility to participate in the 2014 RSU Plan. If the deferral election is made in the first year of eligibility of a Non-Employee Director under the Plan, then it shall only apply to RSUs granted for service earned from the first day of the calendar quarter commencing after such election until the end of such calendar year. A Non-Employee Director could specify multiple deferral dates with a percentage of RSUs to be paid on each such date. Unlike the case with Non-Employee Directors, under the 2014 RSU Plan, neither employees nor consultants have the option of deferring distributions. However, the Company has the option of establishing a RSU award that defers distributions to an employee or a consultant, including in installments (e.g., 25% of RSUs to be paid in 2017, 2018, 2019 and 2020). If a Change of Control occurs, all vested shares of Common Stock underlying an RSU (after payment of $0.01 per share par value) will be distributed by the Company to the holder of the RSU at or about the time of the Change in Control. No dividends accrue on shares of Common Stock underlying RSUs prior to distribution. Participants need not be employees, consultants or directors of the Company on a distribution date. A Change in Control for distribution purposes is generally the same as a Change in Control for vesting purposes, except that in order to have a Change in Control for distribution purposes, a change in control qualifying under Section 409A of the Code must occur.

RSUs may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner by the Participant other than by will or by the laws of descent or distribution and to (i) the spouse, children or grandchildren of the awardee (the "Immediate Family Members"), (ii) a trust or trusts for the exclusive benefit of such Immediate Family Members, or (iii) a partnership in which such Immediate Family Members are the only partners, provided that (x) there may be no consideration for any such transfer, (y) subsequent transfers of transferred RSUs shall be prohibited except those made by will or by the laws of descent or distribution, and (z) such transfer is approved in advance by the Committee (or Board in absence of a Committee). A married Participant may generally designate only a spouse as a beneficiary unless spousal consent is obtained.

Unless other provided in an RSU Award Agreement, Participants have no dividend rights and no voting rights with respect to the shares underlying RSUs until the RSUs settle in shares of Common Stock.

The Board may terminate and, without shareholder approval, unless the same is required by the rules of the exchange where the Company's stock trades, or applicable law, amend the 2014 RSU Plan.

Upon or in contemplation of any reclassification, recapitalization, stock split (including a stock split in the form of a stock dividend) or reverse stock split; any merger, combination, consolidation or other reorganization; any split-up; spin-off, or similar extraordinary dividend distribution with respect to the Common Stock (whether in the form of securities or property); any exchange of stock or other securities of the Company, or any similar, unusual or extraordinary corporate transaction with respect to the Common Stock; or a sale of substantially all the assets of the Company as an entirety; then the Board shall proportionately adjust any or all of (a) the number and type of shares of Common Stock (or other securities or property) that thereafter may be made the subject of RSUs, (b) the number, amount and type of shares of Common Stock (or other securities or property) payable with respect to RSUs, and (c) and the number and type of RSUs (both credited and vested) under the 2014 RSU Plan.

As of January 31, 2017 we had granted RSUs under the 2014 RSU Plan providing for our issuance of up to an aggregate of 396,844 shares of our Common Stock. At January 31, 2017 261,344 RSU awards were outstanding under our 2014 RSU Plan. To date we have only issued RSUs under the 2014 RSU Plan to our Non-Employee Directors.

Outstanding Equity Awards at 2016 Year-End

The following table presents information regarding outstanding stock and stock option awards at December 31, 2016 for each of the 2016 named executive officers.

Outstanding Equity Awards at 2016 Year-End

	Stock Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Option Exercise Price ($)	Option Expiration Date
Robert B. Jones	6,000	—	$ 43.20	04/06/2018
	32,000	—	$ 49.35	05/23/2018
	32,000	—	$ 31.45	04/23/2019
	50,000	—	$ 15.10	12/15/2020
	16,000	—	$ 18.60	12/14/2021
	18,000	—	$ 13.05	12/13/2022
	27,500	—	$ 7.75	12/11/2023
	50,400	—	$ 2.60	12/10/2024
	37,917	32,083	$ 2.01	12/09/2025
	1,958	45,042	$ 0.915	12/09/2026
Peter A. Clemens	20,000	—	$ 49.35	05/23/2018
	24,000	—	$ 31.45	04/23/2019
	8,000	—	$ 15.10	12/15/2020
	7,000	—	$ 18.60	12/14/2021
	10,000	—	$ 13.05	12/13/2022
	15,000	—	$ 7.75	12/11/2023
	36,000	—	$ 2.60	12/10/2024
	27,083	22,917	$ 2.01	12/09/2025
	1,417	32,583	$ 0.915	12/09/2026
Albert W. Brzeczko	19,200	—	$ 28.50	02/08/2019
	6,400	—	$ 15.10	12/15/2020
	7,000	—	$ 18.60	12/14/2021
	14,000	—	$ 13.05	12/13/2022
	15,000	—	$ 7.75	12/11/2023
	28,800	—	$ 2.60	12/10/2024
	27,083	22,917	$ 2.01	12/09/2025
	1,458	33,542	$ 0.915	12/09/2026

(1) In any row for which there are unexercisable options, 1/24th of total option issuance in such row becomes exercisable on the last day of each month.

Securities Authorized For Issuance under Equity Compensation Plans

The following table includes information as of December 31, 2016 relating to our 1998 Stock Option Plan, our 2008 Stock Option Plan, our 2016 Stock Option Plan and our 2014 Restricted Stock Unit Award Plans, which comprise all of our equity compensation plans. The table provides the number of securities to be issued upon the exercise of outstanding options and distributions under outstanding Restricted Stock Unit Awards under such plans, the weighted-average exercise price of outstanding options and the number of securities remaining available for future issuance under such equity compensation plans:

Plan Category	Number Of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (Column a)		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (Column b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column a (Column c)
Stock Option Equity Compensation Plans Approved by Security Holders	1,397,315	$	13.57	416,478
Stock Option Equity Compensation Plans Not Approved by Security Holders	—		—	—
Restricted Stock Unit Equity Compensation Plans Approved by Security Holders	261,345	$	0.01	3,155
Restricted Stock Unit Equity Compensation Plans Not Approved by Security Holders	—		—	—
TOTAL	1,658,660	$	11.43	419,633

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

On or about October 1, 2012, GCE Holdings LLC ("GCE") our then approximately 72.5% stockholder distributed (the "GCE Distribution") all of its securities in the Company to its members, including Galen and certain of its affiliates, Care Capital and certain of its affiliates, and Essex. As a result, as of the date of the GCE Distribution, Galen, Care Capital and Essex and their affiliated entities beneficially owned 29.8%, 23.1% and 22.6%, respectively, of our common stock. GCE was the assignee of all shares of the Company's preferred stock (prior to conversion of such preferred stock into common stock) formerly held by each of Galen, Care Capital and certain of their affiliates and Essex. Messrs. Azad, Markham and Thangaraj, each a Director at the time of the GCE Distribution, exercised investment control over the membership interests in GCE held by Galen, Care Capital and Essex, respectively, and correspondingly exercised investment control over our common stock held by GCE prior to the GCE Distribution.

As a condition to the completion of our 2004 debenture offering, we and the investors in our 2004 debentures and the holders of our outstanding 5% convertible senior secured debentures due March 31, 2006 issued by us during the period from 1998 through 2003 executed a certain Voting Agreement dated as of February 6, 2004, or the Voting Agreement. After giving effect to amendments to the Voting Agreement in November 2005, January 2008 and October 1, 2012, the Voting Agreement provides that our Board of Directors will be comprised of not more than seven (7) members and that each of Galen, Care Capital and Essex had the right to designate one director as a member of our Board of Directors, as long as such shareholder held 600,000 shares of our Common Stock (including warrants to purchase shares), provided that in the event the majority of the Board of Directors were not independent under Nasdaq Marketplace Rules then, the Board would be expanded so that additional independent directors would be added. At the time of the October 1, 2012 amendment, Messrs. Azad, Markham and Thangaraj, the former GCE designees, became the designees of Galen, Care Capital and Essex, respectively. Mr. Azad resigned effective December 31, 2012 and has not been replaced by Galen. Mr. Markham resigned effective March 11, 2013 and was never replaced by Care Capital. Care Capital is no longer entitled to designate a director as it no longer holds the requisite amount of our equity. In addition, each of Galen, Essex has (and Care Capital had) the right to designate a member to any committee of our Board of Directors, provided that in the case of the Audit and Compensation committees they are independent under applicable NASDAQ rules.

Our Board has not adopted formalized written policies and procedures for the review or approval of related party transactions. As a matter of practice, however, our Board has required that all related party transactions, be subject to review and approval by a committee of independent directors established by the Board. The Board's practice is to evaluate whether a related party (including a director, officer, employee, Galen, Essex or other significant shareholder) will have a direct or indirect interest in a transaction in which we may be a party. Where the Board determines that such proposed transaction involves a related party, the Board formally establishes a committee comprised solely of independent directors to review and evaluate such proposed transaction, or the Independent Committee. The Independent Committee is authorized to review any and all information it deems necessary and appropriate to evaluate the fairness of the transaction to us and our shareholders (other than the interested related party to such transaction), including meeting with management, retaining third- party experts (including counsel and financial advisors if determined necessary and appropriate by the Independent Committee) and evaluating alternative transactions, if any. The Independent Committee is also empowered to negotiate the terms of such proposed related party transaction on our behalf. The proposed related party transaction may proceed only following the approval and recommendation of the Independent Committee. Following the Independent Committee's approval, the related party transaction is subject to final review and approval of the Board as a whole, with any interested director abstaining from such action.

Each of the transactions described above under the caption "Certain Relationships and Related Transactions" were subject to the review, evaluation, negotiation and approval of an Independent Committee of the Board.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of the Common Stock, as of January 31, 2017, for individuals or entities in the following categories: (i) each of the Company's Directors; (ii) the Company's principal executive officer, and the next two highest paid executive officers of the Company whose total annual compensation for 2016 exceeded $100,000 (the "2016 named executive officers"); (iii) all Directors and executive officers as a group; and (iv) each person known by the Company to be a beneficial owner of more than 5% of the Common Stock. Unless indicated otherwise, each of the shareholders has sole voting and investment power with respect to the shares beneficially owned. At January 31, 2017, there were 11,882,994 shares of our Common Stock outstanding. Shares of common stock issuable pursuant to stock options, warrants and restricted stock units exercisable or exchangeable within 60 days are deemed outstanding and held by the holder of such options warrants or restricted stock units for computing the percentage of the person holding such options, warrants or restricted stock units, but are not deemed outstanding for computing the percentage of any other person. There were no restricted stock units exchangeable within 60 days of January 31, 2017.

Name of Beneficial Owner	Amount Owned	Percent of Class [1]
Galen Partners III, LP 680 Washington Boulevard, Stamford, CT 06901	2,195,735[2]	18.5%
Essex Woodlands Health Ventures Fund V, L.P. 21 Waterway Avenue, Suite 225 Woodlands, TX 77380	1,956,357[3]	16.5%
Deerfield Special Situations Fund, L.P 780 Third Avenue, 37th Floor New York, NY 10017	1,025,641[4]	8.6%
Robert B. Jones	298,955[5]	2.5%
William G. Skelly	46,345[6]	*
Bruce F. Wesson	76,670[7]	*
Peter A. Clemens	214,181[8]	1.8%
Immanuel Thangaraj	41,812[9]	*
Albert W. Brzeczko	134,766[10]	1.1%
George K. Ross	29,565[11]	*
All Officers and Directors as a Group (10 persons)	1,148,099[12]	9.0%

* Represents less than 1% of the outstanding shares of the Company's Common Stock.

(1) Shows percentage ownership assuming (i) such party converts all of its currently convertible securities or securities convertible within 60 days of January 31, 2016 into the Company's common stock, and (ii) no other Company security holder converts any of its convertible securities. No shares held by any Director or 2016 named executive officer has been pledged as collateral security.

(2) Includes 2,006,538 shares held by Galen Partners III, LP, 180,936 shares held by Galen Partners International III, LP and 8,261 shares held by Galen Employee Fund III, L.P. (collectively, "Galen"). Claudius, L.L.C. serves as the sole General Partner of Galen Partners, III LP and Galen Partners International III, LP and has sole voting and investment control over the shares held by such funds and may be deemed to beneficially own the shares held by such funds. Galen Management, L.L.C. serves as the sole General Partner of Galen Employee Fund III, L.P. and has sole voting and investment control over the shares held by Galen Employee Fund III, L.P. and may be deemed to beneficially own the shares held by Galen Employee Fund III, L.P. Claudius L.L.C. and each Galen entity disclaims beneficial ownership of the shares reported herein, except to the extent of its respective pecuniary interest therein. L. John Wilkerson, David W. Jahns, and Zubeen Shroff exercise voting, investment and dispositive rights over our securities held of record by Galen. The information reported with respect to Galen and Claudius LLC is based on a Form 4 filed on June 18, 2015.

(3) Mr. Thangaraj is the Board designee of Essex Woodlands Health Ventures Fund V, L.P. ("Essex"). Essex Woodlands Health Ventures V, L.L.C., a Delaware limited liability company is the general partner of Essex. Martin P. Sutter and Immanuel Thangaraj, may be deemed to have shared dispositive power and voting power with respect to the securities held by the Essex. Messrs. Sutter and Thangaraj disclaim beneficial ownership of such securities except to the extent of their respective pecuniary interests therein.

(4) Deerfield Management Company, L.P., as the investment advisor of, and Deerfield Mgmt, L.P., as the general partner of, Deerfield Special Situations Fund, L.P. and James Flynn share power to dispose or direct disposition of and to vote or direct the vote of shares held by Deerfield Special Situations Fund, L.P. The foregoing information in this footnote is based on Amendment No.1 to Schedule 13-G filed by Deerfield Management Company, L.P., Deerfield Mgmt, L.P., Deerfield Special Situations Fund, L.P. and James Flynn on February 16, 2016.

(5) Includes 286,400 shares subject to stock options exercisable within 60 days of January 31, 2017.

(6) Includes 18,000 shares subject to stock options exercisable within 60 days of January 31, 2017. Does not include RSUs.

