ACURA PHARMACEUTICALS, INC
Form 10-Q
November 13, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20649

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

¨ **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 o

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 o

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

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer (Do not check if a smaller reporting company)	¨	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. o

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

As of November 10, 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 SEPTEMBER 30, 2017

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited; in thousands except par value)

	September 30, 2017	December 31, 2016
Assets:		
Cash and cash equivalents	$ 4,787	$ 2,681
Restricted cash equivalents (Note 10)	-	2,500
Trade accounts receivable (net of allowances of $- and $7)	-	23
Collaboration revenue receivable	-	79
Royalty receivable	65	50
Inventories (net of allowances of $- and $32) (Note 6)	-	309
Prepaid expenses and other current assets	442	268
Total current assets	5,294	5,910
Property, plant and equipment, net (Note 7)	699	867
Intangible asset, net of accumulated amortization of $724 and $569 (Note 3)	1,276	1,431
Total assets	$ 7,269	$ 8,208
Liabilities:		
Accounts payable	$ 127	$ 77
Accrued expenses (Note 8)	890	703
Accrued interest	26	-
Other current liabilities	36	27
Sales returns liability	303	304
Debt - current (Note 10)	2,917	2,376
Total current liabilities	4,299	3,487
Debt – non-current portion, net of discounts (Note 10)	702	2,979
Accrued interest – non-current portion (Note 10)	668	559
Total liabilities	5,669	7,025
Commitments and contingencies (Note 17)		

Stockholders' equity:		
Common stock - $.01 par value per share; 100,000 shares authorized, 20,796 and 11,834 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	208	118
Additional paid-in capital	380,034	375,763
Accumulated deficit	(378,642)	(374,698)
Total stockholders' equity	1,600	1,183
Total liabilities and stockholders' equity	$ 7,269	$ 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 September 30,		Nine months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenues:				
License fee revenue	$ -	$ -	$ 2,500	$ -
Collaboration revenue	-	74	59	307
Royalty revenue	83	39	226	86
Product sales, net	-	105	107	306
Total revenues, net	83	218	2,892	699
Cost and expenses:				
Cost of sales (excluding inventory provisions)	-	108	128	309
Inventory provisions	-	-	-	26
Research and development	1,077	841	2,808	3,258
Selling, marketing, general and administrative	1,068	1,338	3,427	5,392
Total costs and expenses	2,145	2,287	6,363	8,985
Operating loss	(2,062)	(2,069)	(3,471)	(8,286)
Non-operating income (expense):				
Interest and investment income	1	11	3	59
Interest expense (Note 10)	(139)	(215)	(476)	(697)
Other income (expense)	-	23	-	2
Total other expense, net	(138)	(181)	(473)	(636)
Loss before provision for income taxes	(2,200)	(2,250)	(3,944)	(8,922)
Provision for income taxes	-	-	-	-
Net loss	$ (2,200)	$ (2,250)	$ (3,944)	$ (8,922)
Other comprehensive income:				
Unrealized (losses) gains on securities	-	(26)	-	65
Comprehensive loss	$ (2,200)	$ (2,276)	$ (3,944)	$ (8,857)
Loss per share:				
Basic	$ (0.12)	$ (0.19)	$ (0.27)	$ (0.75)
Diluted	$ (0.12)	$ (0.19)	$ (0.27)	$ (0.75)
Weighted average shares outstanding:				
Basic	16,686	11,880	14,147	11,858
Diluted	16,686	11,880	14,147	11,858

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENT OF CHANGES IN ACCUMULATED STOCKHOLDERS' EQUITY

(Unaudited; in thousands)

	Common Stock				
	Number of Shares	**Par Value**	**Additional Paid-in Capital**	**Accumulated Deficit**	**Total**
Balance at January 1, 2017	11,834	$ 118	$ 375,763	$ (374,698)	$ 1,183
Net loss	-	-	-	(3,944)	(3,944)
Share-based compensation	-	-	353	-	353
Issuance of shares and warrants under private placement	8,913	89	3,911		4,000
Net distribution of common stock pursuant to restricted stock unit award plan	49	1	7	-	8
Balance at September 30, 2017	20,796	$ 208	$ 379,539	$ (378,642)	$ 1,600

