ACURA PHARMACEUTICALS, INC
Form 10-Q
August 14, 2017

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20649

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

or

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

For the transition period from _____ to_____

Commission File Number 1-10113

Acura Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

616 N. North Court, Suite 120

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

847 705 7709

(Registrant's telephone number, including area code)

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

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

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

Yes þ No ¨

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

As of August 11, 2017 the registrant had 20,795,994 shares of common stock, $.01 par value, outstanding.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2017

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited; in thousands except par value)

	June 30, 2017	December 31, 2016
Assets:		
Cash and cash equivalents	$1,079	$ 2,681
Restricted cash equivalents (Note 9)	2,500	2,500
Trade accounts receivable (net of allowances of $- and $7)	-	23
Collaboration revenue receivable	1	79
Royalty receivable	50	50
Inventories (net of allowances of $- and $32) (Note 6)	-	309
Prepaid expenses and other current assets	562	268
Total current assets	4,192	5,910
Property, plant and equipment, net (Note 7)	720	867
Intangible asset, net of accumulated amortization of $672 and $569 (Note 3)	1,328	1,431
Total assets	$6,240	$ 8,208
Liabilities:		
Accounts payable	$582	$ 77
Accrued expenses (Note 8)	691	703
Accrued interest	30	-
Other current liabilities	32	27
Sales returns liability	302	304
Debt - current (Note 9)	2,858	2,376
Total current liabilities	4,495	3,487
Debt – non-current portion, net of discounts (Note 9)	1,431	2,979
Accrued interest – non-current portion (Note 9)	634	559
Total liabilities	6,560	7,025
Commitments and contingencies (Note 14)		
Stockholders’ equity:		

Common stock - $.01 par value per share; 100,000 shares authorized, 11,883 and 11,834 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	119	118
Additional paid-in capital	376,003	375,763
Accumulated deficit	(376,442)	(374,698)
Total stockholders' (deficit) equity	(320)	1,183
Total liabilities and stockholders' (deficit) equity	$6,240	$ 8,208

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		Six months Ended	
	June 30, 2017	2016	June 30, 2017	2016
Revenues:				
License fee revenue	$ -	$ -	$ 2,500	$ -
Collaboration revenue	23	133	59	233
Royalty revenue	69	30	143	47
Product sales, net	-	94	107	201
Total revenues, net	92	257	2,809	481
Cost and expenses:				
Cost of sales (excluding inventory provisions)	-	99	128	201
Inventory provisions	-	26	-	26
Research and development	1,020	1,403	1,731	2,417
Selling, marketing, general and administrative	1,063	1,808	2,359	4,054
Total costs and expenses	2,083	3,336	4,218	6,698
Operating loss	(1,991)	(3,079)	(1,409)	(6,217)
Non-operating income (expense):				
Investment income	1	21	2	48
Interest expense (Note 9)	(159)	(233)	(337)	(482)
Other income (expense)	-	3	-	(21)
Total other expense, net	(158)	(209)	(335)	(455)
Loss before provision for income taxes	(2,149)	(3,288)	(1,744)	(6,672)
Provision for income taxes	-	-	-	-
Net loss	$ (2,149)	$ (3,288)	$ (1,744)	$ (6,672)
Other comprehensive income:				
Unrealized gains on securities	-	21	-	91
Comprehensive loss	$ (2,149)	$ (3,267)	$ (1,744)	$ (6,581)
Loss per share:				
Basic	$ (0.18)	$ (0.28)	$ (0.15)	$ (0.56)
Diluted	$ (0.18)	$ (0.28)	$ (0.15)	$ (0.56)
Weighted average shares outstanding:				
Basic	11,966	11,858	11,938	11,847

Diluted	11,966	11,858	11,938	11,847

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIT

(Unaudited; in thousands)

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance at January 1, 2017	11,834	$ 118	$ 375,763	$ (374,698)	$ 1,183
Net loss	-	-	-	(1,744)	(1,744)
Share-based compensation	-	-	233	-	233
Net distribution of common stock pursuant to restricted stock unit award plan	49	1	7	-	8
Balance at June 30, 2017	11,883	$ 119	$ 376,003	$ (376,442)	$ (320)

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Six months Ended June 30,	
	2017	2016
Cash Flows from Operating Activities:		
Net loss	$(1,744)	$(6,672)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	47	67
Provision to reduce inventory to net realizable value	-	26
Provision for sales returns	49	58
Share-based compensation	233	300
Amortization of debt discount and deferred debt issue costs	56	78
Amortization of bond premium in marketable securities	-	29
Amortization of intangible asset	103	103
Gain on disposal of machinery and equipment	(3)	-
Loss on sales of marketable securities	-	21
Change in assets and liabilities:		
Trade accounts receivable	23	(128)
Collaboration revenue receivable	78	-
Accrued investment income	-	24
Inventories	103	68
Prepaid expenses and other current assets	(294)	(74)
Other assets	-	175
Accounts payable	505	54
Accrued expenses	(12)	240
Accrued interest	105	139
Other current liabilities	11	7
Sales returns liability	(49)	-
Net cash used in operating activities	(789)	(5,485)
Cash Flows from Investing Activities:		
Proceeds from sales and maturities of marketable securities	-	7,362
Proceeds from transfer of equipment to licensee	103	-
Proceeds from transfer of inventory to licensee	206	-
Capital expenditures	-	(63)
Net cash provided by investing activities	309	7,299
Cash Flows from Financing Activities:		
Principal payments on debt	(1,122)	(1,034)
Net cash used in financing activities	(1,122)	(1,034)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(1,602)	780
Cash, cash equivalents, and restricted cash at beginning of period	5,181	2,485

Cash, cash equivalents, and restricted cash at end of period	$3,579	$3,265
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	$176	$265
Income taxes	$-	$-

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

(Unaudited; in thousands)

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet that sum to the total of the same such amounts shown in the consolidated statements of cash flows:

	June 30, 2017	June 30, 2016
	(in thousands)	
Cash and cash equivalents	$1,079	$765
Restricted cash equivalents	2,500	2,500
Total cash, cash equivalents and restricted cash show in the consolidated statements of cash flows	$3,579	$3,265

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2017 AND JUNE 30, 2016

NOTE 1 – OPERATIONS

Principal Operations

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.

- Our Limitx Technology, is designed to retard the release of active drug ingredients when too many tablets are accidently or purposefully ingested. We have completed two clinical studies of our lead Limitx immediate release oral abuse deterrent drug candidate using the opioid hydromorphone HCI (LTX-04). Each of Study AP-LTX-400 or Study 400, and AP-LTX-401, or Study 401, was a two cohort, open label, crossover design pharmacokinetic study in healthy adult subjects. In our initial analysis of Study 400 we concluded that we had (a) identified the appropriate buffer level for the technology, (b) demonstrated the maximum plasma level of the opioid active ingredient, or Cmax, was reduced by an average of approximately 22% when multiple tablets were ingested and (c) a reformulation of the drug containing micro-particles would be required to achieve sufficient levels of drug in the blood stream with a single tablet dose. Study 401 utilized a modified formulation of our Limitx technology with a much faster releasing micro-particle. Since the Cmax in Study 401 at one tablet was essentially unchanged from the results from Study 400, we have subsequently concluded that our formulation contains too much buffering ingredient. This is evidenced in Study 401's Cmax reduction of up to 65% following ingestion of multiple tablets compared to currently marketed products and our re-assessed conclusion of Study 400 indicating a 57% reduction in Cmax with multiple tablets. Because, we believe, Study 401 used too much buffer for even a single tablet, Study 401 achieved insufficient blood levels of the opioid active ingredient with a single tablet. The Company is developing plans for a buffer dose ranging study to guide the reformulation of the tablet buffers to increase the single dose Cmax, while retaining a reduction in Cmax in multiple Limitx tablets. The Company has also changed its development focus from LTX-04, an immediate-release hydromorphone product, to LTX-03, an immediate-release hydrocodone bitartrate product, which is more likely to be abused by excess oral consumption. 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.

Our Aversion Technology incorporates gelling ingredients and irritants into tablets to discourage abuse by snorting and provide barriers to abuse by injection. Aversion is used in Oxaydo® Tablets (oxycodone HCl, CII), and is the first 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. (see Note 3).