(7) Includes 18,000 shares subject to stock options exercisable within 60 days of January 31, 2017. Does not include RSUs.

(8) Includes 158,999 shares subject to stock options exercisable within 60 days of January 31, 2017.

(9) Includes 18,000 shares subject to stock options exercisable within 60 days of January 31, 2017. Mr. Thangaraj's holdings do not include securities held by Essex. Mr. Thangaraj disclaims beneficial ownership in securities held by Essex except to the extent of his pecuniary interest therein. Does not include RSUs.

(10) Includes 129,566 shares subject to stock options exercisable within 60 days of January 31, 2017.

(11) Includes 18,000 shares subject to stock options exercisable within 60 days of January 31, 2017. Does not include RSUs.

(12) Includes 890,565 shares which Directors and executive officers have the right to acquire within 60 days of January 31, 2017 through exercise of outstanding stock options.

DESCRIPTION OF OUR CAPITAL STOCK

The following summary description of our capital stock is based on the provisions of our amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, and the applicable provisions of the New York Business Corporation Law. This information is qualified entirely by reference to the applicable provisions of our certificate of incorporation, bylaws and the New York Business General Corporation Law. Copies of our certificate of incorporation and our bylaws, copies have been filed as exhibits to the registration statement of which this prospectus is a part. See "Where You Can Find More Information."

Authorized Capital Stock

We have authority to issue 100,000,000 shares of common stock. As of January 31, 2017, we had 11,882,994 shares of common stock outstanding and 59,560 shares of common stock subject to outstanding warrants. In addition, as of January 31, 2017, we had an aggregate of 1,658,660 shares of common stock reserved for issuance upon the exercise of outstanding stock options and restricted stock units under our stock option and restricted stock unit award plans, and 419,633 shares reserved for issuance pursuant to future grants under our stock option plans and restricted stock unit plans.

Common Stock

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. The holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefor. Upon the liquidation, dissolution or winding up of the Company, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities. Holders of common stock have no preemptive rights and no right to convert their common stock into any other securities. Our common stock has no redemption or sinking fund provisions. All outstanding shares of common stock are fully paid and non-assessable.

Our certificate of incorporation provides for a maximum of 11 directors. Our Board size is currently seven and we have two vacancies.

Warrants

The following summary of certain terms and provisions of the warrants that are being offered hereby together with our common stock is not complete and is subject to, and qualified in its entirety by, the provisions of the warrant, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions of the form of warrant for a complete description of the terms and conditions of the warrants.

Duration and Exercise Price

Each warrant offered hereby will have an exercise price of $___ per share. The warrants will be immediately exercisable and will expire on the **[**fifth**]** anniversary of the original issuance date. The warrants will be issued separately from our common stock, and may be transferred separately immediately thereafter. Warrants will be issued in certificated form only.

Exercisability

The warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% of the outstanding common stock after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise

If, at the time a holder exercises its warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the warrant to the holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of our common stock determined according to a formula set forth in the warrant.

Certain Adjustments

The warrant provides that the exercise price is subject to adjustment in the event of stock splits, reverse stock splits and similar events.

Fundamental Transactions

In the event of any fundamental transaction, as described in the warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, the holder will have the right to have such warrants and all obligations and rights thereunder assumed by the successor or acquiring corporation.

Transferability

Subject to applicable laws and the restriction on transfer set forth in the warrant, the warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

No Listing

There is no established trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

Right as a Stockholder

Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

Waivers and Amendments

Subject to certain exceptions, any term of the warrants may be amended or waived with our written consent and the written consent of the holders of at least a majority of the then-outstanding warrants.

Certain Provisions of New York Law and of the Company's Voting Agreement

The following paragraphs summarize certain provisions of the New York Business Corporation Law, or NYBCL, and our Voting Agreement. The summary does not purport to be complete and is subject to and qualified in its entirety by reference to the NYBCL, to our bylaws and to the Voting Agreement, copies of which are on file with the SEC as exhibits to the registration statement of which this prospectus forms a part. See "Where You Can Find More Information."

General. Certain provisions of our Voting Agreement and New York law could make our acquisition by a third party, a change in our incumbent management, or a similar change of control more difficult.

These provisions, which are summarized below, are likely to discourage certain types of coercive takeover practices and inadequate takeover bids.

Voting Agreement

Although our certificate of incorporation provides for a maximum of 11 directors, in accordance with the terms of a Voting Agreement dated February 6, 2004, as amended, by and among the Company, GCE Holdings LLC ("GCE"), Care Capital Investments II, LP ("Care Capital"), Essex Woodlands Health Ventures V, L.P. ("Essex"), Galen Partners III, L.P. ("Galen") and others, or the Voting Agreement, we have agreed that the Board of Directors shall be comprised of not more than seven members (or such greater number that is required to assure that we have a majority of independent directors after giving effect to the various designation rights described herein), one of whom shall be the designee of Care Capital, one of whom shall be the designee of Essex, and one of whom shall be the designee of Galen (in the case of each such shareholder, as long as such shareholder held 600,000 shares of our Common Stock (including warrants to purchase shares)), one of whom is our Chief Executive Officer and three of whom are independent directors. The Voting Agreement provides that each of Care Capital's, Essex's and Galen's right to designate one director will terminate when it or its affiliates (determined separately for each of Care Capital, Essex and Galen) fail to hold at least 600,000 shares of our common stock (or warrants exercisable for such shares). Care Capital no longer has the right to designate a director as it no longer holds the requisite equity and Galen's designated director seat is vacant.

As a result of the Voting Agreement it would be difficult for a potential acquirer to replace the Board of Directors in a proxy contest.

New York anti-takeover law.

We are subject to certain "business combination" provisions of Section 912 of the NYBCL and expect to continue to be so subject if and for so long as we have a class of securities registered under Section 12 of the Securities Exchange Act of 1934. Section 912 provides, with certain exceptions, that a New York corporation may not engage in a "business combination" (e.g., merger, consolidation, recapitalization or disposition of stock) with any "interested shareholder" for a period of five years from the date that such person first became an interested shareholder unless:

(i) the transaction resulting in a person becoming an interested shareholder was approved by the board of directors of the corporation prior to that person becoming an interested shareholder; or

(ii) the business combination is approved by the holders of a majority of the outstanding voting stock not beneficially owned by such interested shareholder; or

(iii) the business combination is approved by the disinterested shareholders at a meeting called no earlier than five years after the interested shareholder's stock acquisition date; or

(iv) the business combination meets certain valuation requirements for the stock of a New York corporation.

An "interested shareholder" is defined as any person who (a) is the beneficial owner of 20% or more of the outstanding voting stock of a New York corporation or (b) is an affiliate or associate of a corporation that at any time during the prior five years was the beneficial owner, directly or indirectly, of 20% or more of the then outstanding voting stock.

A "business combination" includes mergers, asset sales and other transactions resulting in a financial benefit to the interested shareholder.

The "stock acquisition date", with respect to any person and any New York corporation, means the date that such person first becomes an interested shareholder of such corporation.

Listing

Our common stock is quoted on the NASDAQ and trades under the symbol "ACUR." On January 31, 2017 the closing price of our common stock on NASDAQ was $0.54. As of January 31, 2017 there are approximately 310 shareholders of record, including approximately 91 holders who are nominees for an undetermined number of beneficial owners based upon a review of the securities position listing provided by our transfer agent.

Transfer Agent and Registrar

The transfer agent and registrar of our common stock is Broadridge Corporate Issuer Solutions, P.O. Box 1342, Brentwood, NY 11717, (877) 830-4935. Acura will act as the transfer agent of the warrants offered hereby.

SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of the offering, ____ shares of our common stock will be outstanding (____ shares of common stock if the underwriters' option to purchase additional shares is exercised in full). All of the ____ shares to be sold in the offering (including shares underlying warrants) (____ shares if the underwriters' option to purchase additional shares is exercised in full) will be freely tradable without restriction or limitation under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 under the Securities Act.

Stock Plans

Even after the lock-up described under "Underwriting-Lock-up Agreements" expires, ____ shares held by our directors and officers are currently eligible for resale subject to volume limitations and in certain cases other requirements of Rule 144. As of _____, there are ___ shares underlying options and restricted stock units, which if exercised or exchanged will be eligible for resale under the limitations of Rule 144 and ____ shares eligible for future grants under our stock option and restricted stock unit plans.

Galen and Essex

In accordance with the terms of the Securities Purchase Agreement dated August 20, 2007 between us and the investors named therein, we filed a registration statement, or the 2007 Registration Statement, with and declared effective by the SEC, to register the shares included in our Units (consisting of four shares and one warrant) issued pursuant to the Securities Purchase Agreement, including shares underlying warrants included in the Units. In addition, pursuant to the exercise of previously granted piggyback registration rights, each of Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP and Essex Woodlands Health Ventures V, L.P., in their own right and as successor to GCE Holdings LLC have exercised their piggyback registration rights to include shares in such registration statement. A majority of shares held by Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P and Essex Woodlands Health Ventures V, L.P are included in the 2007 Registration Statement and freely tradeable and the remainder of the shares held by such entities may be sold subject to volume limitations under Rule 144. The shares included in the 2007 Registration Statement may also be sold under Rule 144. We have been informed that Care Capital no longer holds any of our common stock.

No prediction can be made as to the effect, if any, future sales of our common stock will have on the market price prevailing from time to time. Sales of substantial amounts of our common stock, or the perception that such sales could occur, may adversely affect prevailing market prices of our common stock. See "Risk Factors - Risks Relating to our Common Stock and this Offering."

Rule 144

In general, under Rule 144 under the Securities Act, as in effect on the date of this prospectus, a person who is one of our affiliates and has beneficially owned shares of our common stock for at least six months would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately ____ shares immediately after the completion of this offering; or

- the average weekly trading volume of our common stock on NASDAQ during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

In general, under Rule 144 under the Securities Act, as in effect on the date of this prospectus, a person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than an affiliate, is entitled to sell the shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, and will be subject only to the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144.

UNDERWRITING

We have entered into an underwriting agreement with Roth Capital Partners, LLC, as representative of the underwriters, with respect to the shares of common stock and the warrants to purchase our common stock subject to this offering. Subject to certain conditions, we have agreed to sell to the underwriters, and the underwriters have agreed to purchase, the number of shares of common stock and warrants provided below opposite its name.

Underwriters	Number of Shares	Number of Warrants
[_____]		
Total		

The underwriters are offering the shares of common stock and warrants subject to its acceptance of the shares of common stock and warrants from us and subject to prior sale. We anticipate the underwriting agreement will provide that the obligation of the underwriters to pay for and accept delivery of the shares of common stock and warrants offered by this prospectus is subject to the approval of certain legal matters by its counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock and warrants if any such shares are taken. However, the underwriters are not required to take or pay for the shares of common stock and warrants covered by the underwriters' over-allotment option described below.

Over-Allotment Option

We intend to grant the underwriters an option, exercisable for 45 days from the date of this prospectus, to purchase up to an aggregate of _____ additional shares of common stock and/or warrants to purchase up to ____ shares of our common stock, (assuming a combined public offering price of $____ per share and related warrant, the closing bid price of our common stock on the NASDAQ on _____), to cover over-allotments, if any. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock and warrants offered by this prospectus. If the underwriters exercise this option, the underwriters will be obligated, subject to certain conditions, to purchase the additional shares and/or warrants for which the option has been exercised.

Discount, Commissions and Expenses

It is anticipated that the underwriters will advise us that they propose to offer the shares of common stock and warrants to the public at the combined public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $_____ per share and related warrant. The underwriters may allow, and certain dealers may re-allow, a discount from the concession not in excess of $_____ per share and related warrant to certain brokers and dealers. After this offering, the combined public offering price, concession and reallowance to dealers may be changed by the underwriters. No such change shall change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The shares of common stock and warrants are offered by the underwriters as stated herein, subject to receipt and acceptance by it and subject to its right to reject any order in whole or in part. We anticipate that the underwriters will inform us that they do not intend to confirm sales to any accounts over which they exercises discretionary authority.

The following table shows the anticipated underwriting discount payable to the underwriters by us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' over-allotment option to purchase additional shares and warrants.

	Per Share and Related Warrant	Total Without Exercise of Over-Allotment Option	Total With Exercise of Over-Allotment Option
Combined public offering price	$	$	$
Underwriting discount(1)	$	$	$

1 The discount will be **[**___%**]** of the combined public offering price **[**, except in the case of sales to (i) certain existing institutional investors, in which case the discount will be **[**___%**]** of the combined public offering price, and (ii) certain existing individual investors, in which case, the discount will be **[**___%**]** of the combined public offering price**]**.

We anticipate will reimburse the managing underwriter for certain out-of-pocket expenses (including the reasonable fees and disbursements of counsel to the underwriter) not to exceed $_____ without our prior written consent, such consent not to be unreasonably withheld, subject to a cap of $_____. We estimate that expenses payable by us in connection with this offering, including reimbursement of the managing underwriter's expenses but excluding the underwriting discount referred to above, will be approximately $_____ .

Indemnification

We anticipate that we will agree to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or the Securities Act, and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

Lock-up Agreements

We anticipate that we, our officers and our directors will agree, subject to limited exceptions, for a period of ___ days after the date of the underwriting agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent the managing underwriter. The managing underwriter may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

In connection with the offering the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

- Over-allotment involves sales by the underwriters of securities in excess of the number of securities the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriters is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriters may close out any covered short position by either exercising its over-allotment option and/or purchasing securities in the open market.

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market as compared to the price at which it may purchase securities through the over-allotment option. If the underwriters sell more securities than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.

- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market prices of our common stock and warrants or preventing or retarding a decline in the market price of the common stock. As a result, the price of our common stock may be higher than the prices that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our common stock. In addition, neither we nor the underwriters make any representations that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Electronic Distribution

This prospectus in electronic format may be made available on websites or through other online services maintained by the underwriters, or by their affiliates. Other than this prospectus in electronic format, the information on the underwriters' website and any information contained in any other website maintained by the underwriters is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriters in their capacity as underwriters, and should not be relied upon by investors.