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Nine months Ended September 30,	
	2017	**2016**
Cash Flows from Operating Activities:		
Net loss	$ (3,944)	$ (8,922)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	68	104
Provision to reduce inventory to net realizable value	-	26
Provision for sales returns	49	83
Share-based compensation	353	450
Amortization of debt discount and deferred debt issue costs	79	113
Amortization of bond premium in marketable securities	-	31
Amortization of intangible asset	155	155
(Gain) loss on disposal of machinery and equipment	(3)	2
(Gain) loss on sales of marketable securities	-	(2)
Change in assets and liabilities:		
Trade accounts receivable, net	23	(24)
Collaboration revenue receivable	79	(27)
Royalty receivable	(15)	(30)
Accrued investment income	-	37
Inventories	103	(174)
Prepaid expenses and other current assets	(174)	4
Other assets	-	175
Accounts payable	50	293
Accrued expenses	187	170
Accrued interest	135	176
Other current liabilities	17	17
Sales returns liability	(50)	-
Net cash used in operating activities	(2,888)	(7,343)
Cash Flows from Investing Activities:		
Proceeds from sales and maturities of marketable securities	-	10,873
Proceeds from transfer of equipment to licensee	103	-
Proceeds from transfer of inventory to licensee	206	-
Capital expenditures	-	(72)
Net cash provided by investing activities	309	10,801
Cash Flows from Financing Activities:		
Principal payments on debt	(1,815)	(1,671)
Issuance of common stock	4,000	-
Net cash provided by (used in) financing activities	2,185	(1.671)

Net (decrease) increase in cash, cash equivalents, and restricted cash	(394)	1,787
Cash, cash equivalents, and restricted cash at beginning of period	5,181	2,485
Cash, cash equivalents, and restricted cash at end of period	$ 4,787	$ 4,272
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest on term loan with Oxford Finance LLC	$ 262	$ 407
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:

	September 30, 2017	**September 30, 2016**
	(in thousands)	
Cash and cash equivalents	$4,787	$ 1,772
Restricted cash equivalents	-	2,500
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$4,787	$ 4,272

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2017 AND SEPTEMBER 30, 2016

NOTE 1 – OPERATIONS AND BASIS OF PRESENTATION

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 and development 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 by neutralizing stomach acid with buffer ingredients but deliver efficacious amounts of drug when taken as a single tablet with a nominal buffer dose. We have completed two clinical studies of various product formulations utilizing immediate-release hydromorphone HCl and one clinical study using immediate-release hydrocodone bitartrate and acetaminophen. We plan to conduct another dose ranging study for immediate-release hydrocodone bitartrate and acetaminophen to commence in the fourth quarter of 2017, with topline results expected in the first quarter of 2018. The FDA has designated the development program for immediate-release hydromorphone HCl 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. However, we intend to advance immediate-release hydrocodone bitartrate and acetaminophen as a lead Limitx product candidate due to its larger market size and its known prevalence of oral excessive tablet abuse.

- 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 HCl) and Nexafed® Sinus Pressure + Pain Tablets (30/325mg pseudoephedrine HCl 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). MainPointe is controlled by John Schutte, who became our largest shareholder pursuant to a private placement transaction completed in July 2017.

Basis of Presentation and Going Concern

The accompanying unaudited consolidated financial statements of the Company have been prepared assuming the Company will continue as a going concern and in accordance with generally accepted accounting principles in the United States of America for interim financial information, the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not contain all disclosures required by generally accepted accounting principles. Reference should be made to the Company's Annual Report on Form 10-K for the year ended December 31, 2016. In the opinion of the Company, all normal recurring adjustments have been made that are necessary to present fairly the results of operations for the interim periods. Operating results for the three and nine month periods ended September 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017.