- Our Impede Technology is a proprietary mixture of inactive ingredients that prevents the extraction of pseudoephedrine, or PSE, from tablets using known extraction methods and disrupts the direct conversion of PSE from tablets into methamphetamine. Impede is used in Nexafed® Tablets (30mg pseudoephedrine) and Nexafed® Sinus Pressure + Pain Tablets (30/325mg pseudoephedrine and acetaminophen), and those Nexafed products were launched by us into the United States market in December 2012 and February 2015, respectively. We have multiple PSE products in development utilizing our Impede Technology. On March 16, 2017, we and MainPointe Pharmaceuticals, LLC ("MainPointe"), entered into a License, Commercialization and Option Agreement ("MainPointe Agreement"), pursuant to which we granted MainPointe an exclusive license to our Impede technology in the United States and Canada to commercialize our Nexafed products. The MainPointe Agreement also grants MainPointe the option to expand the licensed territory to the European Union, Japan and South Korea and to add additional pseudoephedrine-containing products utilizing our Impede Technology. (see Note 3).

Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The going concern basis of presentation assumes that we will continue in operation for the next twelve months and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. At June 30, 2017, we had unrestricted cash and cash equivalents of $1.1 million (after giving effect to our $2.5 million cash reserve requirement in effect at June 30, 2017 under our term loan with Oxford), working capital deficit of $2.8 million and an accumulated deficit of $376.4 million. We had loss from operations of $1.4 million and a net loss of $1.7 million for the six months ended June 30, 2017. Historically, we have suffered annual losses from operations and have not generated or have generated limited annual positive cash flows from operations. After giving effect to the net proceeds of $3.9 million from our equity financing completed in July 2017, our $2.5 million cash reserve requirement under our term loan with Oxford Finance has been removed as discussed in Item 2, under the caption "Recent Events", however our current unrestricted cash and cash equivalents is expected to only be sufficient to fund the development of our products and our related operating expenses into April 2018.

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. 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. 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. On March 16, 2017, we and Oxford entered into a third amendment to the Loan Agreement, or the Third Amendment. Pursuant to the Third Amendment (i) we granted Oxford a lien on our intellectual property, (ii) Oxford provided a waiver of compliance with the Unqualified Audit Opinion Covenant in connection with our receipt of our auditor's going concern opinion for our 2016 financial statements and (iii) Oxford consented to the terms of the MainPointe Agreement.

However, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. To fund further operations and product development activities beyond April 2018, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. The Company intends to explore a variety of capital raising and other transactions to provide additional funding to continue operations. These include a registered public offering of the Company's common stock, for which the Company filed a registration statement on Form S-1 with the SEC on February 3, 2017, and potential private offerings of common stock to institutional investors. The Company is also actively seeking a licensing partner for its Limitx Technology, with the objective of receiving an upfront license fee, development milestone payments and royalties on

the net sales of products utilizing the Limitx Technology, similar to the Egalet Agreement. The Company is also exploring licensing or selling select assets and intellectual property in an effort to raise capital and reduce operating expenses. Finally, the Company is evaluating the potential for a strategic transaction which may involve the Company being acquired in a merger or asset purchase transaction. No assurance can be given that we will be successful in completing any one or more of such transactions on acceptable terms, if at all, or if completed, that such transactions will provide payments to the Company sufficient to fund continued operations. In the absence of the Company's completion of one or more of such transactions, 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 2 – 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 related disclosures and have not yet determined the transition method we will utilize to adopt the standard for use in 2018.

Inventories

In July 2015, the FASB issued ASU No. 2015-11, which amended Accounting Standards Codification ("ASC") Topic 330 Inventory. The amendment simplifies the measurement of inventory, applying to inventories for which cost is determined by methods other than last-in first-out (LIFO) and the retail inventory method (RIM), specifying that an entity should measure inventory at the lower of cost and net realizable value instead of at the lower of cost or market. The amendments in this ASU were effective for annual and interim periods, within those fiscal years, beginning after December 15, 2016. The Company adopted the guidance of the standard in the first quarter of 2017 which did not

have a material impact on the Company's consolidated financial statements.

Leases

In February 2016, the FASB issued ASU 2016-02, Leases, which will require most leases (with the exception of leases with terms of one year or less) to be recognized on the balance sheet as an asset and a lease liability. Leases will be classified as an operating lease or a financing lease. Operating leases are expensed using the straight-line method whereas financing leases will be treated similarly to a capital lease under the current standard. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2018 but early adoption is permitted. The new standard must be presented using the modified retrospective method beginning with the earliest comparative period presented. The Company is currently evaluating the impact that the standard will have on the consolidated financial statements and related footnote disclosures, and has not yet determined what effect, if any, the impact of adoption will be.

Employee Share-Based Payments

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 is to be applied either prospectively, retrospectively or using a modified retrospective transition approach depending on the area covered in this update. The new standard was effective for annual and interim periods, within those fiscal years, beginning after December 15, 2016. The Company adopted the guidance in the first quarter of 2017 which did not have a material impact on the Company's consolidated financial statements.

Statement of Cash Flows

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which clarifies existing guidance on how companies present and classify certain cash receipts and cash payments in the statement of cash flows by addressing specific cash flow issues in an effort to reduce diversity in practice, including guidance on debt prepayment or extinguishment costs and contingent consideration payments made after a business combination. This update is effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact that the standard will have on the consolidated financial statements and related footnote disclosures, and has not yet determined what effect, if any, the impact of adoption will be.

Intra-Entity Transfers of Assets Other than Inventory

In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*. ASU 2016-16 eliminates from Topic 740, Income Taxes, the recognition exception for intra-entity asset transfers other than inventory so that an entity's consolidated financial statements reflect the current and deferred tax consequences of those intra-entity asset transfers when they occur. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2017 but early adoption is permitted. The Company is currently evaluating the impact that the standard will have on the consolidated financial statements and related footnote disclosures, and has not yet determined what effect, if any, the impact of adoption will be.

Statement of Cash Flows - Restricted Cash

In November 2016, the FASB issued ASU 2016-18, *Statements of Cash Flows (Topic 230): Restricted Cash*. ASU 2016-18 requires that at statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2017 but early adoption is permitted. The Company early adopted the guidance in the first quarter of 2017 which did not have a material impact on the Company's consolidated financial statements or related footnote disclosures.

Other Income

In February 2017, the FASB issued ASU No. 2017-05, *Other Income—Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets.* The amendments in this ASU address the recognition of gains and losses on the transfer (i.e., sale) of nonfinancial (and in substance nonfinancial) assets to counterparties other than customers. The ASU conforms the derecognition guidance on nonfinancial assets with the model for transactions in the new revenue standard ASU 2014-09, as amended. The amendments are effective at the same time as the new revenue standard.

Compensation – Stock Compensation

In May 2017, the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation (ASC 718) - Scope of Modification Accounting.* The amendments provide guidance as to how an entity should apply modified accounting in Topic 718 when changing the terms and conditions of its share-based payment awards. The guidance clarifies that modification accounting will be applied if the value, vesting conditions or classification of the award changes. The ASU is effective for annual reporting periods, including interim periods within those annual periods, beginning after December 15, 2017 but early adoption is permitted. The Company has not adopted the standard and does not anticipate that the standard will have a material effect, if any, on our consolidated financial statements and related disclosures.

NOTE 3 – LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENTS

MainPointe Agreement covering Nexafed Product Line

On March 16, 2017, we and MainPointe entered into the MainPointe Agreement, pursuant to which we granted MainPointe an exclusive license to our Impede technology to commercialize our Nexafed products in the U.S. and Canada. We also conveyed to MainPointe our existing inventory and equipment relating to our Nexafed products. MainPointe is responsible for all development, manufacturing and commercialization activities with respect to products covered by the Agreement.

On signing the MainPointe Agreement, MainPointe paid us an upfront licensing fee of $2.5 million plus approximately $309 thousand for inventories and equipment being transferred to them. They also paid us $117 thousand for Nexafed inventory under manufacture by one of our contract manufacturing organizations. The contract manufacturer completed delivery of such inventory to MainPointe during the second quarter 2017. The MainPointe Agreement also provides for our receipt of a 7.5% royalty on net sales of the licensed products. The royalty payment for each product will expire on a country-by-country basis when the Impede® patent rights for such country have expired or are no longer valid; provided that if no Impede patent right exists in a country, then the royalty term for that country will be the same as the royalty term for the United States. After the expiration of a royalty term for a country, MainPointe retains a royalty free license to our Impede® technology for products covered by the Agreement in such country.

MainPointe has the option to expand the licensed territory beyond the United States and Canada to the European Union (and the United Kingdom), Japan and South Korea for payments of $1 million, $500 thousand and $250 thousand, respectively. In addition, MainPointe has the option to add to the MainPointe Agreement certain additional products, or Option Products, containing PSE and utilizing the Impede technology for a fee of $500 thousand per product (for all product strengths). MainPointe's option rights extend to the product that was subject to the Bayer Agreement, as described below. If the territory has been expanded prior to the exercise of a product option, the option fee will be increased to $750 thousand per product. If the territory is expanded after the payment of the $500 thousand product option fee, a one-time $250 thousand fee will be due for each product. If a third party is interested in developing or licensing rights to an Option Product, MainPointe must exercise its option for that product or its option rights for such product will terminate.