Other

From time to time, the underwriters and/or their respective affiliates may have provided, and may in the future provide, various investment banking and other financial services for us for which services it may have received and, may in the future receive, customary fees. In the course of its business, the underwriters and its affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the underwriters and their respective affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering and as provided below, the underwriters have not provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus and we do not expect to retain the underwriters to perform any investment banking or other financial services for at least 90 days after the date of this prospectus.

NOTICE TO INVESTORS

Notice to Investors in the United Kingdom

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any securities which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any such securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

(c) by the underwriters to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of these securities shall result in a requirement for the publication by the issuer or the underwriters of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any such securities to be offered so as to enable an investor to decide to purchase any such securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

The underwriters have represented, warranted and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by it in connection with the issue or sale of any of the securities in circumstances in which section 21(1) of the FSMA does not apply to the issuer; and

(b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

European Economic Area

In particular, this document does not constitute an approved prospectus in accordance with European Commission's Regulation on Prospectuses no. 809/2004 and no such prospectus is to be prepared and approved in connection with this offering. Accordingly, in relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (being the Directive of the European Parliament and of the Council 2003/71/EC and including any relevant implementing measure in each Relevant Member State) (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) an offer of securities to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to such securities which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of securities to the public in that Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

- to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in the last annual or consolidated accounts; or

- in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of securities to the public" in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. For these purposes the securities offered hereby are "securities."

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS FOR NON-UNITED STATES HOLDERS

This section summarizes the material United States federal income and estate tax considerations relating to the purchase, ownership and disposition of common stock and warrants by a non-U.S. holder (as defined below). This summary does not provide a complete analysis of all potential tax considerations. The information provided below is based upon provisions of the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated thereunder and administrative rulings and judicial decisions, as currently in effect. These authorities may change at any time, possibly on a retroactive basis, or the United States Internal Revenue Service, or the IRS, might interpret the existing authorities differently. In either case, the tax considerations of purchasing, owning or disposing of common stock or warrants could differ from those described below.

Certain U.S. Federal Income and Estate Tax Considerations for Non-U.S. Holders of Common Stock and Warrants

For purposes of this summary, a "non-U.S. holder" is any holder other than:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation for United States federal income tax purposes, created or organized under the laws of the United States, any state thereof or the District of Columbia;
- a trust that (1) is subject to the primary supervision of a United States court and one or more United States persons have authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable United States Treasury regulations to be treated as a United States person; or
- an estate the income of which is subject to United States federal income tax regardless of source.

If a partnership or other pass-through entity for United States federal income tax purposes is a beneficial owner of common stock or warrants, the tax treatment of a partner in the partnership or an owner of the entity will depend upon the status of the partner or other owner and the activities of the partnership or other entity. Any partner in a partnership or member in a pass-through entity holding shares of our common stock or warrants should consult its own tax advisor.

This discussion assumes that a non-U.S. holder will hold our common stock and warrants as capital assets (generally, property held for investment). This summary generally does not address tax considerations that may be relevant to particular investors because of their specific circumstances, or because they are subject to special rules, including if the investor is a United States expatriate, "controlled foreign corporation," "passive foreign investment company," corporation that accumulates earnings to avoid United States federal income tax, dealer in securities or currencies, financial institution, regulated investment company, real estate investment trust, tax-exempt entity, insurance company, person holding our common stock or warrants as part of a hedging, integrated, conversion or constructive sale transaction or a straddle, trader in securities that elects to use a mark-to-market method of accounting, person liable for the alternative minimum tax, and partnerships or other pass-through entities (and their owners). Finally, this summary does not describe the effects of any applicable foreign, state or local laws, or, except to the extent discussed below, the effects of any applicable gift or estate tax laws.

INVESTORS CONSIDERING THE PURCHASE, OWNERSHIP OR DISPOSITION OF COMMON STOCK OR WARRANTS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE UNITED STATES FEDERAL INCOME AND ESTATE TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES OF FOREIGN, STATE OR LOCAL LAWS, AND TAX TREATIES.

Investment Unit

The common stock and warrants should be treated for U.S. federal income tax purposes as an investment unit consisting of one share of our common stock and one warrant to acquire **[___]** of one share of our common stock. For U.S. federal income tax purposes, the purchase price paid for each unit will be allocated between the shares of common stock and the warrants based on their respective relative fair market values.

Dividends on our Common Stock

We do not expect to declare or pay any distributions on our common stock in the foreseeable future. If we do make any distributions on shares of our common stock, however, such distributions will constitute dividends for United States federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a non-U.S. holder's adjusted tax basis in shares of our common stock. Any remaining excess will be treated as gain realized on the sale or other disposition of our common stock. See "—Sale of Common Stock or Warrants."

Any dividend paid to a non-U.S. holder on our common stock will generally be subject to United States withholding tax at a 30% rate. The withholding tax might not apply, however, or might apply at a reduced rate, under the terms of an applicable income tax treaty between the United States and the non-U.S. holder's country of residence. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty. Generally, in order for us or our paying agent to withhold tax at a lower treaty rate, a non-U.S. holder must certify its entitlement to treaty benefits. A non-U.S. holder generally can meet this certification requirement by providing to us or our paying agent an IRS Form W-8BEN or appropriate successor form (which generally remains valid for three years, after which time a new properly completed and executed IRS Form W-8BEN must be provided to us or our paying agent). If the holder holds the stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to the agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If a non-U.S. holder is eligible for a reduced rate of United States federal withholding tax under an income tax treaty, such non-U.S. holder may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the IRS in a timely manner.

Dividends received by a non-U.S. holder that are effectively connected with a U.S. trade or business conducted by the non-U.S. holder, or, if an income tax treaty between the United States and the non-U.S. holder's country of residence applies, are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder in the United States, are not subject to such withholding tax. To obtain this exemption, a non-U.S. holder must provide us or our paying agent with an IRS Form W-8ECI properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, as defined under the Code, net of certain deductions and credits, subject to any applicable income tax treaty providing otherwise. In addition to the graduated tax described above, dividends received by corporate non-U.S. holders that are effectively connected with a U.S. trade or business of the corporate non-U.S. holder may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

Sale of Common Stock or Warrants

Non-U.S. holders will generally not be subject to United States federal income tax on any gains realized on the sale, exchange or other disposition of common stock or warrants unless:

- the gain (1) is effectively connected with the conduct by the non-U.S. holder of a U.S. trade or business and (2) if an income tax treaty between the United States and the non-U.S. holder's country of residence applies, the gain is attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder in the United States, in which case the special rules described below apply;
- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other disposition of our common stock, and certain other requirements are met, in which case the gain would be subject to a flat 30% tax, or such reduced rate as may be specified by an applicable income tax treaty, which may be offset by United States source capital losses, even though the individual is not considered a resident of the United States; or

- the rules of the Foreign Investment in Real Property Tax Act, or FIRPTA, treat the gain as effectively connected with a U.S. trade or business

The FIRPTA rules would apply to a sale, exchange or other disposition of common stock or warrants if we are, or were within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period, a "U.S. real property holding corporation," or USRPHC. In general, we would be a USRPHC if our interests in United States real estate comprised at least half of the fair market value of our assets. We do not believe that we are a USRPHC and we do not anticipate becoming one in the future. Even if we are or become a USRPHC, as long as our common stock is regularly traded on an established securities market, then only a non-U.S. holder that actually or constructively owns more than 5% of our outstanding common stock will be subject to United States federal income tax on the disposition of our common stock.

Any gain described in the first bullet point above will be subject to United States federal income tax at the regular graduated rates. If the non-U.S. holder is a corporation, under certain circumstances, that portion of its earnings and profits that is effectively connected with its U.S. trade or business, subject to certain adjustments, generally would be subject to a "branch profits tax." The branch profits tax rate is generally 30%, although an applicable income tax treaty between the United States and the non-U.S. holder's country of residence might provide for a lower rate.

Exercise or Lapse of the Warrants.

Upon the exercise of a warrant, a non-U.S. holder generally will not recognize gain or loss, except with respect to cash received in lieu of a fractional share of common stock. If a warrant is allowed to lapse unexercised, a non-U.S. holder generally will not recognize a capital loss unless such holder is otherwise subject to United States federal income tax. The receipt of cash in lieu of a fractional share of common stock in connection with an exercise of warrants will generally be treated as if you received the fractional share and then received such cash in redemption of such fractional share, which shall generally be treated as described above under "—Sale of Common Stock or Warrants".

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or "FATCA") on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or gross proceeds from the sale or other disposition of, our common stock or warrants paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code) (including, in some cases, when such foreign financial institution or non-financial foreign entity is acting as an intermediary), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each direct and indirect substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules and provides appropriate documentation (such as IRS Form W-8BEN-E). If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock, and will apply to payments of gross proceeds from the sale or other disposition of such stock or warrants on or after January 1, 2019.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock and warrants.

United States Federal Estate Tax

The estates of nonresident alien individuals generally are subject to United States federal estate tax on property with a United States situs. Because we are a United States corporation, our common stock and warrants will be United States situs property and therefore will be included in the taxable estate of a nonresident alien decedent, unless an applicable income tax treaty between the United States and the decedent's country of residence provides otherwise.

Backup Withholding and Information Reporting

We must report to a non-U.S. holder and the IRS the amount of dividends paid during each calendar year, if any, and the amount of any tax withheld. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the non-U.S. holder's conduct of a U.S. trade or business, or withholding was eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, however, generally will not apply to dividends paid a non-U.S. holder of shares of our common stock provided the non-U.S. holder furnishes to us or our paying agent the required certification under penalties of perjury as to its non-U.S. status, such as by providing a valid IRS Form W-8BEN or IRS Form W-8ECI, or certain other requirements are met. Notwithstanding the foregoing, backup withholding may apply if either we or our paying agent has actual knowledge, or reason to know, that the non-U.S. holder is a U.S. person as defined under the Code that is not an exempt recipient.

The payment of proceeds from the disposition of shares of our common stock or warrants by a non-U.S. holder made to or through a U.S. office of a broker generally will be subject to information reporting and backup withholding unless the non-U.S. holder furnishes to the broker the required certification as to its non-U.S. status, such as by providing the forms referenced above (and the broker does not have actual knowledge, or reason to know, that the holder is a U.S. person) and certain other conditions are met, or the non-U.S. holder otherwise establishes an exemption. The payment of proceeds from the disposition of shares of our common stock or warrants by a non-U.S. holder made to or through a non-U.S. office of a broker generally will not be subject to backup withholding or information reporting. Information reporting, but not backup withholding, will apply to a payment of proceeds, even if that payment is made outside of the United States, if a non-U.S. holder sells our common stock through a non-U.S. office of a broker with certain connections to the United States, unless the non-U.S. holder furnishes to the broker the required certification as to its non-U.S. status as described above and certain other conditions are satisfied, or the non-U.S. holder otherwise establishes an exemption (and the broker has no actual knowledge or reason to know to the contrary). Brokers required to file information returns with respect to stock in a corporation acquired on or after January 1, 2011 must also report (1) each customer's adjusted basis (computed in accordance with rules formulated for this reporting requirement) and (2) whether any gain or loss realized is long-term or short-term.

Backup withholding is not an additional tax and may be refunded to the extent it results in an overpayment of tax and appropriate information is timely supplied to the IRS.

THE PRECEDING DISCUSSION OF UNITED STATES FEDERAL TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR UNITED STATES FEDERAL, STATE, LOCAL AND FOREIGN TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK OR WARRANTS, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

LEGAL MATTERS

Certain legal matters with respect to the validity of the securities offered in this prospectus will be passed upon by LeClairRyan, a Virginia professional corporation, Newark, New Jersey for the Company and by [_____] for the underwriters.

EXPERTS

The consolidated financial statements of Acura Pharmaceuticals, Inc. as of December 31, 2015 and 2014 and for each of the years then ended included in this Prospectus have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, appearing elsewhere herein, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-_____) under the Securities Act with respect to the securities offered hereby. This prospectus, which constitutes part of the registration statement, does not contain all of the information included in the registration statement and exhibits. For further information pertaining to us and the securities offered hereby, you should refer to the registration statement and to its exhibits. Statements contained in this prospectus about the contents of any contract or any other document are not necessarily complete and, in each instance, we refer to you to the copy of the contract or other documents filed as an exhibit to or incorporated by reference to our filings with the SEC. Each of these statements is qualified in all respects by this reference.

We are subject to the reporting requirements of the Exchange Act and file annual, quarterly and current reports, proxy statements and other information with the SEC. We make available through our website at *www.acurapharm.com* annual reports, quarterly reports, current reports and amendments thereto as reasonably practicable after filing with the SEC. The contents of our website are not part of this prospectus, and you should not consider the contents of our website in making an investment decision with respect to our securities. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at *www.sec.gov*. You may also read and copy any document we file with the SEC at its Public Reference Room at 100 F. Street, N.E., Washington, D.C. 20549.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room.

ACURA PHARMACEUTICALS, INC
INDEX TO 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.