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 September 30, 2017, we had cash and cash equivalents of $4.8 million, working capital of $1.0 million and an accumulated deficit of $378.6 million. We had loss from operations of $3.5 million and a net loss of $3.9 million for the nine months ended September 30, 2017. Historically, we have suffered annual losses from operations and have not generated or have generated limited annual positive cash flows from operations. We expect our cash and cash equivalents will be sufficient to fund the development of our products and our related operating expenses only 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. There can be no assurance, however, that Oxford will grant a similar waiver of compliance with the Unqualified Audit Opinion Covenant in connection with our receipt of our auditor's opinion relating to our 2017 financial statements.

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 potential private offerings of common stock to accredited and/or institutional investors, and licensing transactions with pharmaceutical company partners for our proprietary technologies, including Limitx. We are actively seeking a licensing partner for our 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. We are 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 funding 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 us on January 1, 2018, 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 modified retrospective approach with the cumulative accounting effect of initially adopting ASU 2014-09 to be recognized on January 1, 2018. We have determined the transition method we will utilize to adopt the standard for use in 2018 to be the modified retrospective approach.

Under the modified retrospective method, we will recognize the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of retained earnings account along with having additional footnote disclosures. The comparative information will not be restated and will continue to be reported under the accounting standards in effect for those periods. In order to evaluate the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements and related disclosures, we have initiated a comprehensive review of revenues. We have identified four significant contracts that will need to be evaluated under the standard. We are reviewing these four contracts and agreements to identify significant performance obligations and other factors to determine what impact the adoption of the standard will have on our consolidated financial statements and related disclosures. We are reviewing our current accounting policies, procedures and controls with respect to these contracts and arrangements to determine what changes, if any, may be required by the adoption of ASU 2014-09.We expect to complete our evaluation prior to the filing of, and make disclosures in, the 2017 Form 10-K. Additional disclosures will be required to enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows

arising from contracts with customers.

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 establishes a comprehensive new lease accounting model. The new standard will require most leases (with the exception of leases with terms of one year or less) to be recognized on the balance sheet as a lease liability with a corresponding right-of-use asset. 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 transition method existing at or entered into after the beginning of the earliest comparative period presented in the financial statements, but it does not require transition accounting for leases that expire prior to the date of initial application. Upon adoption, operating leases will be reported on the balance sheet as a gross-up of assets and liabilities. The Company is currently evaluating the impact that the standard will have on the consolidated financial statements and related footnote disclosures.

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 expects that the standard will not have an impact on the Company’s consolidated financial statements and related footnote disclosures.

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 expects that the standard will not have an impact on the Company's consolidated financial statements and related footnote disclosures.

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.

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. 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 $1.0 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). Such Option Products include the product candidate Loratadine with pseudoephedrine. 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 nine months ended September 30, 2017 and 2016, we recorded amortization expense of approximately $52 thousand in each three month period and approximately $155 thousand in each nine 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 in March 2017, 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 did not have collaboration revenue for the three months ended September 30, 2017 and recognized $74 thousand of revenue for the three months ended September 30, 2016. We recognized $59 thousand and $307 thousand of collaboration revenue during the nine months ended September 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 recognized royalty revenue of $78 thousand and $39 thousand for the three months ended September 30, 2017 and 2016, respectively and $213 thousand and $86 thousand for the nine months ended September 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 $5 thousand and $13 thousand for the three months and nine months ended September 30, 2017, respectively. (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 nine month periods ended September 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 Nexafed 30mg tablet while moving supply to an alternate contract manufacturer. Approximately $50 thousand of services was remaining under this agreement at December 31, 2016. During the second quarter of 2017, this project was completed and our Impede 2.0 technology was integrated into Nexafed 30mg tablets. Also during the second quarter of 2017, we entered into a cancelable arrangement with a CRO for Study 401 and it was completed during the third quarter of 2017. Also during the third quarter of 2017 we entered into a cancelable arrangement for Study 300 and it was substantially completed at September 30, 2017. We did not have any remaining obligations under cancelable CRO arrangements at September 30, 2017. We did not have prepaid CRO costs nor did we have prepaid clinical trial study expenses at either September 30, 2017 or December 31, 2016.