The MainPointe Agreement may be terminated by either party for a material breach of the other party, or by Acura if MainPointe challenges certain of its patents. Upon early termination of the MainPointe Agreement, MainPointe's licenses to the Impede technology and all products will terminate. Upon termination, at Acura's request the parties will use commercially reasonable efforts to transition the Nexafed® and Nexafed® Sinus Pressure + Pain products back to Acura.

KemPharm Agreement Covering Certain Opioid Prodrugs

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.

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 two 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.

Egalet Agreement covering Oxaydo

In April 2014, we terminated an agreement with Pfizer and the return to us of Aversion Oxycodone (formerly known as Oxecta®) 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 Aversion Oxycodone, which was 9.7 years as of the date the agreement was terminated. During each of the three and six months ended June 30, 2017 and 2016, we recorded amortization expense of $52 thousand in each three month period and $104 thousand in each six month period, respectively. Annual amortization of the patent for years 2017 through 2021 is expected to approximate $208 thousand.

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.

Terminated Bayer Agreement Covering Methamphetamine Resistant Pseudoephedrine-containing Product

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. On June 28, 2017, we received Bayer's notice of termination of the Bayer Agreement pursuant to its convenience termination right exercised prior to the Company's completion of its product development obligations under the Bayer Agreement. We have received reimbursement of certain of our development costs under the Bayer Agreement.

Following Bayer's termination of the Bayer Agreement the Bayer License Product is now subject to MainPointe's option rights under the MainPointe Agreement.

NOTE 4 - REVENUE RECOGNITION

License Fee Revenue

On signing the MainPointe Agreement, MainPointe paid us an upfront licensing fee of $2.5 million. 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.

Collaboration Revenue

Collaboration revenue is derived from research and development services we provide from time to time and are recognized when those services 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 service’s hourly rates pursuant to the collaboration agreement. We recognized $59 thousand and $233 thousand of collaboration revenue during the six months ended June 30, 2017 and 2016, respectively.

Royalty Revenue

In connection with our Collaboration and License Agreement with Egalet to commercialize Oxaydo tablets we are receiving 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. We have recorded royalties of $135 thousand and $47 thousand on net sales for the six months ended June 30, 2017 and 2016, respectively. (see Note 3).

In connection with our License, Commercialization and Option Agreement with MainPointe, which occurred on March 16, 2017, we are receiving a royalty of 7.5% on net sales of the licensed products over the term of the agreement. Such royalty shall be payable for sales made during each calendar quarter and payment will be remitted within forty-five (45) days after the end of the quarter to which it relates. We have recorded royalties of $8 thousand on net sales for the six months ended June 30, 2017 (see Note 3).

Product Sales

Nexafed was launched in mid-December 2012 and Nexafed Sinus Pressure + Pain was launched in February 2015. Prior to entering into the MainPointe Agreement, we sold our Nexafed products in the United States to wholesale pharmaceutical distributors as well as directly to chain drug stores. Our Nexafed products were 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 had been extended to thirty-six months for Nexafed product supplied to us during 2016 from one of the Company’s contract manufacturers. Prior to entering into the MainPointe Agreement, we recognized revenue from our Nexafed product line sales when the price was fixed and determinable at the date of sale, title and risk of ownership were transferred to the customer, and returns could be reasonably estimated, which generally occurred at the time of product shipment.

Shipping and Handling Costs

We record shipping and handling costs in selling expenses. As of mid-March 2017 we no longer manufacture, distribute or sell the Nexafed product line as the Company granted MainPointe an exclusive license to our Impede technology to commercialize our Nexafed products in the U.S. and Canada. The amounts recorded to selling expenses from the shipments of the Nexafed product line during each of the six month periods ended June 30, 2017 and 2016 were not material.

NOTE 5 - RESEARCH AND DEVELOPMENT ACTIVITIES

Research and Development (“R&D”) expenses include internal R&D activities, external Contract Research Organization (“CRO”) services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, formulation work, 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 $50 thousand was remaining under this agreement at December 31, 2016. During the second quarter 2017, this project was completed and our Impede 2.0 technology has been integrated into Nexafed 30mg tablets. Also during the second quarter 2017, we entered into a cancelable arrangement with a CRO for Study 401. At June 30, 2017 the remaining obligations under cancelable CRO arrangements were approximately $0.2 million, for services to be incurred as subjects are enrolled and progress through the studies and the final study reports are completed. We did not have prepaid CRO costs or prepaid clinical trial study expenses at either June 30, 2017 or December 31, 2016.

NOTE 6 – INVENTORIES

We did not have inventories at June 30, 2017 as all our inventories were transferred to MainPointe under the MainPointe Agreement. Inventories are stated at the lower of cost (first-in, first-out method) or 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 at December 31, 2016 are summarized as follows:

	December 31, 2016
	(in thousands)
Raw and packaging materials	$ 98
Finished goods	243
Total	341
Less: reserve for finished goods	(32)
Net inventories	$ 309

NOTE 7 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at June 30, 2017 and December 31, 2016 are summarized as follows:

	June 30, 2017	December 31, 2016
	(in thousands)	
Building and improvements	$1,273	$ 1,273
Scientific equipment	598	598
Computer hardware and software	109	109
Machinery and equipment	275	568
Land and improvements	162	162

Other personal property	70	70
Office equipment	27	27
Total	2,514	2,807
Less: impairment reserve	-	(82)
Less: accumulated depreciation	(1,794)	(1,858)
Net property, plant and equipment	$720	$ 867

The impairment reserve of $82 thousand at December 31, 2016 was for our machinery and other equipment used in the production of our Nexafed product line which was not conveyed to MainPointe under the MainPointe Agreement. During 2017, we applied the reserve against the disposal of these assets. We do not have leasehold improvements nor do we have capitalized leases. Costs of betterments are capitalized while maintenance costs and repair costs are charged to operations as incurred. When a depreciable asset is retired from service, the cost and accumulated depreciation will be removed from the respective accounts.

NOTE 8 - ACCRUED EXPENSES

Accrued expenses at June 30, 2017 and December 31, 2016 are summarized as follows:

	June 30, 2017	December 31, 2016
	(in thousands)	
Cost sharing expenses under license agreement	$ 217	$ 150
Other fees and services	56	47
Payroll, payroll taxes and benefits	74	116
Professional services	181	232
Clinical, non-clinical and regulatory services	133	131
Marketing, advertising, and promotion	-	10
Property taxes	13	16
Franchise taxes	17	1
Total	$ 691	$ 703

NOTE 9 – DEBT

On December 27, 2013, we entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford" or the "Lender"), for a term loan to the Company in the principal amount of $10.0 million (the "Term Loan"). The 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 security for its obligations under the initial Loan Agreement (prior to the Third Amendment), the Company granted Lender a security interest in substantially all of its existing and after−acquired assets, exclusive of its intellectual property assets, which the Company was prohibited from pledging 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 relative fair value of the Warrants and are amortizing it to interest expense over the term of the loan using the loan's effective interest rate. The Warrants are immediately exercisable for cash or by net exercise and will expire December 27, 2020.

On January 7, 2015, we and Oxford entered into an amendment to the Loan Agreement. Pursuant to the amendment, (i) the exercise price of the warrants was lowered from $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.

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 $5.0 million in principal was repaid under the Term Loan was modified so that the $2.5 million cash balance reserve remains in place until we raise 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. On July 24, 2017, the Company completed a private placement of its equity units to an investor, each unit consisting of one share of common stock and a warrant to purchase one-fifth of a share of common stock. The net proceeds to the Company from the private offering was approximately $3.9 million. Giving effect to the $2.5 million upfront payment received from MainPointe pursuant to the MainPointe Agreement and the $3.9 million in net proceeds from the July 2017 private offering, the Company has satisfied the condition in the Second Amendment to the Oxford Loan Agreement to waive the $2.5 million cash reserve requirement.

On March 16, 2017, we and Oxford entered into a third amendment to the Loan Agreement (the "Third Amendment"). Pursuant to the Third Amendment (i) we granted Oxford a lien on our intellectual property, (ii) Oxford provided a waiver of compliance with the Unqualified Audit Opinion Covenant in connection with our receipt of our auditor's going concern opinion for our 2016 financial statements and (iii) Oxford consented to the terms of the MainPointe Agreement. Under the Loan Agreement, an audit opinion with an explanatory paragraph noting substantial doubt about the Company's ability to continue in business is deemed to violate the Unqualified Audit Opinion Covenant.