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. 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. 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

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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Acura Pharmaceuticals, Inc.
Palatine, Illinois

We have audited the accompanying consolidated balance sheets of Acura Pharmaceuticals Inc. as of December 31, 2015 and 2014 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Acura Pharmaceuticals Inc. at December 31, 2015 and 2014, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP
Chicago, Illinois

February 29, 2016

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2015 and 2014
(in thousands, except par value)

	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,485	$ 774
Marketable securities (Note 4)	10,837	11,322
Accounts receivable, net of allowances of $91 and $5	83	76
Accrued investment income	37	66
Inventories, net (Note 5)	276	304
Prepaid expenses and other current assets	417	471
Other current deferred assets	-	218
Total current assets	14,135	13,231
Property, plant and equipment, net (Note 6)	1,013	957
Intangible asset, net of accumulated amortization of $362 and $155 (Note 3)	1,638	1,845
Other assets	175	-
Total assets	$ 16,961	$ 16,033
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 110	$ 217
Accrued expenses (Note 7)	564	568
Accrued interest	-	70
Other current liabilities	45	26
Sales returns liability	205	-
Deferred revenue	-	353
Current maturities of long-term debt (Note 8)	2,320	1,758
Total current liabilities	3,244	2,992
Long-term debt, net of debt discount of $193 and $281 and debt issuance costs of $97 and $162 (Note 8)	5,430	7,799
Long-term portion of accrued interest	387	190
Total liabilities	9,061	10,981
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock: $.01 par value per share; 100,000 shares authorized, 11,801 and 9,770 shares issued and outstanding at 2015 and 2014, respectively	118	98
Additional paid-in capital	375,157	367,288
Accumulated deficit	(367,310)	(362,321)
Accumulated other comprehensive loss	(65)	(13)
Total stockholders' equity	7,900	5,052
Total liabilities and stockholders' equity	$ 16,961	$ 16,033

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
YEARS ENDED DECEMBER 31, 2015 and 2014
(in thousands, except per share amounts)

	2015	2014
Revenues:		
License fee revenue	$ 5,250	$ 500
Milestone revenue	2,500	-
Collaboration revenue	170	-
Royalty revenue	5	4
Product sales, net	662	247
Total revenues, net	8,587	751
Operating expenses:		
Cost of sales (excluding inventory write-down)	656	227
Inventory write-down (Note 5)	330	201
Research and development	2,608	4,582
Selling, marketing, general and administrative	8,994	7,940
Total operating expenses	12,588	12,950
Operating loss	(4,001)	(12,199)
Non-Operating income (expense):		
Investment income	166	198
Interest expense (Note 8)	(1,157)	(1,212)
Other income	3	4
Total other expense, net	(988)	(1,010)
Loss before income taxes	(4,989)	(13,209)
Provision for income taxes	-	-
Net loss	$ (4,989)	$ (13,209)
Other comprehensive loss:		
Unrealized losses on marketable securities	(52)	(32)
Total other comprehensive loss	(52)	(32)
Comprehensive loss	$ (5,041)	$ (13,241)
Loss per share:		
Basic	$ (0.46)	$ (1.35)
Diluted	$ (0.46)	$ (1.35)
Weighted average shares outstanding:		
Basic	10,796	9,779
Diluted	10,796	9,779

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2015 and 2014
(in thousands)

	Common Stock Shares	Common Stock $ Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at Jan. 1, 2014	9,665	$ 97	$ 366,919	$ (349,112)	$ 19	$ 17,923
Net loss	-	-	-	(13,209)	-	(13,209)
Other comprehensive loss	-	-	-	-	(32)	(32)
Share-based compensation	-	-	890	-	-	890
Net distribution of common stock pursuant to restricted stock unit award plan	165	2	(1)	-	-	1
Common shares withheld for withholding taxes on distribution of restricted stock units	(63)	(1)	(524)	-	-	(525)
Net issuance of common stock pursuant to cashless exercise of stock options	2	-	-	-	-	-
Common shares withheld for withholding taxes on cashless exercise of stock options	-	-	(4)	-	-	(4)
Issuance of common stock for exercise of stock options	1	-	8	-	-	8
Balance at Dec. 31, 2014	9,770	$ 98	$ 367,288	$ (362,321)	$ (13)	$ 5,052
Net loss	-	-	-	(4,989)	-	(4,989)
Other comprehensive loss	-	-	-	-	(52)	(52)
Share-based compensation	-	-	606	-	-	606
Net distribution of common stock pursuant to restricted stock unit award plan	19	-	-	-	-	-
Modification to warrants issued with promissory notes	-	-	33	-	-	33
Issuance of common stock under “at the market” offerings, net of offering costs of $8	54	-	217	-	-	217
Issuance of common stock under registered direct offering, net of offering costs of $603	1,958	20	7,013	-	-	7,033
Balance at December 31, 2015	11,801	$ 118	$ 375,157	$ (367,310)	$ (65)	$ 7,900

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2015 and 2014
(in thousands)

	2015	2014
Cash Flows from Operating Activities:		
Net loss	$ (4,989)	$ (13,209)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	125	119
Provision to reduce inventory to net realizable value	330	201
Provision for sales returns	267	-
Share-based compensation	606	890
Amortization of debt discount and debt issuance costs	186	188
Amortization of bond premium in marketable securities	127	250
Amortization of intangible asset	207	155
Gain on sales of marketable securities	(3)	(4)
Loss on disposals of property, plant and equipment	19	-
Changes in assets and liabilities:		
Accounts receivable, net	(69)	118
Accrued investment income	29	54
Inventories	(302)	(254)
Prepaid expenses and other current assets	54	158
Other current deferred assets	218	(32)
Other assets	(175)	5
Accounts payable	(107)	(57)
Accrued expenses	(4)	27
Deferred revenue	(353)	66
Accrued interest – current and long term	127	260
Other current and non-current liabilities	19	21
Net cash used in operating activities	(3,688)	(11,044)
Cash Flows from Investing Activities:		
Purchases of marketable securities	(3,522)	(2,203)
Proceeds from sale and maturities of marketable securities	3,830	4,336
Acquisition of product rights	-	(2,000)
Additions to property, plant and equipment	(214)	(135)
Proceeds from disposals of property, plant and equipment	14	-
Net cash provided by (used in) by investing activities	108	(2)
Cash Flows from Financing Activities:		
Proceeds from exercise of stock options	-	8
Proceeds from distribution of restricted stock units	1	1
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	-	(529)
Proceeds from “at-the-market” offering	225	-
Proceeds from registered direct offering	7,636	-
Offering transaction costs	(611)	-
Principal payments on debt	(1,960)	-
Net cash provided by (used in) financing activities	5,291	(520)
Net increase (decrease) in cash and cash equivalents	1,711	(11,566)
Cash and cash equivalents at beginning of year	774	12,340
Cash and cash equivalents at end of year	$ 2,485	$ 774
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest	$ 844	$ 765
Income taxes, net of refunds	$ -	$ 14

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
YEAR ENDED DECEMBER 31, 2015 and 2014

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

Year ended December 31, 2015

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

Year ended December 31, 2014

1. 166 thousand shares of common stock were eligible for distribution pursuant to our 2005 RSU Plan utilizing various cashless exercise features of the plan. After withholding 1 thousand shares for $7 in exercise costs and withholding 63 thousand shares for $525 in statutory minimum payroll taxes, we issued 102 thousand shares of common stock.

2. Options to purchase 5 thousand shares of common stock were exercised utilizing various cashless exercise features of the stock option plan. After withholding 3 thousand shares for $32 in exercise costs and withholding 1 thousand shares for $4 in statutory minimum payroll taxes, we issued 1 thousand shares of common stock.

See accompanying Notes to Consolidated Financial Statements.

NOTE 1 - DESCRIPTION OF BUSINESS

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the "Company", "We", or "Our") is a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Aversion® and Limitx™ Technologies are intended to address methods of product tampering associated with opioid abuse while our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine into methamphetamine. Oxaydo® Tablets (oxycodone HCl, CII), which utilizes the Aversion Technology, is the first and only approved immediate-release oxycodone product in the United States with abuse deterrent labeling. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation (collectively, "Egalet") pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is currently approved by the FDA for marketing in the United States in 5mg and 7.5mg strengths. Egalet launched Oxaydo in the United States late in the third quarter of 2015. We launched our first Impede Technology product, Nexafed, into the United States market in December 2012 and launched our Nexafed Sinus Pressure + Pain product in the United States in February 2015. We have multiple pseudoephedrine products in development utilizing our Impede Technology. On June 15, 2015, we and Bayer Healthcare LLC ("Bayer") entered into a License and Development Agreement (the "Bayer Agreement") pursuant to which we granted Bayer an exclusive worldwide license to our Impede Technology for use in an undisclosed methamphetamine resistant pseudoephedrine – containing product and providing for the joint development of such product using our Impede Technology for the U.S. market. Our third abuse deterrent technology, Limitx, is designed to retard the release of active drug ingredients when too many tablets are accidently or purposefully ingested. In January 2016, our Investigational New Drug Application, or IND, filed with the FDA for our lead Limitx oral abuse deterrent drug candidate using the opioid hydromorphone HC1 ("LTX-04"), was allowed to proceed to clinical testing. We have commenced our initial Phase I exploratory pharmacokinetic study of LTX-04. We are also developing an immediate-release hydrocodone bitartrate with acetaminophen product utilizing our Limitx technology.

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

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The consolidated financial statements include the accounts of our wholly-owned subsidiary, Acura Pharmaceutical Technologies Inc., after elimination of intercompany accounts and transactions.

Reclassifications

Certain reclassifications have been made to the prior years' amounts to conform to the current year's presentation.

Management Estimates

Management is required to make certain estimates and assumptions in order to prepare consolidated financial statements in conformity with GAAP. Such estimates and assumptions affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. Management periodically evaluates estimates used in the preparation of the consolidated financial statements for continued reasonableness. Appropriate adjustments, if any, to the estimates used are made prospectively based on such periodic evaluations.

Cash and Cash Equivalents

The Company considers cash and cash equivalents to include cash in financial institutions and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Our cash and cash equivalents are governed by our investment policy as approved by our Board of Directors. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term nature.

Marketable Securities

The Company's marketable securities at December 31, 2015 and 2014 primarily consist of corporate debt securities and exchange-traded funds. Our marketable securities are governed by our investment policy as approved by our Board of Directors. The Company's marketable securities are classified as available-for-sale and are recorded at fair value, based upon quoted market prices or net asset value. Unrealized temporary adjustments to fair value are included in a separate component of stockholders' equity as unrealized gains and losses and reported as a component of accumulated other comprehensive income (loss). No gains or losses on marketable securities are realized until shares are sold or a decline in fair value is determined to be other-than-temporary. If a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established.

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.

Concentration of Credit Risk

Credit Risk: Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and cash equivalents, marketable securities and accounts receivable. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. However, management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company's excess cash is invested in accordance with the investment policy approved by our Board of Directors that seeks a combination of both liquidity and safety of principal using diversification of investments, through investments such as investment grade corporate debt securities with varying maturities. To date, the Company has not experienced any material realized losses on its cash, cash equivalents, and marketable securities.

Customers: We launched our first Impede Technology product, Nexafed®, in the United States in December 2012 and our Nexafed Sinus Pressure + Pain product in the United States in February 2015. Our accounts receivable arise from our sales of our Nexafed product line and represent amounts due from wholesalers in the health care and pharmaceuticals industries and from chain drug stores. The Company has performed a credit evaluation of its customers and may maintain an allowance for potentially uncollectable accounts. We have not experienced any losses on uncollectable accounts in 2015 or 2014.

Sales to certain of our customers during 2015 and 2014 accounting for 10% or more of our annual product sales, whether the product shipment was recognized immediately as a sales or as a deferred sale, are presented below. Sales to customers designated with an " * " accounted for less than 10% of our annual product sales.

Customer	2015	2014
Rite Aid Corporation	54%	28%
Cardinal Health, Inc.	14%	24%
AmerisourceBergen Corporation	*	13%
McKesson Corporation	*	13%
Kroger Foods	*	11%

Accounts receivable from certain of our customers at December 31, 2015 and 2014 accounting for 10% or more of our gross accounts receivable are presented below. Accounts receivable from customers designated with an " ** " accounted for less than 10% of our gross accounts receivable.

Customer	2015	2014
Rite Aid Corporation	68%	83%
McKesson Corporation	11%	**
Kroger Foods	**	13%

Inventories

Inventories at December 31, 2015 consist of finished goods held for distribution and sale on our Nexafed® product line. Inventories at December 31, 2014 consisted of both raw and packaging materials on our Oxaydo product and finished goods held for distribution and sale on our Nexafed® product. During 2014, we purchased raw material and packaging material inventories for $260 thousand from Pfizer on the Oxaydo product we reacquired from them. Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value). The Company writes down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results.

Our purchases of active pharmaceutical ingredients and raw materials required for our development and clinical trial manufacture of product candidates utilizing our Aversion®, Impede® or Limitx Technologies are expensed as incurred.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation. We have no leasehold improvements. Betterments are capitalized and maintenance and repairs are charged to operations as incurred. When a depreciable asset is retired from service, the cost and accumulated depreciation is removed from the respective accounts.

Depreciation expense is recorded on a straight-line basis over the estimated useful lives of the related assets. The estimated useful lives of the major classification of depreciable assets are:

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

Deferred Debt Issuance Costs and Debt Discount

Deferred debt issuance costs include costs of debt financing undertaken by the Company, including legal fees, placement fees and other direct costs of the financing. Debt discount is the value attributable to warrants issued in conjunction with the financing. Debt issuance costs and debt discount are amortized into interest expense over the term of the related debt using the effective interest method. See *Recent Accounting Pronouncements* for discussion on the presentation of deferred debt issuance costs as a direct reduction against long-term debt.

License Fee Revenue

In December 2014, the Company entered into an agreement with Purdue Pharma to settle a patent interference action regarding certain intellectual property held by Acura (U.S. Patent No. 8,101,630). The dispute centered on 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 into an agreement whereby Acura conceded Purdue's claim of priority in exchange for certain financial consideration to Acura including an immediate non-refundable payment of $500 thousand. In June 2015, the Company received an additional $250 thousand payment from Purdue relating to the December 2014 agreement. These amounts were recognized as revenue when received.

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 $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 3).

Milestone Revenue

Milestone revenue is contingent upon the achievement of certain pre-defined events in the development agreements. Milestone payments are recognized as revenue upon achievement of the "at risk" milestone events, which represent the culmination of the earnings process related to that milestone. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones are substantially at risk at the inception of an agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment. Each milestone payment is non-refundable and non-creditable when made and is recognized as revenue when received. In October 2015, Egalet paid us a $2.5 million milestone payment in connection with the event of the first commercial sale of Oxaydo.

Collaboration Revenue

Collaboration revenue is derived from reimbursement of development expenses, such as under our agreement with Bayer, and are recognized when costs are incurred pursuant to the agreements. The ongoing research and development services being provided under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration agreements. We recognized $170 thousand of collaboration revenue during the year 2015.

Royalty Revenue

In connection with our Collaboration and License Agreement with Egalet to commercialize Oxaydo tablets we will receive a stepped royalty at percentage rates ranging from mid-single digits to double-digits based on Oxaydo net sales during each calendar year over the term of the agreement (excluding net sales resulting from any co-promotion efforts by us). We recognize royalty revenue each calendar quarter based on net sales reported to us by Egalet in accordance with the agreement. Egalet's first commercial sale of Oxaydo occurred in October 2015 and we have recorded royalties of $5 thousand on net sales during the fourth quarter 2015 (see Note 3).