NOTE 6 – INVENTORIES

We did not have inventories at September 30, 2017 as all our inventories were transferred to MainPointe under the MainPointe Agreement in March 2017. (See Note 3). Inventories at December 31, 2016 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 September 30, 2017 and December 31, 2016 are summarized as follows:

	September 30, 2017	December 31, 2016
	(in thousands)	
Building and improvements	$1,273	$ 1,273
Scientific equipment	598	598
Computer hardware and software	107	109
Machinery and equipment	275	568
Land and improvements	162	162

Other personal property	70	70
Office equipment	27	27
Total	2,512	2,807
Less: impairment reserve	-	(82)
Less: accumulated depreciation	(1,813)	(1,858)
Net property, plant and equipment	$699	$ 867

The impairment reserve of $82 thousand at December 31, 2016 was for specific machinery and other equipment which was used in the production of our Nexafed product line and which was not conveyed to MainPointe under the MainPointe Agreement. During 2017, we applied the reserve against the disposal of these specific 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 September 30, 2017 and December 31, 2016 are summarized as follows:

	September 30, 2017	December 31, 2016
	(in thousands)	
Cost sharing expenses under license agreement	$ 274	$ 150
Other fees and services	80	47
Payroll, payroll taxes and benefits	114	116
Professional services	157	232
Clinical, non-clinical and regulatory services	236	131
Marketing, advertising, and promotion	-	10
Property taxes	15	16
Franchise taxes	14	1
Total	$ 890	$ 703

NOTE 9 – EQUITY FINANCING

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). We have assigned a relative fair value of $495 thousand to the warrants out of the total $4.0 million proceeds from the private placement transaction and have accounted these warrants as equity. 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.

Investor is a principal of MainPointe, a Kentucky limited liability company. In March 2017, we granted MainPointe an exclusive license to our Impede technology to commercialize our Nexafed® and Nexafed® Sinus Pressure + Pain Products in the United States and Canada for an upfront licensing fee of $2.5 million plus approximately $425 thousand 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.

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. Neither Galen nor Investor has designated a director.

NOTE 10 – 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 September 30, 2017 and December 31, 2016, we have accumulated and accrued $668 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 September 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	(1,815)	-	(1,815)
Classification	2,211	(2,211)	-
Balance at Sept. 30, 2017	$2,917	$ 768	$3,685

Debt Discount	Current	Long-term	Total
Balance at Jan. 1, 2017	$ (98)	$ -	$ (98)
Classification	98	(98)	-
Amortization expense	-	52	52
Balance at Sept. 30, 2017	$ -	$ (46)	$ (46)

Deferred Debt Issuance Costs	**Current**	**Long-term**	**Total**
Balance at Jan. 1, 2017	$ (47)	$ -	$ (47)
Classification	47	(47)	-
Amortization expense	-	27	27
Balance at Sept. 30, 2017	$ -	$ (20)	$ (20)
Current Debt, net at Sept. 30, 2017	$2,917	$ 702	$3,619

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

	Three months Ended September 30,		**Nine months Ended September 30,**	
Interest expense:	**2017**	**2016**	**2017**	**2016**
Term loan	$ 116	$ 180	$ 397	$ 584
Debt discount	15	23	52	74
Debt issue costs	8	12	27	39
Total interest expense	$ 139	$ 215	$ 476	$ 697

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

	Remaining Annual Principal Payments

Year	(in thousands)
2017	$ 707
2018	2,978
Total	$ 3,685

NOTE 11 – FAIR VALUE MEASUREMENTS

The Company's financial instruments consist primarily of cash and cash equivalents, receivables from trade, royalties and collaboration, trade accounts payable, and our long-term debt. The carrying amounts of these financial instruments, other than our long-term debt, are representative of their respective fair values due to their relatively short maturities.

NOTE 12 - COMMON STOCK WARRANTS

At September 30, 2017 and 2016, we have outstanding common stock purchase warrants as follows (in thousands except price data):

	Nine months Ended September 30, 2017		2016	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, Jan. 1	60	$ 2.52	60	$ 2.52
Issued	1,783	0.53	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Modification	-	-	-	-
Outstanding, Sept. 30	1,843	$ 0.59	60	$ 2.52

In connection with the issuance of the $10.0 million secured promissory notes in December 2013, we issued 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 10 for a discussion of the reduction of the exercise price of these warrants to $2.52 per share. These warrants contain a cashless exercise feature.