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 June 30, 2017 and December 31, 2016, we have accumulated and accrued $634 thousand and $559 thousand, respectively, of this additional interest.

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

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

Our debt at June 30, 2017 is summarized below (in thousands):

Current Debt	Current	Long-term	Total
Balance at Jan. 1, 2017	$2,521	$ 2,979	$5,500
Principal payments	(1,122)	-	(1,122)
Classification	1,459	(1,459)	-
Balance at Jun. 30, 2017	$2,858	$ 1,520	$4,378

Debt Discount	Current	Long-term	Total
Balance at Jan. 1, 2017	$-	$ (98)	$(98)
Amortization expense	-	37	37
Classification	-	-	-
Balance at Jun. 30, 2017	$-	$ (61)	$(61)

Deferred Debt Issuance Costs	Current	Long-term	Total
Balance at Jan. 1, 2017	$-	$ (47)	$(47)
Amortization expense	-	19	19
Classification	-	-	-
Balance at Jun. 30, 2017	$-	$ (28)	$(28)

Current Debt, net at Jun 30, 2017	$2,858	$ 1,431	$4,289

Our interest expense for the three and six months ended June 30, 2017 and 2016 consisted of the following (in thousands):

	Three months Ended June 30,		Six months Ended June 30,	
	2017	2016	2017	2016
Interest expense:				
Term loan	$ 133	$ 195	$ 281	$ 404
Debt discount	17	25	37	51
Debt issue costs	9	13	19	27
Total interest expense	$ 159	$ 233	$ 337	$ 482

The remaining annual principal payments of the debt outstanding at June 30, 2017 are as follows:

Year	Remaining Annual Principal Payments (in thousands)
2017	$ 1,400
2018	2,978
Total	$ 4,378

NOTE 10 - COMMON STOCK WARRANTS

At June 30, 2017 and 2016, 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 9 for a discussion of the reduction of the exercise price of these warrants to $2.52 per share which were originally issued to the Lender in connection with the issuance of the $10.0 million secured promissory notes in December 2013. The warrants contain a cashless exercise feature.

NOTE 11 - SHARE-BASED COMPENSATION

Share-based Compensation

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

We measure our compensation cost related to share-based payment transactions based on fair value of the equity or liability instrument issued. For purposes of estimating the fair value of each stock option unit on the date of grant, we utilize the Black-Scholes option-pricing model. Option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of our common stock (as determined by reviewing our historical public market closing prices). Our accounting for share-based compensation for RSUs is based on the market price of our common stock on the date of grant, less its exercise cost.

Our non-cash 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 June 30,		Six months Ended June 30,	
	2017	2016	2017	2016
Research and development expense:				
Stock options	$ 34	$ 43	$ 68	$ 85
Restricted stock units	-	-	-	-
Subtotal	$ 34	$ 43	$ 68	$ 85
General and administrative expense:				
Stock options	$ 53	$ 77	$ 106	$ 155
Restricted stock units	30	30	59	60
Subtotal	$ 183	$ 107	$ 165	$ 215
Total	$ 117	$ 150	$ 233	$ 300

Stock Option Award Plans

We maintain various stock option plans. A summary of our stock option plan activity during the six month periods ending June 30, 2017 and 2016 is shown below:

	Six Months Ended June 30,			
	2017		2016	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, Jan. 1	1,397	$ 13.57	1,198	$ 15.67
Granted	-	-	-	-
Exercised	(1)	(0.92)	-	-
Forfeited or expired	-	-	-	-
Outstanding, Jun. 30	1,396	$ 13.58	1,198	$ 15.67
Options exercisable	1,190	$ 15.71	938	$ 19.43

The following table summarizes information about nonvested stock options outstanding at June 30, 2017 (in thousands except price data):

	Number of Options Not Exercisable	Weighted Average Fair Value
Outstanding, Jan. 1, 2017	335	$ 1.18
Granted	-	-
Vested	(129)	1.36
Forfeited	-	-
Outstanding, Jun. 30, 2017	206	$ 1.07

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 intrinsic value of the option awards which were vested and outstanding at June 30, 2017 and 2016 was $0 thousand and $70 thousand, respectively. The total remaining unrecognized compensation cost on unvested option awards outstanding at June 30, 2017 was $222 thousand, and is expected to be recognized in operating expenses in varying amounts over the 17 months remaining in the requisite service periods.

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:

	Six months Ended June 30,			
	2017		2016	
	(in thousands)			
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, Jan. 1	91	91	45	45
Granted	238	-	88	-
Distributed	(67)	(67)	(42)	(42)
Vested	-	118	-	44
Forfeited or expired	-	-	-	-
Outstanding, Jun. 30	262	142	91	47

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 June 30, 2017, we had 3 thousand shares available for award under the 2014 RSU Plan.

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

- On January 2, 2015, we awarded approximately 10 thousand RSUs to each of our four 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. 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.
- On January 4, 2016, we awarded approximately 22 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 $27 thousand at December 31, 2016. Distributions of stock under the January 4, 2016 award are generally distributed on the first business day of the year after vesting, but such distribution can be deferred until a later date at the election of the non-employee director.

- On January 3, 2017, we awarded approximately 60 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 2017. 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 $32 thousand at June 30, 2017. Distributions of stock under the January 3, 2017 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 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.
- On January 3, 2017, 1 thousand RSUs from the May 1, 2014 award and 66 thousand RSUs from the January 4, 2016 award were distributed. There are 1 thousand RSUs from the May 1, 2014 award and 22 thousand RSUs from the January 4, 2016 award which remain deferred until a future distribution date. Of the 67 thousand RSUs distributed, 49 thousand RSUs were distributed in common stock and 18 thousand RSUs were settled in cash.

NOTE 12 – INCOME TAXES

We account for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities and are accounted for using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At both June 30, 2017 and December 31, 2016, 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 $47.2 million federal income tax benefits at December 31, 2016 derived from $138.8 million Federal NOLs at the U.S. statutory tax rate of 34% and $2.1 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 2017 and 2036 if not used, and those expirations will cause fluctuations in our valuation allowances. As of December 31, 2016 we had federal research and development tax credits of approximately $1.2 million, which expire in the years 2024 through 2034 if gone unused. We also had approximately $0.2 million of Indiana state research and development tax credits, which will expire in 2017 if gone unused.

NOTE 13 – 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. Common stock equivalents are excluded from the computation where their inclusion would be anti-dilutive. No such

adjustments were made for either 2017 or 2016 as the Company reported a net loss for the three and six month periods, and including the effects of the common stock equivalents in the diluted EPS calculations would have been antidilutive. The weighted-average common shares outstanding (diluted) computation is not impacted during any period where the exercise price of a stock option is greater than the average market price.

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

	Three months Ended June 30,		Six months Ended June 30,	
	2017	2016	2017	2016
EPS – basic and diluted				
Numerator: net loss	$(2,149)	$(3,288)	$(1,744)	$(6,672)
Denominator (weighted):				
Common shares	11,883	11,834	11,883	11,833
Vested RSUs	83	24	54	14
Basic and diluted weighted average shares outstanding	11,966	11,858	11,937	11,847
EPS – basic and diluted	$(0.18)	$(0.28)	$(0.15)	$(0.56)
Excluded securities (non-weighted):				
Common shares issuable:				
Stock options	1,396	1,198	1,396	1,198
Nonvested RSUs	120	44	120	44
Common stock warrants	60	60	60	60
Total excluded common shares	1,576	1,302	1,576	1,302

NOTE 14 – COMMITMENTS AND CONTINGENCIES

Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to Acura, 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 were 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 taken 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. The trial court proceedings were stayed on January 12, 2017. On June 15, 2017, a Stipulation of Dismissal without prejudice was entered as to nearly all of the Pennsylvania cases pending against us. We expect that the remaining few cases will be dismissed based on lack of product identification and the Court will finally dismiss the Pennsylvania-based litigation against us with prejudice later this year. 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 there is a lack of product identification. On January 13, 2017, the Court also entered a general stay of this entire litigation. To date, none of these plaintiffs have confirmed they ingested any of the generic metoclopramide manufactured by us. Plaintiffs are proceeding to resolve all of their claims with co-defendants. Therefore, upon completion of this process, we expect that the lawsuits filed against us will be dismissed voluntarily with prejudice later this year. Legal fees related to this matter are currently covered by our insurance carrier.

As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of June 30, 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. (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.

Egalet Agreement covering Oxaydo

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 June 30, 2017 and December 31, 2016, we have accrued approximately $217 thousand and $150 thousand, respectively, of these potential cost sharing expenses under the Egalet Agreement.