In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer Inc. (the "Pfizer Agreement"), we began earning royalties on Oxecta starting in February 2013. We recorded royalties of approximately $4 thousand for the year ended December 31, 2014. Effective April 9, 2014, the Pfizer Agreement was terminated and the rights to Oxecta were returned to us after making a one-time payment of $2.0 million to Pfizer (see Note 3).

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 2014, we continued deferring the recognition of revenue and at December 31, 2014 we had accumulated deferred revenue of $353 thousand of Nexafed shipments. 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 recorded cost of sales of $255 thousand. We currently recognize revenue from our Nexafed product line when the price is fixed and determinable at the date of sale, title and risk of ownership have been transferred to the customer, and returns can be reasonably estimated, which generally occurs at the time of product shipment. At December 31, 2015, we have a $205 thousand sales returns liability which will be reviewed against sales returns activity each calendar quarter for adjustment.

Advertising Costs

The Company records the cost of its advertising efforts when services are performed or goods are delivered.

Shipping and Handling Costs

The Company records shipping and handling costs in selling expenses. The amounts recorded from the sales of Nexafed® were not material.

Impairment of Long-Lived Assets

Long-lived assets such as the intangible asset and property, plant and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of the assets to be held and used is measured by a comparison of the carrying amount of the asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying value of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. We had no impairment charges for the years ended 2015 and 2014.

Research and Development Activities

Research and Development (“R&D”) expenses include internal R&D activities, external Contract Research Organization (“CRO”) services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. We make payments to the CRO's based on agreed upon terms and may include payments in advance of a study starting date. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. During 2015, we entered into a 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 $0.2 million was remaining under this agreement at December 31, 2015. During 2014, we entered into several cancelable CRO arrangements and our remaining obligations under these arrangements were approximately $0.1 million at December 31, 2014 for services to be incurred as subjects are enrolled and progress through the studies. We did not have prepaid CRO costs and clinical trial study expenses at either December 31, 2015 or 2014.

Share-based Compensation

We have several share-based compensation plans covering stock options and RSUs for our employees and directors, which are described more fully in Note 11.

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 instruments issued comprised the following (in thousands):

	Year ended December 31,	
	2015	2014
Research and development:		
Stock option awards	$ 158	$ 220
RSU awards	-	-
	$ 158	$ 220
Selling, general and administrative:		
Stock option awards	384	550
RSU awards	95	146
	$ 479	$ 696
Total share-based compensation expense	$ 637	$ 916

Comprehensive Income (Loss)

Comprehensive income (loss) includes all changes in equity during a period except those that resulted from investments by or distributions to the Company's stockholders. Other comprehensive income (loss) refers to revenues, expenses, gains and losses that, under GAAP, are included in comprehensive income (loss), but excluded from net income (loss) as these amounts are recorded directly as an adjustment to stockholders' equity. The Company's other comprehensive income (loss) is composed of unrealized gains (losses) on certain holdings of marketable securities, net of any realized gains (losses) included in net income (loss).

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 the financial reporting and the income tax basis of assets and liabilities and are measured 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 December 31, 2015 and 2014, 100% of all remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss 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.

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 11). Diluted EPS is based on the treasury stock method and computed based on the same number of shares used in the basic share calculation and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and stock warrants, assuming the exercise of all in-the-money stock options and warrants. alents are excluded from the computation where their inclusion would be anti-dilutive. No such adjustments were made for 2015 or 2014 as the Company reported a net loss for the years and including the effects of common stock equivalents in the diluted EPS calculation would have been antidilutive.

A reconciliation of the numerators and denominators of basic and diluted EPS consisted of the following (in thousands, except per share data):

	Years ended December 31,	
	2015	2014
EPS - basic		
Numerator: net loss	$ (4,989)	$ (13,209)
Denominator (weighted):		
Common shares	10,777	9,770
Vested RSUs	19	9
Basic weighted average shares outstanding	10,796	9,779
EPS - basic	$ (0.46)	$ (1.35)
EPS – assuming dilution		
Numerator: net loss	$ (4,989)	$ (13,209)
Denominator (weighted):		
Common shares	10,777	9,770
Vested RSUs	19	9
Stock options	-	-
Common stock warrants	-	-
Diluted weighted average shares outstanding	10,796	9,779
EPS - diluted	$ (0.46)	$ (1.35)
Excluded dilutive securities:		
Common stock issuable (non weighted):		
Stock options	1,198	911
Common stock warrants	60	60
Total excluded potentially dilutive shares	1,258	971

Recent Accounting Pronouncements

Revenue from Contracts with Customers

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

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

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

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

Presentation of Debt Issuance Costs

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

NOTE 3 – LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENTS

Egalet Agreement

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

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

Egalet paid us a $5.0 million license fee upon signing of the Egalet Agreement and a $2.5 million milestone on October 9, 2015 in connection with the first commercial sale 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. We are receiving from Egalet a stepped royalty at percentage rates ranging from mid-single digits to double-digits based on Oxaydo net sales during each calendar year (excluding net sales resulting from our co-promotion efforts). In any calendar year of the agreement in which net sales exceed a specified threshold, we will receive a double digit royalty on all Oxaydo net sales in that year (excluding net sales resulting from our co-promotion efforts). If we exercise our co-promotion rights, we will receive a share of the gross margin attributable to incremental Oxaydo net sales from our co-promotion activities. Egalet's royalty payment obligations commence on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA's Orange Book remains with respect to Oxaydo). Royalties will be reduced upon the entry of generic equivalents, as well as for payments required to be made by Egalet to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

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

Bayer Agreement

On June 15, 2015, we and Bayer entered into a License and Development Agreement (the "Bayer Agreement") granting Bayer an exclusive worldwide license to our Impede Technology for use in an undisclosed methamphetamine resistant pseudoephedrine –containing product (the "Bayer Licensed Product") and providing for the joint development of such product utilizing our Impede Technology for the U.S. market. The 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 Agreement with respect to each country expires when royalties are no longer payable with respect to such country. After expiration of the term Bayer retains a license to sell the Bayer Licensed Product on a royalty free basis. Either party may terminate the Agreement in its entirety if the other party materially breaches the Agreement, subject to an applicable cure period, or in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws. Bayer may terminate the Agreement immediately prior to completion of our development obligations or at any time upon six (6) months prior written notice thereafter. We may terminate the Agreement with respect to the U.S. if Bayer ceases or suspends development or commercialization of the Bayer Licensed Product for a certain period of time.

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 two letter agreements 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 the year ended December 31, 2015 and 2014, we recorded amortization expense of $207 thousand and $155 thousand, respectively. We also purchased from Pfizer selected raw and packaging material inventories for $260 thousand relating to Oxaydo. In 2015, we wrote off and disposed of these inventories.

NOTE 4 – INVESTMENTS IN MARKETABLE SECURITIES

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

	December 31, 2015	December 31, 2014
Marketable securities:		
Corporate bonds — maturing within 1 year	$ 3.1	$ 3.5
Corporate bonds — maturing after 1 year and through March 2017	0.4	2.8
Exchange-traded funds	7.3	5.0
Total marketable securities	$ 10.8	$ 11.3

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

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

	December 31, 2015			
	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

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

Fair Value Measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants. Fair values determined based on Level 1 inputs utilize quoted market prices in active markets for identical assets or liabilities. Fair values determined based on Level 2 inputs utilize observable market-based inputs or unobservable inputs that are corroborated by market data. Fair values determined based on Level 3 inputs utilize unobservable inputs reflecting the reporting entity's own assumptions. A financial asset or liability's classification within the above hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

Our assets measured at fair value or disclosed at fair value on a recurring basis as at December 31, 2015 and 2014 consisted of the following (in millions):

	December 31, 2015			
	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	$ -

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

Accumulated Other Comprehensive Income (Loss)

Unrealized gains or losses on marketable securities are recorded in accumulated other comprehensive income (loss). Accumulated other comprehensive income (loss) at December 31, 2015 and 2014 consisted of unrealized losses on securities of $65 thousand and $13 thousand, respectively.

NOTE 5 – INVENTORIES

Inventories at December 31, 2015 consist of finished goods held for distribution and sale on our Nexafed product line. Inventories at December 31, 2014 consisted of both raw and packaging materials on our Oxaydo product and finished goods held for distribution and sale on Nexafed product. During 2014, we purchased selected raw and packaging material inventories for $260 thousand from Pfizer related to the Oxaydo product we reacquired from them (see Note 3). During 2015, we wrote off and disposed of the inventories. 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.

At December 31, 2014 we had deferred revenue of $350 thousand from our Nexafed product shipments to customers. The related cost of sales of $218 thousand is reported in our balance sheet in the other current deferred assets account and excluded from the reported year end inventories at December 31, 2014. During 2015, we recorded a one-time adjustment 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 we recorded cost of sales of $255 thousand.

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

Inventories are summarized as follows (in thousands):

	December 31,	
	2015	2014
Raw and packaging	$ -	$ 260
Finished goods	346	44
Total inventory	346	304
Less: inventory reserve - finished goods	(70)	(-)
Net inventory	$ 276	$ 304

Inventory reserve activity during the years ended December 31, 2015 and 2014 was as follows (in thousands):

	2015	2014
Beginning of year	$ -	$ 250
Reserve expense - raw and packaging	260	-
Reserve expense - finished goods	70	201
	330	451
Inventory write-offs - raw and packaging	(260)	-
Inventory write-offs - finished goods	-	(451)
End of year	$ 70	$ -

NOTE 6 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows (in thousands):

	December 31,	
	2015	2014
Building and improvements	$ 1,265	$ 1,259
Scientific equipment	598	595
Computer hardware and software	124	252
Machinery and equipment	508	386
Land and improvements	162	162
Other personal property	70	70
Office equipment	27	27
	2,754	2,751
Less: accumulated depreciation	(1,741)	(1,794)
Total property, plant and equipment, net	$ 1,013	$ 957

Depreciation expense was approximately $0.1 million for each of the years ended December 31, 2015 and 2014.

NOTE 7 – ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	December 31,	
	2015	2014
Professional services	$ 171	$ 253
Other fees and services	64	110
Payroll, payroll taxes and benefits	101	94
Clinical and regulatory services	92	83
Marketing, advertising, and promotion	115	-
Property taxes	15	15
Franchise taxes	6	13
	$ 564	$ 568

NOTE 8 – DEBT

On December 27, 2013, we entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford" or the "Lender"), for a term loan to 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 December 31, 2015, we have made $1.96 million in principal payments. As security for its obligations under the Loan Agreement, the Company granted Lender a security interest in substantially all of its existing and after−acquired assets, exclusive of its intellectual property assets. Pursuant to the Loan Agreement, the Company is not allowed to pledge its intellectual property assets to others. Upon the execution of the Loan Agreement, we issued to the Lender warrants to purchase an aggregate of up to 60 thousand shares of our common stock at an exercise price equal to $7.98 per share (after adjustment for our one-for-five reverse stock split) (the "Warrants"). We recorded $400 thousand as debt discount associated with the fair value of the Warrants and are amortizing it to interest expense over the term of the loan using the loan's effective interest rate. The Warrants are immediately exercisable for cash or by net exercise and will expire December 27, 2020. The fair value of the warrants was determined using the Black-Scholes option-pricing model. Significant assumptions used in the Black-Scholes model were:

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

On January 7, 2015, we and Oxford entered into an amendment to the Loan Agreement. Pursuant to the amendment, (i) the exercise price of the Warrants was lowered from $7.98 to $2.52 per share (the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the amendment and after giving effect to our one-for-five reverse stock split) and we recorded additional debt discount of $33 thousand representing the fair value of the warrant modification, (ii) we agreed to maintain $2.5 million cash reserves until such time as we have repaid $5.0 million in principal of the Term Loan, and (iii) the Lender consented to the terms of our Collaboration and License Agreement with Egalet relating to our Oxaydo product.

The Company may voluntarily prepay the Term Loan in full, but not in part, and any prepayment is subject to a prepayment premium equal to 1% of the principal prepaid. In addition, at the maturity, termination or upon voluntary or mandatory prepayment of the Term Loan the Company must pay the Lender an additional one-time interest payment of $795 thousand. We are accruing additional monthly interest expense over the term of the loan for this additional one-time interest payment using the loan's effective cash interest rate.

The Company was obligated to pay customary lender fees and expenses, including a one-time facility fee of $50 thousand and the Lender's expenses in connection with the Loan Agreement. Combined with the Company's own expenses and a $100 thousand consulting placement fee, the Company incurred $231 thousand in deferred debt issue costs. We are amortizing these costs, including debt modification additional costs, into interest expense over the term of the loan using the loan's effective interest rate of 10.16%.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, limits or restrictions on the Company's ability to incur liens, incur indebtedness, pay dividends, redeem stock, and merge or consolidate and dispose of assets. In addition, it contains customary events of default that entitles the Lender to cause any or all of the Company's indebtedness under the Loan Agreement to become immediately due and payable. The events of default (some of which are subject to applicable grace or cure periods), include, among other things, non−payment defaults, covenant defaults, a material adverse change in the Company, bankruptcy and insolvency defaults and material judgment defaults.

Our debt is summarized below (in thousands):

Long-term Debt	Current	Long-term	Total
Balance at Dec 31, 2014	$ 1,758	$ 8,242	$ 10,000
Principal payments	(1,960)	-	(1,960)
Classification	2,522	(2,522)	-
Balance at Dec 31, 2015	$ 2,320	$ 5,720	$ 8,040

Debt Discount	Current	Long-term	Total
Balance at Dec 31, 2014	$ -	$ (281)	$ (281)
Modification of warrants	-	(33)	(33)
Amortization expense	-	121	121
Balance at Dec 31, 2015	$ -	$ (193)	$ (193)

Deferred Debt Issuance Costs	Current	Long-term	Total
Balance at Dec 31, 2014	$ -	$ (162)	$ (162)
Amortization expense	-	65	65
Balance at Dec 31, 2015	$ -	$ (97)	$ (97)
Long-term Debt, net at Dec 31, 2015	$ 2,320	$ 5,430	$ 7,750

Our interest expense consisted of the following (in thousands):

	2015	2014
Interest expense:		
Term Loan	$ 971	$ 1,024
Debt discount	121	119
Debt issue costs	65	69
Total interest expense	$ 1,157	$ 1,212

The annual principal payments of the debt at December 31, 2015 are as follows:

Year	Annual Principal Payments (in thousands)
2016	$ 2,320
2017	2,741
2018	2,979
Total	$ 8,040

NOTE 9 – EQUITY FINANCINGS

Our universal shelf registration statement on Form S-3 was declared effective by the Securities and Exchange Commission ("SEC") on March 15, 2013. On April 18, 2013, we filed a prospectus supplement with the SEC pursuant to which we could sell shares of our common stock from time to time in "at the market" offerings and certain other transactions, having sales proceeds of up to $13 million. We did not sell any shares of our common stock pursuant to our prospectus supplement during the year ended December 31, 2014. During the year ended December 31, 2015, we sold approximately 54 thousand shares of our common stock (after giving effect to our one-for-five reverse stock split) for gross proceeds of $225 thousand. Transaction costs were approximately $8 thousand. The net proceeds of $217 thousand were used for general corporate purposes. In order to allow for the sale of our shares of common stock under our shelf registration statement pursuant to the Placement Agency Agreement and Securities Purchase Agreement described below, on June 30, 2015, we and MLV & Co., LLC, as sales agent, terminated the at-market issuance sales agreement dated April 18, 2013, thereby terminating any further "at the market offerings" under our prospectus supplement filed with the SEC on April 18, 2013.

On June 30, 2015, we entered into a Placement Agency Agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC ("Roth"), pursuant to which we engaged Roth to act as sole placement agent in a registered direct offering (the "Offering") of 1.958 million shares of our common stock, par value $.01 (after giving effect to our one-for-five reverse stock split). On June 30, 2015, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors (the "Purchasers"), pursuant to which we agreed to sell 1.958 million shares of our common stock at a price of $3.90 per share (after giving effect to our one-for-five reverse stock split) to the Purchasers in the Offering, for gross proceeds to the Company of $7.64 million, before expenses. The Offering was made pursuant to a prospectus supplement dated June 30, 2015 filed with the Securities and Exchange Commission in connection with a takedown from the Company's shelf registration statement on Form S-3 (File No. 333-187075), which became effective on March 15, 2013, and the related base prospectus included in the Registration Statement, as supplemented by the prospectus supplement. The transactions contemplated by the Placement Agency Agreement and the Purchase Agreement closed on July 7, 2015.

Pursuant to the terms of the Placement Agency Agreement, we paid Roth a cash placement fee equal to 6.5% of the gross proceeds in the Offering or $496 thousand, and reimbursed Roth $35 thousand for its expenses. The net proceeds from the Offering, after these and other legal expenses, was $7.0 million.

NOTE 10 – 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 8 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 years ended December 31, 2015 and 2014 is shown below (in thousands except price data):

	December 31,			
	2015		2014	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, beginning	60	$ 7.98	431	$ 15.75
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	(371)	17.00
Modification	-	(5.46)	-	-
Outstanding, ending	60	$ 2.52	60	$ 7.98

NOTE 11 – EMPLOYEE BENEFIT PLANS

401(k) and Profit-Sharing Plan

We have a 401(k) and Profit-Sharing Plan (the "Plan") for our employees. Employees may elect to make a basic contribution of up to 80% of their annual earnings subject to certain regulatory restrictions on their total contribution. The Plan provides that the Company can make discretionary matching contributions along with a discretionary profit-sharing contribution. We did not contribute a matching contribution or a profit sharing contribution to the Plan in years 2015 or 2014.

Stock Option Plans

We maintain various stock option plans. A summary of our stock option plans as of December 31, 2015 and 2014 and for the years then ended consisted of the following (in thousands except exercise price):

	Years Ended December 31,			
	2015		2014	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, beginning	911	$ 20.70	747	$ 24.95
Granted	315	2.01	180	2.60
Exercised	-	-	(6)	6.50
Forfeited or expired	(28)	26.75	(10)	17.50
Outstanding, ending	1,198	$ 15.67	911	$ 20.70
Options exercisable	814	$ 22.04	695	$ 26.05

The following table summarizes information about nonvested stock options outstanding at December 31, 2015 (in thousands except per price data):

	Number of Options Not Exercisable	Weighted Average Fair Value
Outstanding at December 31, 2014	216	$ 3.30
Granted	315	2.01
Vested	(146)	3.70
Forfeited	(1)	2.69
Outstanding at December 31, 2015	384	$ 1.85

We estimate the option's fair value on the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to expected term, forfeitures, volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as we have not paid any cash dividends) and employee exercise behavior. Expected volatilities utilized in the Black-Scholes model are based on the historical volatility of our common stock price. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected life of the grants is derived from historical exercise activity. Historically, the majority of our stock options have been held until their expiration date.

The assumptions used in the Black-Scholes model to determine fair value for the 2015 and 2014 stock option grants were:

	2015	2014
Expected dividend yield	0.0%	0.0%
Risk-free interest rates	2.2%	2.2%
Average expected volatility	89%	97%
Expected term (years)	10	10
Weighted average grant date fair value	$ 1.72	$ 2.30

The intrinsic value of the option awards which were vested and outstanding at December 31, 2015 and 2014 was $6 thousand and $0 thousand, respectively. The total remaining unrecognized compensation cost on unvested option awards outstanding at December 31, 2015 was $711 thousand, and is expected to be recognized in operating expense in varying amounts over the 23 months remaining in the requisite service period.

Information about the cashless stock option exercises during the last two years is as follows:

- There were no option awards exercised during 2015.
- During 2014, options to purchase 5 thousand shares of common stock were exercised utilizing various cashless exercise features of our stock option plan and after withholding 3 thousand shares for $32 thousand in exercise costs and $1 thousand in statutory minimum withholding payroll taxes, we issued 2 thousand shares of common stock.

Restricted Stock Unit Award Plan

We have two Restricted Stock Unit Award Plans for our employees and non-employee directors, a 2014 Restricted Stock Unit Award Plan (the "2014 RSU Plan") and a 2005 Restricted Stock Unit Award Plan (the "2005 RSU Plan"). Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. The share-based compensation cost to be incurred on a granted RSU is the RSU's fair value, which is the market price of our common stock on the date of grant, less its exercise cost. The compensation cost is amortized to expense over the vesting period of the RSU award.

A summary of the grants under the RSU Plans as of December 31, 2015 and 2014, and for the years then ended consisted of the following (in thousands):

	Years Ended December 31,			
	2015		2014	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	29	29	166	166
Granted	42	-	29	-
Distributed	(26)	(26)	(166)	(166)
Vested	-	42	-	29
Forfeited or expired	-	-	-	-
Outstanding, ending	45	45	29	29

2014 Restricted Stock Unit Award Plan

Our 2014 RSU Plan was approved by shareholders on May 1, 2014 and permits the grant of up to 400 thousand shares of our common stock pursuant to awards under the 2014 RSU Plan. As of December 31, 2015, 330 thousand shares are available for award under the 2014 RSU Plan.

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

- On May 1, 2014, we awarded approximately 7 thousand RSUs to each of our 4 non-employee directors. Such RSU awards vested 50% on June 30, 2014 and 25% on each of September 30 and December 31, 2014. Such non-employee director awards allow for non-employee directors to receive payment in cash, instead of stock, for up to 40% of each RSU award. The RSU awards subject to cash settlement were recorded as a liability in the Company's balance sheet. The liability was $26 thousand at December 31, 2014. Accordingly the vested portion of the awards containing the cash settlement feature are being marked-to-market each reporting period until they are distributed. Marked-to-market accounting can create fluctuations in our compensation expense including the need to record additional expense. RSU awards are generally distributed on the first business day of the year after vesting, but such distribution can be deferred until a later date at the election of the non-employee director.
- On January 2, 2015, we awarded approximately 10 thousand RSUs to each of our 4 non-employee directors which also allow for them to receive payment in cash, instead of stock, for up to 40% of each RSU award. Such awards vest 25% at the end of each calendar quarter in 2015. The RSU awards subject to cash settlement are subject to marked-to market accounting and the liability recorded in the Company's balance sheet was $45 thousand at December 31, 2015. Distributions of stock under the January 2, 2015 award cannot be deferred until a later date and the stock under such awards were distributed on January 4, 2016.

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

- On January 2, 2015, 26 thousand RSUs from the May 1, 2014 award were distributed and 4 thousand RSUs were deferred until a future distribution date. Of the 26 thousand RSUs distributed, 19 thousand RSUs were distributed in common stock and 7 thousand RSUs were settled in cash.
- On January 4, 2016, 1 thousand RSUs from the May 1, 2014 award and 41 thousand RSUs from the January 2, 2015 award were distributed. There are 2 thousand RSUs from the May 1, 2014 award which remain deferred until a future distribution date. Of the 42 thousand RSUs distributed, 33 thousand RSUs were distributed in common stock and 9 thousand RSUs were settled in cash.

2005 Restricted Stock Unit Award Plan

Under our 2005 RSU Plan, one-fourth of vested shares of common stock underlying the aggregate RSU awards of 660 thousand shares, or 166 thousand shares, were distributed (after payment of exercise costs of $0.01 par value per share) on January 1 of each of the years 2011 thru 2014. On January 1, 2014, 102 thousand shares were distributed to the holders while 63 thousand shares were withheld by the Company upon elections made to exchange RSUs in satisfaction of $525 thousand withholding tax obligations. All RSUs granted under the 2005 RSU Plan had been distributed effective January 1, 2014.

NOTE 12 – INCOME TAXES

Provision for Income Taxes

The reconciliation between our provision for income taxes and the amounts computed by multiplying our loss before taxes by the U.S. statutory tax rate is as follows (in thousands):

	December 31, 2015	2014
Benefit at U.S. statutory 34% tax rate	$ (1,696)	$ (4,491)
State taxes (benefit), net of federal effect	41	65
Research and development tax credits	-	(30)
Share-based compensation	184	262
Other	11	2
Change in valuation allowance	1,460	4,192
Provision for income taxes	$ -	$ -

Deferred Tax Assets and Valuation Allowance

Deferred tax assets reflect the tax effects of net operating losses ("NOLs"), tax credit carryovers, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The most significant item of our deferred tax assets is derived from our Federal NOLs. 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. The net change in the valuation allowance in 2015 and 2014 was approximately $0.6 million and $2.4 million, respectively.

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. The components of our deferred tax assets are as follows:

	December 31, 2015	2014
	(in thousands)	
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	$ 52,772	$ 51,503
- State	2,050	2,898
Research and development tax credits	1,394	1,398
Share-based compensation	38	45
Other, net	368	151
Total deferred taxes	56,622	55,995
Valuation allowance	(56,622)	(55,995)
Net deferred tax assets	$ -	$ -

Realization of deferred tax assets is dependent upon future earnings, if any, and the timing and amount of which may be uncertain. Valuation allowances are placed on deferred tax assets when uncertainty exists on their near term utilization. We make periodic reviews of our valuation allowances and fluctuations can occur. Those fluctuations may be reflected as income tax expenses or benefits in the period they occur. We continue to maintain full valuation allowance against all of our deferred tax assets at December 31, 2015 due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that amounts of our deferred tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and a benefit from income taxes in such period would be recognized.

Uncertainty in Income Taxes

We adopted FASB's statement regarding accounting for uncertainty in income taxes which defined the threshold for recognizing the benefits of tax-return positions in the consolidated financial statements as "more-likely-than-not" to be sustained by the taxing authorities. Our adoption of the standard did not result in establishing a contingent tax liability reserve or a corresponding charge to retained earnings. At each of December 31, 2015 and 2014, we had no liability for income tax associated with uncertain tax positions. If in the future we establish a contingent tax liability reserve related to uncertain tax positions, our practice will be to recognize the interest in interest expense and the penalties in other non-operating expense.

The Company files federal and state income tax returns and in the normal course of business the Company is subject to examination by these taxing authorities. As of December 31, 2015, the Company's tax years 2012, 2013 and 2014 are subject to examination by the taxing authorities. With few exceptions, we believe the Company is no longer subject to U.S. federal, state and local examinations by taxing authorities for years before 2012.

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Purdue Pharma Complaints

In April 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (collectively, "Purdue") commenced a patent infringement lawsuit against us and our Oxaydo product licensee Egalet US, Inc. and its parent Egalet Corporation in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's U.S. Patent No. 8,389,007 (the "'007 patent"). The complaint seeks injunctive relief as well as awards of damages and attorneys' fees. In January 2016, the District Court issued a claim construction order in the patent infringement action. The order stated that the term polyvinylpyrrolidone as that term is defined in the claims of the Purdue patent covers all polymeric forms of vinylpyrrolidone, including crospovidone used in Oxaydo. We deny the allegations in the complaint, believe they are without merit and are defending the action vigorously. As is the case with patent litigation, there is a risk that the Court may enjoin the making, using, selling and offering for sale Oxaydo and/or may find that Oxaydo infringes the '007 patent. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to this matter as of December 31, 2015.

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

Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to us, has been named along with numerous other companies as a defendant in cases filed in three separate state coordinated litigations pending in Pennsylvania, New Jersey and California, respectively captioned In re: Reglan®/Metoclopramide Mass Tort Litigation, Philadelphia County Court of Common Pleas, January Term, 2010, No. 01997; In re: Reglan Litigation, Superior Court of New Jersey, Law Division, Atlantic County, Case No. 289, Master Docket No. ATL-L-3865-10; and Reglan/Metoclopramide Cases, Superior Court of California, San Francisco County, Judicial Council Coordination Proceeding No. 4631, Superior Court No.: CJC-10-004631. In addition, Acura was served with a similar complaint by two individual plaintiffs in Nebraska federal court, which plaintiffs voluntarily dismissed in December 2014. In this product liability litigation against numerous pharmaceutical product manufacturers and distributors, including Acura, plaintiffs claim injuries from their use of the Reglan brand of metoclopramide and generic metoclopramide.