Facility Lease

The Company leases administrative office space in Palatine, Illinois on a month to month basis at the rate of approximately $2,000 per month.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This discussion and analysis should be read in conjunction with the Company's financial statements and accompanying notes included elsewhere in this Report. Historical operating results are not necessarily indicative of results in future periods.

Forward-Looking Statements

Certain statements in this Report constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to:

- our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our Limitx and Impede technologies;
- our ability to remain in compliance with our obligations under our term loan with Oxford Finance LLC, or to obtain a waiver from Oxford Finance LLC for our failure to comply with our covenants contained in such term loan agreement;

- the expected results of clinical studies relating to LTX-04 or any successor product candidate, the date by which such studies will be complete and the 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 or any successor product candidate, to provide an efficacious level of drug when one or two tablets are taken;
- whether a reformulated Limitx formulation that achieves an efficacious level of drug will continue to demonstrate acceptable abuse deterrent performance;
- whether we will be able to reformulate LTX-04 or any successor product candidate, 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 or our licensees' 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; and
- whether Oxaydo or our Aversion and Limitx product candidates will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede technology product candidates will disrupt the processing of pseudoephedrine into methamphetamine.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expe “plans,” “anticipates,” “believes,” “estimates,” “indicates,” “projects,” “predicts,” “potential” and similar expressions intended identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our 2016 Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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

Company Overview

We are a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Aversion® and Limitx™ Technologies are intended to address methods of abuse associated with opioid analgesics while our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine, or PSE, into methamphetamine. Oxaydo Tablets (oxycodone HCl, CII), which utilizes the Aversion Technology, is the first 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 March 16, 2017, we and MainPointe Pharmaceuticals, LLC (“MainPointe”), entered into a License, Commercialization and Option Agreement (“MainPointe Agreement”), pursuant to which we granted MainPointe an exclusive license to our Impede technology in the U.S. and Canada to commercialize our Nexafed products. The MainPointe Agreement also grants MainPointe the option to expand the licensed territory to the European Union, Japan and South Korea and to add additional pseudoephedrine-containing products utilizing our Impede technology.

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 two clinical studies, Study AP-LTX-400, or Study 400, and Study AP-LTX-401, or Study 401, of our lead Limitx immediate release oral abuse deterrent drug candidate using the opioid hydromorphone HCI (LTX-04). Each of Study 400 and Study 401 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.

For Study 401, we utilized a new, faster releasing micro-particle formulation for LTX-04. Study 401 demonstrated that the Cmax following excessive tablet abuse (in excess of 2 tablets at a time) of the modified LTX-04 formulation are reduced by up to 65% compared to currently marketed products. The single tablet dose of LTX-04 in Study 401 did not achieve an efficacious blood level, having a Cmax that was 52% of the Cmax of the marketed comparator product. We believe the Study 401 results indicate that the current LTX-04 formulation contains excess buffering ingredients resulting in incomplete release of drug. The Company is developing plans for a buffer dose ranging study AP-LTX-300 or Study 300 to guide the reformulation of the tablet buffers in tandem with its change in development focus from LTX-04, an immediate-release hydromorphone product, to LTX-03, an immediate release hydrocodone bitartrate product, for subsequent Limitx studies. Hydrocodone bitartrate is more likely to be abused by excess oral ingestion. Study 300 is expected to commence dosing in early September. Since this will be a parallel design study – that is, each subject will only be dosed with one test article for the entire study – all subject dosing is expected to be completed in a couple of days. Thus, we anticipate topline results from this study to be available in October. We expect the results from Study 300 to guide us on the final formulation for LTX-03 tablets which will combine the hydrocodone micro-particles, acetaminophen and buffer ingredients into a single tablet. We will then progress to identifying a commercial manufacturer so that we may finalize the to-be-marketed formulation which is required for all future NDA development work.

Opioid analgesics are one of the largest prescription drug markets in the United States with 222 million prescriptions dispensed in 2016. 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 2016, sales in the immediate-release opioid product segment were approximately 208 million prescriptions and $2.7 billion, of which approximately 98% was attributable to generic products. Immediate-release oxycodone tablets represent 20.1 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 50 sales representatives promoting Oxaydo to a target group of approximately 6,000 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. At March 15, 2017, Nexafed, our 30mg pseudoephedrine hydrochloride immediate-release tablet, were 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 have a development program to develop an extended-release version of our Impede Technology to capitalize on higher sales products in the category. We also have investigated 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.

Recent Events

On July 24, 2017, we completed a $4.0 million private placement with John Schutte (the "Investor"), consisting of 8,912,655 units ("Units") of the Company, at a price of $0.4488 per Unit (the "Transaction"). Each Unit consists of one share of Common Stock and a Warrant to purchase one fifth (0.2) of a share of Common Stock. The issue price of the Units was equal to 85% of the average last sale price of our Common Stock for the five trading days prior to completion of the Transaction. The Warrants are immediately exercisable at a price of $0.528 per share (which equals the average last sale price of the Company's Common Stock for the five trading days prior to completion of the Transaction) and expire five years after issuance (subject to earlier expiration in event of certain acquisitions). The Transaction was completed through a private placement to an accredited investor and was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended and/or Regulation D promulgated under the Securities Act of 1933.

We estimate that the net cash proceeds to us after expenses of the Transaction are approximately $3.9 million. We intend to use the net proceeds of the Transaction for working capital purposes, including the funding of Phase I clinical trials for one or more products utilizing our LimitX technology.

After giving effect to our issuance of the Units, we have 20,745,994 shares of Common Stock outstanding and the Investor will beneficially own approximately 47.5% of the Company's Common Stock (calculated in accordance with Rule 13d-3 of the Securities Exchange Act of 1934). Prior to Investor's acquisition of Units, Galen Partners III, LP and Essex Woodlands Health Ventures Fund V, L.P. or their affiliates were the Company's largest shareholders and beneficially owned approximately 18.5% and 16.5%, respectively, of the Company's Common Stock.

As part of the closing of the Transaction, the Company, Essex Woodlands Health Ventures V, L.P. ("Essex") and Galen Partners III, L.P. ("Galen") amended and restated the existing Voting Agreement between the parties to provide for the Investor to join as a party (as so amended, the "Second Amended and Restated Voting Agreement"). The Second Amended and Restated Voting Agreement provides that our Board of Directors shall remain comprised of no more than seven members (subject to certain exceptions), (i) one of whom is the Company's Chief Executive Officer, (ii) three of whom are independent under Nasdaq standards, and (iii) one of whom shall be designated by each of Essex, Galen and Investor. The right of each of Essex, Galen and Investor to designate one director to our Board will continue as long as he or it and their affiliates collectively hold at least 600,000 shares of our Common Stock (including warrants exercisable for such shares). Immanuel Thangaraj is the designee of Essex. Galen has not designated a director. Investor has not designated a director as of the date of filing of this Report.

Investor is a principal of MainPointe, a Kentucky limited liability company. In March 2017, MainPointe acquired from the Company rights to Nexafed® and Nexafed® Sinus Pressure + Pain in the United States and Canada for an upfront licensing fee of $2.5 million plus approximately $425,000 for transferred inventory and equipment. The Company will receive a 7.5% royalty on sales of licensed products. MainPointe also has options to expand the territory and products covered for additional sums.

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.

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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 although an FDA Advisory Committee recently recommended an opioid analgesic product for approval that did not meet the FDA's bioequivalence standard.

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 are in the process of redirecting our development focus from LTX-04 to 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 by the National Institute on Drug Abuse 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 was 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)	Two Phase I exploratory pharmacokinetic studies completed
Immediate-release hydrocodone bitartrate with acetaminophen (LTX-03)	Formulation development in process Buffer dose ranging study expected to commence 3Q 2017
Immediate-release oxycodone HCl (LTX-01) & (LTX-02)	Formulation development in process

Study 400

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.

In our initial analysis of Study 400 we concluded that we (a) had identified the appropriate buffer level for the technology, (b) demonstrated the maximum plasma level of the opioid active ingredient, or Cmax, was reduced by an average of approximately 22% when multiple tablets were ingested and (c) needed to reformulate the drug containing micro-particles to achieve sufficient levels of drug in the blood stream with a single tablet dose. Based on the results of Study 401, we have revised these conclusions and determined that (a) we have too much buffer ingredient in a single tablet so that the micro-particles are not completely and immediately releasing all the drug even at a single tablet and (b) a 57% reduction in Cmax was demonstrated with the multiple tablet dose.

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.

Study 401

Our second LTX-04 clinical study, or Study 401, also was a two cohort, open label, crossover design pharmacokinetic study in fasted, health adult subjects. Study 401 utilized a modified LTX-04 formulation containing micro-particles intended to improve drug delivery with one and two tablet dosing. Study 401 measured the rate and extent of absorption of the active drug ingredient into the blood stream with the Cmax typically associated with an increase in drug abuse. 27 subjects completed Cohort 1 swallowing a single dose tablet of LTX-04 compared to a generic hydromorphone tablet. 13 subjects completed Cohort 2 swallowing 7 LTX-04 and generic tablets doses. 15 subjects followed an undisclosed, exploratory protocol.

All tablets contained 2 mg of hydromorphone hydrochloride. All subjects received dosages of naltrexone and/or naloxone and there was a one week washout between dosages. Blood samples were taken at pre-designated time-points after dosing and were subsequently analyzed for the concentration of hydromorphone contained in the sample. The objective of Cohort 1 was to determine if adequate active drug entered the bloodstream when one Limitx tablet was swallowed. The objective of Cohort 2 was to explore the extent to which the release of the hydromorphone active ingredient from LTX-04 tablets is retarded at a seven tablet dose (oral excess abuse levels). A safety assessment of Limitx hydromorphone would be made from both study cohorts.

The topline results from Study 401 at one tablet was essentially unchanged from the results from Study 400; that is the average Cmax for an LTX-04P3 dose was approximately 50% of the active comparator. Since the micro-particles used in Study 401 release drug much faster than the micro-particles used in Study 400, we have concluded that the buffer levels used in both studies were too much and is retarding the release of drug even with a single dose.

Based on this conclusion, we believe Study 401 demonstrated a Cmax reduction of up to 65% following ingestion of multiple tablets compared to currently marketed products as the 7 tablet dose Cmax was 65% less than the comparator. This also means our conclusion of Study 400 changed such that an 8 tablet dose demonstrated a 57% reduction in Cmax with an 8 tablet dose. Because, we believe, Study 401 used too much buffer for even a single tablet, Study 401 achieved insufficient blood levels of the opioid active ingredient with a single tablet.

Study 300

We are in the process of commencing Study 300, the first study for LTX-03. Study 300 will be a buffer dose ranging study. That is, we are in the process of producing an active component that will include 10mg of hydrocodone bitartrate micro-particles and 325mg of acetaminophen. This active component will contain no buffering capacity. Separately, we are producing a buffering component which will have a fraction of the buffering capacity that we have previously used in testing LTX-04. In Study 300, we will encapsulate the active component with an incremental number of buffering units. Subjects will be assigned into one of seven subgroups and administered a dose with either no buffering component or up to 5 buffering units. For one group, encapsulated commercially available reference product 10 mg hydrocodone bitartrate/325 mg acetaminophen will be administered as the positive control. The analysis of this study data will allow us to incrementally assess the distinct levels of buffer amounts on the in vivo micro-particle performance. Our goal is to identify the highest buffer level that allows for a full release of hydrocodone at a single tablet dose relative to the positive control before the LIMITx buffering effect is observed. Acetaminophen blood levels will also be analyzed and compared to the positive control.

Study 300 is expected to commence dosing in early September. Since this will be a parallel design study – that is, each subject will only be dosed with one test article for the entire study – all subject dosing is expected to be completed in a couple of days. Thus, we anticipate topline results from this study to be available in October. We expect the results

from Study 300 to guide us on the final formulation for LTX-03 tablets which will combine the hydrocodone microparticles, acetaminophen and buffer ingredients into a single tablet. We will then progress to identifying a commercial manufacturer so that we may finalize the to-be-marketed formulation which is required for all future NDA development work.

Aversion Technology

Aversion Technology incorporates gelling ingredients and irritants into tablets to discourage abuse by snorting and provide barriers to abuse by injection. Our Aversion Technology and related opioid products, like Oxaydo, are covered by claims in five issued U.S. patents, which expire between 2023 and 2025. Our Aversion Technology products are intended to provide the same therapeutic benefits of the active drug ingredient as currently marketed products containing the same active pharmaceutical ingredient.

Oxaydo Tablets

Oxaydo (oxycodone HCI tablets) is a Schedule II narcotic indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is approved in 5mg and 7.5mg strengths. Egalet launched Oxaydo in the United States late in the third quarter of 2015.

The 2015 market for immediate-release oxycodone products was 20.1 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:

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- 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 is targeting approximately 6,000 immediate-release opioid prescribing physicians using approximately 50 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.

On June 20, 2017, Egalet announced that it had received a complete response letter from the FDA in response to its prior approval supplement to the Oxaydo NDA seeking approval for 10mg and 15mg strengths of Oxaydo. Eaglet has

advised that the FDA is requesting more information regarding the effect of food on Oxaydo 15mg and the intranasal abuse-deterrent properties of Oxaydo 10mg and 15mg.

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 have completed process validation on this new formulation and expect MainPointe will introduce the new formulation into the market in the 3rd quarter of 2017.

Nexafed Products

The Nexafed products currently marketed consist 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. Prior the MainPointe Agreement completed in March 2017, we capitalized 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 launched Nexafed commercially in mid-December 2012 into the United States OTC market for cold and allergy products. At March 15, 2017, Nexafed was stocked in approximately 13,900 pharmacies or about approximately 21% of the estimated 65,000 U.S. pharmacy outlets. Initial adoption was primarily in independent pharmacies in predominately rural communities with high meth awareness. Chain pharmacies, with more centralized control of the pharmacy operations, began adopting in mid-2013, including Kroger, Publix, Fruth and Bartells. Some pharmacists actively recommend 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.

In February 2015, we began initial shipments of Nexafed Sinus Pressure + Pain. Prior to the MainPointe Agreement, we were 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.

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

MainPointe Agreement covering Nexafed Products

On March 16, 2017, we and MainPointe entered into a License, Commercialization and Option Agreement, or the MainPointe Agreement, pursuant to which we granted MainPointe an exclusive license to our Impede technology to commercialize our Nexafed products in the U.S. and Canada. We also conveyed to MainPointe our existing inventory and equipment relating to our Nexafed products. MainPointe is responsible for all development, manufacturing and commercialization activities with respect to products covered by the Agreement.

On signing the MainPointe Agreement, MainPointe paid us an upfront licensing fee of $2.5 million plus approximately $425,000 for the net book value of inventory and equipment being transferred. The MainPointe Agreement also provides for our receipt of a 7.5% royalty on net sales of licensed products. The royalty payment for each product will expire on a country-by-country basis when the Impede® patent rights for such country have expired or are no longer valid; provided that if no Impede patent right exists in a country, then the royalty term for that country will be the same as the royalty term for the United States. After the expiration of a royalty term for a country, MainPointe retains a royalty free license to our Impede® technology for products covered by the Agreement in such country.

MainPointe has the option to expand the licensed territory beyond the United States and Canada to the European Union (and the United Kingdom), Japan and South Korea for payments of $1 million, $500,000 and $250,000, respectively. In addition, MainPointe has the option to add to the MainPointe Agreement certain additional products, or Option Products, containing PSE and utilizing the Impede technology for a fee of $500,000 per product (for all product strengths), including the product previously subject to our agreement with Bayer. If the territory has been expanded prior to the exercise of a product option, the option fee will be increased to $750,000 per product. If the territory is expanded after the payment of the $500,000 product option fee, a one-time $250,000 fee will be due for each product. If a third party is interested in developing or licensing rights to an Option Product, MainPointe must exercise its option for that product or its option rights for such product will terminate.

The MainPointe Agreement may be terminated by either party for a material breach of the other party, or by Acura if MainPointe challenges certain of its patents. Upon early termination of the MainPointe Agreement, MainPointe's licenses to the Impede technology and all products will terminate. Upon termination, at Acura's request the parties will use commercially reasonable efforts to transition the Nexafed® and Nexafed® Sinus Pressure + Pain products back to Acura.

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	Manufacturing validation complete with commercial shipments pending.
Immediate-release pseudoephedrine HCl in combination with other cold and allergy active ingredients	Nexafed Sinus Pressure + Pain launched and licensed to MainPointe. 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	Bayer's rights terminated. Pilot clinical testing complete. Formulation ready for final development and NDA submission.

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.

In March 2017, we completed a pilot pharmacokinetic study for the PSE-containing combination product using our Impede 1.0 technology we were formerly developing for Bayer. The study in 24 healthy adult subjects demonstrated sufficient, but not bioequivalent blood levels of PSE to the comparator while the second active ingredient achieved bioequivalence. Based on the product profile, the Company believes this formulation can be moved into final development for a 5050(b)(2) NDA submission. The Company intends to upgrade this formulation with its Impede 2.0 technology before determining any advancement in development.