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

In the lawsuits filed to date, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by Acura. We discontinued manufacture and distribution of generic metoclopramide more than 18 years ago. In addition, we believe the June 23, 2011 decision by the U.S. Supreme Court in *PLIVA v. Mensing ("Mensing* decision") holding that state tort law failure to warn claims against generic drug companies are pre-empted by the 1984 Hatch-Waxman Act Amendments and federal drug regulations will assist us in favorably resolving these cases.

In New Jersey, Generic Defendants, including Acura, filed dispositive motions based on the *Mensing* decision, which the Court granted with a limited exception. In June 2012, the New Jersey trial court dismissed all of the New Jersey cases pending against Acura with prejudice. It is possible that this ruling may eventually be appealed by plaintiffs at the conclusion of the litigation in the trial court.

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

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

In California, the trial court entered a May 25, 2012 Order denying Generic Defendants' dispositive preemption motions. The Generic Defendants' appeals from this order were denied by the California appellate courts. In May 2014, the California Court denied a subsequent demurrer and motion to strike seeking dismissal of plaintiffs' manufacturing defect and defective product claims to the extent that they are barred by federal preemption based upon the June 2013 *Bartlett* decision. Thus far, Acura and most Generic Defendants have not been required to file answers or other responsive pleadings in each individual case in which they are named defendants. However, the individual cases against Acura have been stayed pending resolution of certain jurisdictional issues relating to cases filed by non-resident California plaintiffs and further action by the trial court. Subject to further developments, plaintiffs may be permitted to proceed with these lawsuits against Acura including state law claims based on (1) failing to communicate warnings to physicians through "Dear Doctor" letters; and (2) failure to update labeling to adopt brand labeling changes. The California trial court also has acknowledged the preemptive effect of *Mensing* so that any claim "that would render the generic defendants in violation of federal law if they are found responsible under a state law cause of action, would not be permissible." To date, however, none of these plaintiffs have confirmed they ingested any of the generic metoclopramide manufactured by Acura. Therefore, we expect the number of plaintiffs with possible claims to be reduced voluntarily or by motion practice. Action will be taken in an effort to dismiss Acura from these cases, although there can be no assurance in this regard. Legal fees related to this matter are currently covered by our insurance carrier.

As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of December 31, 2015 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

Paragraph IV ANDA Litigation and License Grants

On or about September 17, 2012, the FDA began accepting Abbreviated New Drug Applications, or ANDAs, referencing Oxaydo. To date, we have received Paragraph IV Certification Notices under 21 U.S.C. 355(j) (a Paragraph IV Notice) from five separate generic sponsors of an ANDA for a generic drug listing Oxaydo as the reference listed drug. The Paragraph IV Notices state that each generic sponsor believes that our Aversion Technology patents listed in FDA's Orange Book are invalid, unenforceable or not infringed. We initiated suit against each of Watson Laboratories, Inc. – Florida (Watson), Par Pharmaceutical, Inc., Impax Laboratories, Inc., Sandoz Inc., and Ranbaxy, Inc., each in the United States District Court for the District of Delaware alleging infringement of our U.S. Patent No. 7,510,726 listed in the FDA's Orange Book.

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

We have entered into distinct Settlement Agreements with each of Par, Impax, Ranbaxy and Sandoz to settle our patent infringement actions. Par is the first filer of an ANDA for a generic Oxaydo product and is entitled to the 180-day first filer exclusivity under applicable law and FDA regulations. Par is entitled to launch its generic Oxaydo product in the U.S., through the grant of a non-exclusive, royalty-bearing license from us that would trigger on January 1, 2022. We currently have Orange Book patents that are due to expire between November 2023 and March 2025. In certain limited circumstances, our license to Par would become effective prior to January 1, 2022. Par is required to pay us royalties in the range of 10% to 15% of Par's net profits from the sale of its generic Oxaydo product.

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

Our Settlement Agreement with Ranbaxy provides that Ranbaxy's current generic of our Oxaydo product that is the subject of its ANDA filing does not infringe our Orange Book listed patents with the FDA. We have not provided Ranbaxy a license to our patents and we may re-commence patent infringement litigation against Ranbaxy if Ranbaxy changes the formulation of its current generic Oxaydo product.

Notwithstanding the settlement of these prior infringement actions, it is possible that other generic manufacturers may also seek to launch a generic version of Oxaydo and challenge our patents. Any determination in such infringement actions that our patents covering our Aversion Technology and Oxaydo are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents could have a material adverse effect on our operations and financial condition.

Facility Lease

The Company leases administrative office space in Palatine, Illinois under a lease expiring March 31, 2017 for approximately $25 thousand annually.

SUPPLEMENTARY DATA (UNAUDITED)

Selected unaudited quarterly consolidated financial data is shown below (in thousands except per share amounts):

	For Three Month Periods Ended			
	Mar. 31, 2015	June 30, 2015	Sept. 30, 2015	Dec. 31, 2015
Net revenues	$ 5,357	$ 341	$ 210	$ 2,679
Operating expenses	3,845	2,739	2,615	3,389
Operating income (loss)	1,512	(2,398)	(2,405)	(710)
Net income (loss)	$ 1,239	$ (2,663)	$ (2,649)	$ (916)
Basic income (loss) per share	$ 0.13	$ (0.28)	$ (0.23)	$ (0.08)
Diluted income (loss) per share	$ 0.13	$ (0.28)	$ (0.23)	$ (0.08)

	For Three Month Periods Ended			
	Mar. 31, 2014	June 30, 2014	Sept. 30, 2014	Dec. 31, 2014
Net revenues	$ 42	$ 35	$ 145	$ 529
Operating expenses	3,868	3,307	2,791	2,984
Operating loss	(3,826)	(3,272)	(2,646)	(2,455)
Net loss	$ (4,088)	$ (3,521)	$ (2,904)	$ (2,696)
Basic loss per share	$ (0.40)	$ (0.35)	$ (0.30)	$ (0.30)
Diluted loss per share	$ (0.40)	$ (0.35)	$ (0.30)	$ (0.30)

_____ Shares of Common Stock

Warrants to Purchase up to ____ Shares of Common Stock

ACURA PHARMACEUTICALS, INC.

PROSPECTUS

_____, 2017

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale and distribution of the common stock being registered hereby. All amounts shown are estimates, except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and the NASDAQ Capital Market listing fee.

	Amount
SEC registration fee	$ 580
FINRA filing fee	*
NASDAQ Listing Fee for Additional Shares	*
Legal fees and expenses	*
Accounting fees and expenses	*
Printing expenses	*
Transfer agent fees	*
Miscellaneous fees and expenses	*
Total	$ *

* To be filed by amendment

Item 14. Indemnification of Directors and Officers.

Section 722 of the New York Business Corporation Law (the "BCL") provides that a corporation may indemnify directors and officers as well as other employees and individuals against judgments, fines, amounts paid in settlement and reasonable expenses, including attorney's fees, in connection with actions or proceedings, whether civil or criminal (other than an action by or in the right of the corporation, referred to as a "derivative action"), if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification only extends to amounts paid in settlement and reasonable expenses (including attorney's fees) incurred in connection with the defense or settlement of such actions, and the statute does not apply in respect of a threatened action, or a pending action that is settled or otherwise disposed of, and requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. Section 721 of the BCL provides that Article 7 of the BCL is not exclusive of other indemnification that may be granted by a corporation's certificate of incorporation or by-laws. Article Ninth of our Restated Certificate of Incorporation and Article IV, Section 6 of our Restated By-Laws require us to indemnify our officers and directors to the fullest extent permitted under the BCL.

Set forth below is Article Ninth of Acura Pharmaceuticals, Inc.'s Restated Certificate of Incorporation:

> NINTH: The Corporation shall, to the fullest extent possible permitted by Sections 721 through 726 of the Business Corporation Law of New York, indemnify any and all directors and officers whom it shall have the power to indemnify under said sections from and against any and all of the expenses, liabilities or other matters referred to in or covered by such sections of the Business Corporation Law, and the indemnification provided for herein shall not be deemed exclusive of any other rights to which the person so indemnified may be entitled under any By-Law, agreement, vote of shareholders or disinterested directors or otherwise, both as to action in his/her official capacity and as to action in another capacity by holding such office, and shall continue as to a person who has ceased to be a director or officer and shall inure to the benefit of the heirs, executors and administrators of such person.

Set forth below is Article IV, Section 6 of Acura Pharmaceuticals' Inc.'s Restated By-Laws:

> SECTION 6. Indemnification. It is expressly provided that any and every person made a party to any action, suit, or proceeding by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he, his testator or intestate, is or was a director or officer of this corporation or of any corporation which be served as such at the request of this corporation, may be indemnified by the corporation to the full extent permitted by law, against any and all reasonable expenses, including attorneys' fees, actually and necessarily incurred by him in connection with the defense of such action or in connection with any appeal therein, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such officer or director has breached his duty to the corporation.
>
> It is further expressly provided that any and every person made a party to any action, suit, or proceeding other than one by or in the right of the corporation to procure a judgment in its favor, whether civil or criminal, including an action by or in the right of any other corporation of any type or kind, domestic or foreign, which any director or officer of the corporation served in any capacity at the request of the corporation, by reason of the fact that he, his testator or interstate, was a director or officer of the corporation, or served such other corporation in any capacity, may be indemnified by the corporation, to the full extent permitted by law, against judgments, fines, amounts paid in settlement, and reasonable expenses, including attorneys' fees, actually and necessarily incurred as a result of such action, suit or proceeding, or any appeal therein, if such person acted in good faith for a purpose which he reasonably believed to be in the best interests of the corporation and, in criminal actions or proceedings, in addition, had no reasonable cause to believe that his conduct was unlawful.

Section 402(b) of the BCL provides that a corporation may include a provision in its certificate of incorporation limiting the liability of its directors to the corporation or its shareholders for damages for the breach of any duty, except for a breach involving intentional misconduct, bad faith, a knowing violation of law or receipt of an improper personal benefit or for certain illegal dividends, loans or stock repurchases. Article Tenth of our Restated Certificate of Incorporation contains such a provision, applicable to acts or omissions after its effectiveness.

We maintain a director and officer liability insurance policy that, subject to the terms, conditions and limits of the policy, provides coverage for wrongful acts (as defined by the policy) committed by a director or officer acting in his or her capacity as our director or officer. The policy reimburses us for amounts spent in lawful indemnification of a director or officer or amounts provided by us to indemnify its directors and officers as required or permitted by law.

Item 15. Recent Sales of Unregistered Securities.

On January 7, 2015, in connection with a Collaboration and License Agreement dated as of such date between us and Egalet U.S. Inc. and certain of its affiliates, or Egalet, to commercialize Oxaydo™ (oxycodone hydrochloride) tablets containing our Aversion® Technology, we, our subsidiary Acura Pharmaceutical Technologies, Inc. and our lender, Oxford Finance LLC entered into an amendment to a Loan and Security Agreement dated as of December 27, 2013 to gain the lender's consent to the Collaboration and License Agreement and amend certain provisions of the Loan and Security Agreement that were inconsistent with the Collaboration and License Agreement and to provide for us to maintain certain cash reserves. In addition, pursuant to the amendment, the exercise price of the warrants previously issued to the lender to purchase 59,561 shares of our Common Stock, or the Oxford Warrants, was lowered from $7.95 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).

The Oxford Warrants were initially issued December 27, 2013 and are exercisable for cash or by net exercise and will expire December 27, 2020.

The offer and sale of the Oxford Warrants and the modifications thereto were not registered under the Securities Act of 1933, as amended, or the Securities Act. The Oxford Warrants were offered and sold to an accredited investor in reliance upon exemptions from registration under Section 4(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder.

Item 16. Exhibit and Financial Statement Schedule.

A list of exhibits filed herewith is included on the Exhibit Index which immediately follows the signature page of this registration statement and is incorporated by reference.

Item 17. Undertakings.

The undersigned registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

2. For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Summit, State of New Jersey, on the 3rd day of February, 2017.

ACURA PHARMACEUTICALS, INC.

By: /s/Robert B. Jones
Robert B. Jones
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert B. Jones and Peter A. Clemens, and each of them, as his attorney-in-fact, with full power of substitution in each, for him in any and all capacities, to sign any amendments (including post-effective amendments) to this registration statement and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/S/ Robert B. Jones **Robert B. Jones**	President and Chief Executive Officer, Director (Principal Executive Officer)	February 3, 2017
/S/ Peter A. Clemens **Peter A. Clemens**	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 3, 2017
/S/ Bruce Wesson **Bruce F. Wesson**	Director	February 3, 2017
/S/ William Skelly **William Skelly**	Director	February 3, 2017
/S/ Immanuel Thangaraj **Immanuel Thangaraj**	Director	February 3, 2017
/S/ George Ross **George Ross**	Director	February 3, 2017

EXHIBIT INDEX

ACURA PHARMACEUTICALS, INC.
EXHIBIT INDEX

The following exhibits are included as a part of this Annual Report on Form 10-K or incorporated herein by reference.

Exhibit Number	Exhibit Description
1.1***	Form of Underwriting Agreement
1.2	Placement Agency Agreement dated June 30, 2015 between Roth Capital Partners LLC and the Registrant (incorporated by reference to Exhibit 1.1 to our Form 8-K filed July 1, 2015)
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on June 25, 2009).
3.2	Certificate of Amendment Reverse Splitting Common Stock and restating but not changing text of part of Article III of Restated Certificate of Incorporation (incorporated by Reference to Exhibit 3.1 to the Form 8-K filed December 4, 2007).
3.3	Certificate of Amendment Reverse Splitting Common Stock and restating but not changing text of part of Article III of Restated Certificate of Incorporation (incorporated by Reference to Exhibit 3.1 to the Form 8-K filed August 27, 2015).
3.4	Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on March 3, 2009).
4.1	Form of Common Stock Certificate (incorporated by Reference to Exhibit 4.1 to the Form S-3 filed on March 9, 2016)
4.2***	Form of Warrant being issued pursuant to this Registration Statement
4.4	Amended and Restated Warrant A-1 issued to Oxford Finance LLC on January 7, 2015 (incorporated by reference to Exhibit 10.9 to our Form 10-K filed March 2, 2015).
4.5	Amended and Restated Warrant A-2 issued to Oxford Finance LLC on January 7, 2015 (incorporated by reference to Exhibit 10.10 to our Form 10-K filed March 2, 2015).
4.6	Amended and Restated Warrant A-3 issued to Oxford Finance LLC on January 7, 2015 (incorporated by reference to Exhibit 10.11 to our Form 10-K filed March 2, 2015).
5.1***	Legal Opinion of LeclairRyan regarding the legality of the securities being registered
10.1	Manufacturing Services Agreement dated as of July 19, 2011 between the Registrant and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to our Form 8-K filed July 27, 2011) (confidential treatment has been granted for portions of this Exhibit).
10.2	Securities Purchase Agreement dated as of August 20, 2007 ("PIPE SPA") among the Registrant, Vivo Ventures Fund VI, L.P., Vivo Ventures VI Affiliates Fund, L.P., GCE Holdings LLC, and certain other signatories thereto (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 21, 2007).