Our objective is to establish, either directly or through third-party licensees, the 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. In addition to the MainPointe Agreement, we may license our Impede technology to commercial partners to 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. We received reimbursement of certain our development expenses, and were entitled to success-based development and regulatory milestone payments, and low mid-single digit royalties on the net sales of the developed product. On June 28, 2017, we received Bayer’s written notice terminating the Bayer Agreement. Bayer exercised its convenience termination right prior to the completion of our development obligations under the Bayer Agreement, which we believe is as a result of Bayer’s de-prioritization of development of the methamphetamine resistant PSE-containing product contemplated in the Agreement. As a result of the termination, MainPointe has the option to license such product in the U.S. and Canada upon payment to us of $500,000, together with royalty of 7.5% of net sales of such product, under the MainPointe Agreement.

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. Prior to the MainPointe Agreement, Nexafed was priced at $4.39 for a box of 24 tablets and Nexafed Sinus Pressure + Pain at $7.95 for a box of 24 tablets. MainPointe will control the price of Nexafed and Nexafed Sinus under the terms of the MainPointe Agreement.

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

Nexafed and Nexafed Sinus Pressure + Pain products are marketed pursuant to the FDA's OTC Monograph regulations, which require that our product have labeling as specified in the regulations. Marketing for the Nexafed products includes advertising the extraction characteristics and methamphetamine-resistant benefits of these 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 222 million tablet and capsule prescriptions dispensed in 2016 of which approximately 208 million were for IR opioid products and 14 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 66 tablets or capsules. According to IMS Health, in 2016, sales in the IR opioid product segment were approximately $2.7 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 2016 is provided below:

IR Opioid Products[1]	**2016 US Prescriptions (Millions)[2]**	% of Total
Hydrocodone	90	43 %
Oxycodone	55	26 %
Tramadol	43	21 %
Codeine	15	7 %
4 Others	5	3 %
Total	208	100 %

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

2 IMS Health, 2016

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
9,662,393 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Mar. 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	Jan. 2009	Nov. 2023

	opioid analgesic product misuse and abuse		
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
1694260 (EUR)	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	Sep. 2030
2,775,890 (CAN)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sep. 2030
2,488,029 (EUR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Mar. 2016	Sep. 2030
218533 (ISR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jan. 2016	Sep. 2030

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, and the MainPointe 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 our Annual Report on Form 10K under the caption "Item 1A. Risk Factors – Generic manufacturers are using litigation and regulatory means to seek approval for generic versions of Oxaydo, which could cause Egalet's sales to suffer and adversely impact our royalty revenue" for a discussion of the settlements and license grants relating to such patent litigation. Notwithstanding the settlement of these prior infringement actions, it is possible that other generic manufacturers may also seek to launch a generic version of Oxaydo and challenge our patents. Any determination in such infringement actions that our patents covering our Aversion Technology and Oxaydo are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents could have a material adverse effect on our operations and financial condition.

In April, 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc., 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. The Settlement Agreement specifically excludes our patents related to our Impede and Limitx technologies from the scope of our patents subject to the Settlement Agreement.

Reference is made to the Risk Factors contained in our Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion, among other things, of patent applications and patents owned by third parties, including claims that may encompass our Aversion Technology and Oxaydo tablets, and the risk of infringement, interference or opposition proceedings that we may be subject to arising from such patents and patent applications.

Company's Present Financial Condition

At June 30, 2017, we had unrestricted cash and cash equivalents of $1.1 million, compared to $2.7 million of unrestricted cash and cash equivalents at December 31, 2016 (in each case which is after the deduction of the $2.5 million compensating balance requirement under our term loan with Oxford). Under our term loan with Oxford Finance LLC, we were required to maintain a $2.5 million compensating balance until such time as we raised an additional approximately $3.5 million through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions. On July 24, 2017 we completed a private placement of our equity securities, resulting in net proceeds to the Company of approximately $3.9 million. At a result, we are no longer subject to the $2.5 million compensating balance requirement under our term loan with Oxford. We had an accumulated deficit of approximately $376.4 million at June 30, 2017. We had loss from operations of $1.4 million and net loss of $1.7 million for the six months ended June 30, 2017 and we had a net loss from operations of $6.6 million and net loss of $7.4 million for the year ended December 31, 2016. Giving effect to our July 2017 private placement and the lapse of the $2.5 million cash balance requirement under our term loan with Oxford, we had unrestricted cash and cash equivalents of $6.6 million at August 1, 2017. Our current unrestricted cash and cash equivalents is expected to be sufficient to fund the development of our products and our related operating expenses only into April 2018.

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 June 30, 2017 Compared to Three months Ended June 30, 2016

	June 30 2017 $000's	2016	Increase (decrease)	Percent
Revenues:				
Collaboration revenue	$23	$133	(110)	(83)%
Royalty revenue	69	30	39	130
Product sales, net	-	94	(94)	(100)
Total revenues, net	92	257	(165)	(64)
Cost and expenses:				
Cost of sales (excluding inventory provisions)	-	99	(99)	(100)
Inventory provisions	-	26	(26)	(100)
Research and development	1,020	1,403	(383)	(27)
Sales, marketing, general and administrative	1,063	1,808	(745)	(41)
Total operating expenses	2,083	3,336	(1,253)	(38)
Operating loss	(1,991)	(3,079)	(1,088)	(35)
Non-operating income (expense):				
Investment income	1	21	(20)	(95)
Interest expense	(159)	(233)	(74)	(32)
Other expense	-	3	(3)	100
Total other expense, net	(158)	(209)	(51)	(24)
Loss before provision for income taxes	(2,149)	(3,288)	(1,139)	(35)
Provision for income taxes	-	-	-	-
Net loss	(2,149)	$(3,2,88)	(1,139)	(35)

Revenue

Collaboration

Collaboration revenue is derived from reimbursement of development expenses under various development agreements, such as from our former collaboration agreement with Bayer, and are recognized when costs are incurred pursuant to the collaboration agreement. We recognized $23 thousand and $133 thousand of collaboration revenue during the three months ended June 30, 2017 and 2016, respectively.

Royalties

In connection with our Collaboration and License Agreement with Egalet to commercialize Oxaydo tablets we are receiving 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. We recognized $64 thousand and $30 thousand of royalty revenue during the three months ended June 30, 2017 and 2016, respectively.

In connection with our License, Commercialization and Option Agreement with MainPointe on March 16, 2017, we are receiving a royalty of 7.5% on net sales of the licensed products over the term of the agreement. Such royalty shall be payable for sales made during each calendar quarter and payment will be remitted within forty-five (45) days after the end of the quarter to which it relates. We recognized $5 thousand of royalty revenue during the three months ended June 30, 2017.

Net Product Sales

As of March 16, 2017, our licensee, MainPointe, is manufacturing, distributing, and selling the Nexafed product line.

Cost and Expenses

Research and Development

Research and development expense (R&D) is primarily for our Aversion and our Impede Technologies development and includes 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 the results for the three months ended June 30, 2017 and 2016 is approximately $5 thousand and $92 thousand, respectively 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 $24 thousand and $186 thousand, respectively of cost sharing expenses of the FDA required post-marketing study for Oxaydo under the Egalet Agreement.

Also included in each of 2017 and 2016 quarterly results are non-cash share-based compensation expenses of approximately $34 thousand and $43 thousand, respectively. Excluding the share-based compensation expense, our R&D expenses decreased approximately $375 thousand between reporting periods.

The initial LTX-04 clinical study, Study AP-LTX-400 or Study 400, was completed during 2016. During the first quarter 2017, our activities were addressing certain excipient issues in our LTX-04 tablet formulation and developing a new, faster releasing micro-particle formulation for LTX-04. We substantially completed our second pharmacokinetic study, AP-LTX-401 during the second quarter 2017.

General, Administrative, Selling and Marketing

Selling and marketing expenses are primarily of advertising and marketing activities on the Nexafed product line. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the three months ended June 30, 2017 and 2016 results are non-cash share-based compensation expenses of approximately $83 thousand and $107 thousand, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased by approximately $720 thousand between reporting periods, resulting primarily from decreases in advertising and marketing activities for our Nexafed product line as well as patent and general legal activities. In March 2017 we licensed the Nexafed product line to MainPointe.

Non-Operating Income (Expense)

During the three months ended June 30, 2017 and 2016, non-operating expense consisted principally of interest expense on our term loan from Oxford, which originated in December 2013, less any interest income and investment income derived from any of our investments.

Income Taxes

Our results for the three months ended June 30, 2017 and 2016 show no federal or state income tax benefit provisions due to 100% allowances placed against their deferred tax asset for uncertainty of their future utilization.