Exhibit Number	Exhibit Description
10.3	Registration Rights Agreement dated as of February 6, 2004 between the Registrant and certain investors (incorporated by reference to Exhibit 10.6 of the Form 8-K filed on February 10, 2004)
10.4	Loan and Security Agreement dated as of December 27, 2013 between Acura Pharmaceuticals, Inc. Acura Pharmaceutical Technologies, Inc. and Oxford Finance LLC (incorporated by reference to Exhibit 10.6 to the Form 10-K filed March 3, 2014).
10.5	First Amendment to Loan and Security Agreement entered into as of January 7, 2015 between Oxford Finance LLC, the Registrant and APT (incorporated by reference to Exhibit 10.8 to our Form 10-K filed March 2, 2015).
10.6*	Second Amendment to Loan and Security Agreement entered into as of October 13, 2016 between Oxford Finance LLC, the Registrant and APT
10.7	Form of Mortgage dated December 27, 2013 (incorporated by reference to Exhibit 10.8 to the Form 10-K filed March 3, 2014).
10.8	Collaboration and License Agreement entered into as of January 7, 2015 between the Registrant, Egalet US, Inc., Egalet Limited and with respect to Section 17.21, Egalet Corporation (certain information has been omitted and filed separately with the Securities and Exchange Commission and confidential treatment has been granted with respect to the omitted portion) (incorporated by reference to Exhibit 10.13 to the Form 10-K for the year ending December 31, 2014, filed March 2, 2015).
10.9	License and Development Agreement dated as of June 5, 2015 between the Registrant and Bayer HealthCare LLC (certain information has been omitted and filed separately with the Securities and Exchange Commission and confidential treatment has been granted with respect to the omitted portion) (incorporated by reference to Exhibit 10.1 to our Form 10-Q/A filed February 16, 2016).
10.10	Amended and Restated Voting Agreement dated as of February 6, 2004 among the Registrant, Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P., and others (incorporated by reference to Exhibit 10.5 of the Form 8-K filed on February 10, 2004 (the "February 2004 Form 8-K")).
10.11	Joinder and Amendment to Amended and Restated Voting Agreement dated November 9, 2005 between the Registrant, GCE Holdings, Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Galen Partners III, L.P. and others (incorporated by reference to Exhibit 10.1 to the Form 8-K filed November 10, 2005).
10.12	Second Amendment to Amended and Restated Voting Agreement dated as of January 24, 2008 between the Registrant and GCE Holdings, LLC (incorporated by reference to Exhibit 10.1 to the Form 8-K filed January 28, 2008).
10.13	Third Amendment to Amended and Restated Voting Agreement dated as of October 1, 2012 between the Registrant, Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P., and others (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on October 3, 2012).

Exhibit Number	Exhibit Description
†10.14	Registrant's 1998 Stock Option Plan, as amended (incorporated by reference to Appendix C to the Registrant's Proxy Statement filed on May 12, 2009).
†10.15	Registrant's 2005 Restricted Stock Unit Award Plan, as amended (incorporated by reference to Appendix B to the Registrant's Proxy Statement filed on April 2, 2008).
†10.16	Registrant's 2014 Restricted Stock Unit Award Plan, (incorporated by reference to Appendix A to the Registrant's Proxy Statement filed on March 12, 2014).
†10.17	Registrant's 2008 Stock Option Plan, as amended on June 25, 2009 (incorporated by reference to Appendix B to our Proxy Statement filed on May 12, 2009).
†10.18	Registrant's 2016 Stock Option Plan (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on April 28, 2016).
†10.19	Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens ("Clemens") (incorporated by reference to Exhibit 10.44 to the Form 10-K for the period ending December 31, 2007, filed on April 15, 1998).
†10.20	First Amendment to Employment Agreement made as of June 28, 2000 between the Registrant and Clemens (incorporated by reference to Exhibit 10.44A to the Registrant's Form 10-K filed on February 21, 2006).
†10.21	Second Amendment to Executive Employment Agreement between Registrant and Clemens, dated as of January 5, 2005 (incorporated by reference to Exhibit 99.1 to the Registrant's Form 8-K filed January 31, 2005).
†10.22	Third Amendment to Executive Employment Agreement dated December 22, 2005 between Registrant and Clemens (incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed December 23, 2005).
†10.23	Fourth Amendment to Executive Employment Agreement dated December 16, 2007 between Registrant and Clemens (incorporated by reference to Exhibit 10.28 to the Form 10-K for the year ending December 31, 2007, filed on March 5, 2008).
†10.24	Fifth Amendment to Executive Employment Agreement executed July 9, 2008 between Registrant and Clemens (incorporated by reference to Exhibit 10.4 to our Form 8-K filed on July 10, 2008).
†10.25	Sixth Amendment to Executive Employment Agreement executed December 14, 2012 between the Registrant and Clemens (incorporated by reference to Exhibit 10.2 to our Form 8-K filed on December 17, 2012).
†10.26	Seventh Amendment to Executive Employment Agreement executed December 12, 2013 between the Registrant and Clemens (incorporated by reference to Exhibit 10.24 to the Form 10-K for the year ending December 31, 2013 filed on March 3, 2014).
†10.27	Employment Agreement dated as of March 18, 2008 between the Registrant and Robert B. Jones (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on March 24, 2008).

Exhibit Number	Exhibit Description
†10.28	Amendment to Executive Employment Agreement dated as of April 28, 2011 between the Registrant and Robert B. Jones (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed July 28, 2011).
†10.29	Second Amendment to Executive Employment Agreement between Registrant and Robert B. Jones executed December 14, 2012 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed December 17, 2012).
10.30	Form of Securities Purchase Agreement entered into between the Registrant and institutional investors on June 30, 2015 (incorporated by reference to Exhibit 10.1 of our Form 8-K filed July 1, 2015).
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21 to the Form 10-K for the fiscal year ended December 31, 2006 filed on March 15, 2007).
23.1*	Consent of Independent Registered Accounting Firm
23.2 ***	Consent of LeclairRyan (included as part of Exhibit 5.1)
24**	Power of Attorney
101.INS ***	XBRL Instance Document
101.SCH ***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Extension Calculation Linkbase
101.LAB ***	XBRL Extension Label Linkbase
101.PRE ***	XBRL Extension Presentation Linkbase
101.DEF ***	XBRL Taxonomy Extension Definition Linkbase

* Filed or furnished herewith.
** Included on Signature Page
*** To be filed by amendment
† Management contract or compensatory plan or arrangement

Exhibit 10.6

CONSENT AND SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS CONSENT AND SECOND AMENDMENT to Loan and Security Agreement (this "**Amendment**") is entered into as of October 13, 2016 (the "**Second Amendment Date**"), by and among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 (in its individual capacity, "**Oxford**"; and in its capacity as Collateral Agent, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 thereof from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**") and ACURA PHARMACEUTICALS, INC., a New York corporation with offices located at 616 N. North Court, Suite 120, Palatine, Illinois ("**Parent**") and ACURA PHARMACEUTICAL TECHNOLOGIES, INC., an Indiana corporation with offices locates at 16235 State Road 17, Culver, IN 46511 ("**APT**", and along with Parent, individually and collectively, jointly and severally, "**Borrower**").

WHEREAS, Collateral Agent, Borrower and Lenders party thereto from time to time have entered into that certain Loan and Security Agreement, dated as of December 27, 2013 (as amended, supplemented or otherwise modified from time to time, the "**Loan Agreement**") pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof;

WHEREAS, Borrower is simultaneously herewith entering into a License Agreement with KEMPHARM, INC. a Delaware corporation, with its principal place of business at 2656 Crosspark Road, Coralville, IA 52241 ("**KemPharm**"), dated as of the date hereof, a true and complete copy of which is attached hereto as Exhibit A (the "**License Agreement**");

WHEREAS, Borrower has requested that Collateral Agent and Lenders consent to certain licenses by Borrower to KemPharm, pursuant to the License Agreement, as described herein below to the extent that such consent may be required pursuant to Section 7.1 of the Loan Agreement;

WHEREAS, Collateral Agent and Lenders have agreed to provide such consent, but only to the extent set forth herein, in accordance with the terms and subject to the conditions set forth herein, and in reliance upon the representations and warranties set forth herein; and

WHEREAS, Borrower, Lenders and Collateral Agent desire to amend certain provisions of the Loan Agreement as provided herein and subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, Lenders and Collateral Agent hereby agree as follows:

1. Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Loan Agreement.

2. Subject to the terms and conditions hereof, the Collateral Agent and the Required Lenders hereby consent to the Borrower's entry into the License Agreement in the form, and only in the form, attached hereto as Exhibit A, and consummation of the transactions contemplated therein; provided, however, Borrower may enter into and deliver any amendment to the License Agreement and consummate the transactions as contemplated by the License Agreement after giving effect to such amendment if, and only if, such amendments to the terms of the License Agreement: (i) would not require the consent of the Required Lenders under Section 7 of the Loan Agreement, (ii) are not be adverse to the interests of Borrower, (iii) do not reduce the amount or change the form of consideration due to Borrower under the License Agreement and (iv) do not postpone any payment due to Borrower under the License Agreement.

3. Section 6.10 of the Loan Agreement is hereby amended and restated in its entirety as follows:

   "6.10 **Financial Covenant**. Until the occurrence of the Equity/License Event, Borrower shall maintain total cash reserves of at least Two Million Five Hundred Thousand Dollars ($2,500,000.00) in Collateral Accounts which are subject to a Control Agreement in favor of Collateral Agent and maintained in accordance with the terms of Section 6.6."

4. Section 13.1 of the Loan Agreement is hereby amended by adding the following definition thereto in alphabetical order:

"**Equity/License Event**" is the receipt by Borrower of the following: (i) unrestricted net cash proceeds of Three Million Five Hundred Thousand Dollars ($3,500,000.00) in the form of upfront payment (and excluding any royalty payments) under the KemPharm License Agreement, on or before November 1, 2016, and (ii) unrestricted net cash proceeds of not less than Six Million Dollars ($6,000,000.00), on or after the Second Amendment Date, from (A) the issuance and sale by Borrower of its equity securities (including securities convertible into or exercisable for equity securities) and/or (B) "up front" payments in connection with a license, joint venture, collaboration or other partnering transaction (each of which must *not* be pursuant to or in furtherance of the KemPharm License Agreement or any other agreement that is in effect on the Second Amendment Date); provided, however, the unrestricted net cash proceeds to Borrower under clause (A) must be equal to or greater than Three Million Dollars ($3,000,000).

"**KemPharm License Agreement**" is that certain License Agreement by and between Borrower and KEMPHARM, INC. a Delaware corporation, with its principal place of business at 2656 Crosspark Road, Coralville, IA 52241, dated October 13, 2016, 2016, a true and complete copy of which was provided to Collateral Agent on or before the Second Amendment Date; provided, however, KemPharm License Agreement for the purposes of this Agreement shall not include any amendment thereto that: (i) would require the consent of the Required Lenders under Section 7 of the Loan Agreement, (ii) is adverse to the interests of Borrower, (iii) reduces the amount or change the form of consideration due to Borrower thereunder or (iv) postpones any payment due to Borrower thereunder, unless such amendment is specifically consented to by Collateral Agent in its discretion in writing.

"**Second Amendment Date**" is October 13, 2016, 2016.

5. Limitation of Amendment.

   a. The amendments and the consent set forth in Sections 2 through 4 above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

   b. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

6. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

   a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

   b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

c. The organizational documents of Borrower delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by the Borrower to the Collateral Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (i) any law or regulation binding on or affecting Borrower, (ii) any contractual restriction with a Person binding on Borrower, (iii) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

e. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

f. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

7. Collateral Agent represents and warrants to Borrower that all Required Lenders have executed this Amendment.

8. Except as expressly set forth herein, the Loan Agreement shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

9. This Amendment shall be deemed effective as of the Second Amendment Date upon (a) the due execution and delivery to Collateral Agent of this Amendment by each party hereto and (b) Borrower's payment of all Lenders' Expenses incurred through the date hereof, which may be debited from any of Borrower's accounts with Lenders, provided, however, that Lender's Expenses in connection with this Amendment shall not exceed $7,500.

10. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument.

11. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of New York.

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IN WITNESS WHEREOF, the parties hereto have caused this Consent and Second Amendment to Loan and Security Agreement to be executed as of the Second Amendment Date.

BORROWER:

ACURA PHARMACEUTICALS, INC.

By /s/ Peter A. Clemens
Name: Peter A. Clemens
Title: Sr. VP & CFO

BORROWER:

ACURA PHARMACEUTICAL TECHNOLOGIES, INC.

By /s/ Peter A. Clemens
Name: Peter A. Clemens
Title: Sr. VP & CFO

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By /s/ Mark Davis
Name: Mark Davis
Title: Vice President – Finance, Secretary & Treasurer

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Acura Pharmaceuticals, Inc.
Palatine, Illinois

We hereby consent to the use in the Prospectus constituting a part of this Registration Statement of our report dated February 29, 2016, relating to the consolidated financial statements of Acura Pharmaceuticals, Inc., which is contained in that Prospectus.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ BDO USA, LLP

Chicago, Illinois
February 3, 2017