Six months Ended June 30, 2017 Compared to Six months Ended June 30, 2016

	June 30 2017 $000's	2016	Increase (decrease)	Percent
Revenues:				
License fee revenue	$2,500	$-	$ 2,500	-%
Collaboration revenue	59	233	(174)	(75)
Royalty revenue	143	47	96	204
Product sales, net	107	201	(94)	(47)
Total revenues, net	2,809	481	2,328	484
Cost and expenses:				
Cost of sales (excluding inventory provisions)	128	201	(73)	(36)
Inventory provisions	-	26	(26)	(100)
Research and development	1,731	2,417	(686)	(28)
Sales, marketing, general and administrative	2,359	4,054	(1,695)	(42)
Total costs and expenses	4,218	6,698	(2,480)	(37)
Operating loss	(1,409)	(6,217)	(4,808)	(77)
Non-operating income (expense):				
Investment income	2	48	(46)	(96)
Interest expense	(337)	(482)	(145)	(30)
Other expense	-	(21)	(21)	(100)
Total other expense, net	(335)	(455)	(120)	(26)
Loss before provision for income taxes	(1,744)	(6,672)	(4,928)	(74)
Provision for income taxes	-	-	-	-
Net loss	(1,744)	$(6,672)	(4,928)	(74)

Revenue

License Fees

In March 2017, under our Collaboration and License Agreement with MainPointe Agreement, we granted MainPointe an exclusive license to our Impede technology to commercialize our Nexafed products in the U.S. and Canada. On signing the MainPointe Agreement, MainPointe paid us an upfront licensing fee of $2.5 million.

Collaboration

Collaboration revenue is derived from reimbursement of development expenses under various development agreements, such as from our former collaboration agreement with Bayer, and are recognized when costs are incurred pursuant to the collaboration agreement. We recognized $59 thousand and $233 thousand of collaboration revenue during the six months ended June 30, 2017 and 2016, respectively.

Royalties

In connection with our Collaboration and License Agreement with Egalet to commercialize Oxaydo tablets we are receiving 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. We recognized $135 thousand and $47 thousand of royalty revenue during the six months ended June 30, 2017 and 2016, respectively.

In connection with our License, Commercialization and Option Agreement with MainPointe on March 16, 2017, we are receiving a royalty of 7.5% on net sales of the licensed products over the term of the agreement. Such royalty shall be payable for sales made during each calendar quarter and payment will be remitted within forty-five (45) days after the end of the quarter to which it relates. We recognized $8 thousand of royalty revenue during the six months ended June 30, 2017.

Net Product Sales

Nexafed® was launched in December 2012. Nexafed® Sinus Pressure + Pain was launched in February 2015. Prior to the MainPointe Agreement, the Company sold 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's expiration date. As of March 16, 2017, our licensee, MainPointe, is manufacturing, distributing, and selling the Nexafed product line.

Cost and Expenses

Cost of Sales

Cost of sales includes third-party acquisition costs, third-party warehousing and product distribution charges and inventory reserve expenses for the Nexafed product line. Our cost of sales for the six months ended June 30, 2017 and 2016 were $128 thousand and $227 thousand, respectively. As of March 16, 2017, our licensee, MainPointe, is manufacturing, distributing, and selling the Nexafed product line.

Research and Development

Research and development expense (R&D) is primarily for our Limitx and our Impede Technologies development and includes 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 the results for the six months ended June 30, 2017 and 2016 is approximately $86 thousand and $92 thousand, respectively 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 $47 thousand and $186 thousand, respectively of cost sharing expenses of the FDA required post-marketing study for Oxaydo under the Egalet Agreement.

Also included in each of 2017 and 2016 six month results are non-cash share-based compensation expenses of approximately $68 thousand and $85 thousand, respectively. Excluding the share-based compensation expense, our R&D expenses decreased approximately $670 thousand between reporting periods.

The initial LTX-04 clinical study, Study AP-LTX-400 or Study 400, was completed during 2016. During the first quarter 2017, our activities were addressing certain excipient issues in our LTX-04 tablet formulation and developing a new, faster releasing micro-particle formulation for LTX-04. We substantially completed our second pharmacokinetic study, AP-LTX-401 during the second quarter 2017.

General, Administrative, Selling and Marketing

Selling and marketing expenses are primarily of advertising and marketing activities on the Nexafed product line. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the six months ended June 30, 2017 and 2016 results are non-cash share-based compensation expenses of approximately $166 thousand and $214 thousand, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased by approximately $1.6 million between reporting periods, resulting primarily from decreases in advertising and marketing activities for our Nexafed product line as well as patent and general legal activities. In March 2017 we licensed the Nexafed product line to MainPointe.

Non-Operating Income (Expense)

During the six months ended June 30, 2017 and 2016, non-operating expense consisted principally of interest expense on our term loan from Oxford, which originated in December 2013, less any interest income and investment income derived from any of our investments.

Income Taxes

Our results for the six months ended June 30, 2017 and 2016 include no federal or state income tax benefit provisions due to 100% allowances placed against their deferred tax asset for uncertainty of their future utilization.

Liquidity and Capital Resources

At June 30, 2017, we had unrestricted cash and cash equivalents of $1.1 million compared to unrestricted cash and cash equivalents of $2.7 million at December 31, 2016. Under our term loan with Oxford, we were required to maintain a $2.5 million compensating balance until such time as we raised an additional $3.5 million through the issuance of our equity securities. On July 24, 2017, we completed a private placement of our equity securities, resulting in net proceeds to the Company of approximately $3.9 million. As a result, we are no longer subject to the $2.5 million compensating balance requirement under our term loan with Oxford. Giving effect to the lapse of such compensating balance requirement and the net proceeds from our July 2017 private placement, at August 1, 2017, we had unrestricted cash and cash equivalents of approximately $6.6 million. We estimate that our unrestricted working capital, together with milestone and royalty payments, if any, that may be made under the Egalet Agreement, the KemPharm Agreement, and the MainPointe Agreement, is expected to be sufficient to fund our continuing operations only into April 2018.

To fund further operations and product development activities beyond April 2018, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. The Company intends to explore a variety of capital raising and other transactions to provide additional funding to continue operations. These include a registered public offering of the Company's common stock, for which the Company filed a registration statement on Form S-1 with the SEC on February 3, 2017, and additional potential private offerings of common stock to institutional and/or accredited investors. The Company is also actively seeking a licensing partner for its Limitx Technology, with the objective of receiving an upfront license fee, development milestone payments and royalties on the net sales of products utilizing the Limitx Technology, similar to the Egalet Agreement. The Company is also exploring licensing or selling select assets and intellectual property in an effort to raise capital and reduce operating expenses. Finally, the Company is evaluating the potential for a strategic transaction which may involve the Company being acquired in a merger or asset purchase transaction. 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. Our auditors have included in their report relating to our 2016 financial statements a "going concern" explanatory paragraph as to substantial doubt of our ability to continue as a going concern. 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 KemPharm Agreement, the MainPointe Agreement and similar agreements for our Limitx products in development with other pharmaceutical company partners, for which there can be no assurance.

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

Critical Accounting Policies

Note A of the Notes to Consolidated Financial Statements, in the Company's 2016 Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company's critical accounting policies described in the 2016 Annual Report are also applicable to 2017.

Item 4. Controls and Procedures

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

(b) *Changes in Internal Controls over Financial Reporting*. There were no changes in our internal controls over financial reporting during the second fiscal quarter of 2017 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

The information required by this Item is incorporated by reference to Note 14, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

Item 1A. Risk Factors

Investors in our common stock should consider the following risk factors, in addition to those risk factors set forth in our 2016 Annual Report on Form 10-K:

We require additional funding; if we fail to raise additional funding we will cease operations and/or seek protection under applicable bankruptcy laws.

We require additional financing or entry into license or collaborative agreements with third parties providing for net proceeds to us in order to continue to fund operations. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaborative agreements will provide for funding or payments to us sufficient to continue to fund operations. Our auditors have included in their report relating to our 2016 financial statements a "going concern" explanatory paragraph as to substantial doubt of our ability to continue as a going concern. After giving effect to the net proceeds from our July 2017 private placement, we believe we have unrestricted cash sufficient to fund operations only into April 2018. In the absence of the receipt of additional financing or payments under third-party license or collaborative agreements prior to such time, we will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. This could result in a complete loss of shareholder value in the Company. Even assuming we are successful in securing additional sources of financing to fund continued operations, there can be no assurance that the proceeds of such financing will be sufficient to fund operations until such time, if at all, that we generate sufficient revenue from our products and product candidates to sustain and grow our operations.

Item 6. Exhibits

The exhibits required by this Item are listed below.

31.1	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
31.2	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
32.1	Certification of Periodic Report by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase

Signatures

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

August 14, 2017 ACURA PHARMACEUTICALS, INC.

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

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