As part of our July 2017 private placement transaction, we issued warrants to purchase 1,782,531 shares of our common stock. The Warrants are immediately exercisable at a price of $0.528 per share and expire five years after issuance. We have assigned a relative fair value of $495 thousand to the warrants out of the total $4.0 million proceeds from the private placement transaction and have accounted these warrants as equity.

NOTE 13 - 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 September 30,		**Nine months Ended September 30,**	
	2017	**2016**	**2017**	**2016**
Research and development expense:				
Stock options	$ 38	$ 43	$ 106	$ 128
Restricted stock units	-	-	-	-
Subtotal	$ 38	$ 43	$ 106	$ 128
General and administrative expense:				
Stock options	$ 52	$ 77	$ 158	$ 232
Restricted stock units	30	30	89	90
Subtotal	$ 82	$ 107	$ 247	$ 322
Total	$ 120	$ 150	$ 353	$ 450

Stock Option Award Plans

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

	Nine Months Ended September 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	185	0.31	-	-
Exercised	(1)	(0.92)	-	-
Forfeited or expired	87	6.48	-	-
Outstanding, Sept. 30	1,494	$ 12.33	1,198	$ 15.67
Options exercisable	1,176	$ 15.46	1,000	$ 18.37

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

	Number of Options Not Exercisable	**Weighted Average Fair Value**
Outstanding, Jan. 1, 2017	335	$ 1.18
Granted	185	0.31
Vested	(188)	1.36
Forfeited	(14)	1.05
Outstanding, Sept. 30, 2017	318	$ 0.58

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.

There was no intrinsic value of any option awards vested and outstanding at either September 30, 2017 or 2016. The total remaining unrecognized compensation cost on unvested option awards outstanding at September 30, 2017 was $174 thousand, and is expected to be recognized in operating expenses in varying amounts over the 14 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:

	Nine months Ended September 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	-	178	-	66
Forfeited or expired	-	-	-	-
Outstanding, Sept. 30	262	202	91	69

Our 2014 RSU Plan was approved by shareholders on May 1, 2014 and permits the grant of up to 400 thousand shares of our common stock pursuant to awards under the 2014 RSU Plan. As of September 30, 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 $36 thousand at September 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 14 – 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 September 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. We believe our equity financing transaction on July 24, 2017 under IRS Section 382 appears to have triggered further limitation on all the NOLs available to us for future use. 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 15 – 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 13). 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, common stock purchase warrants and nonvested RSUs, assuming the exercise of all in-the-money stock securities. The weighted-average common shares outstanding computation for Diluted EPS is not impacted during any period where the exercise price of the security is greater than the period's average market price of our common stock. Common stock equivalents are excluded from the Diluted EPS 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 nine month periods, and including the effects of the common stock equivalents in the Diluted EPS calculations would have been antidilutive.

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

	Three months Ended September 30,		Nine months Ended September 30,	
	2017	2016	2017	2016
EPS – basic and diluted				
Numerator: net loss	$ (2,200)	$ (2,250)	$ (3,944)	$ (8,922)
Denominator (weighted):				
Common shares	18,544	11,834	14,103	11,833
Vested RSUs	142	46	44	25
Basic and diluted weighted average shares outstanding	16,686	11,880	14,147	11,858
EPS – basic and diluted	$ (0.12)	$ (0.19)	$ (0.27)	$ (0.75)
Excluded securities (non-weighted):				
Common shares issuable:				
Stock options	1,494	1,198	1,494	1,198
Nonvested RSUs	60	22	60	22
Common stock purchase warrants	1,843	60	1,843	60
Total excluded common shares	3,397	1,280	3,397	1,280

NOTE 16 – RELATED PARTY TRANSACTIONS

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").

Investor is a principal of MainPointe, a Kentucky limited liability company. In March 2017, we granted MainPointe an exclusive license to our Impede technology to commercialize Nexafed® and Nexafed® Sinus Pressure + Pain in the United States and Canada for an upfront licensing fee of $2.5 million plus approximately $425 thousand 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. Included in the reported revenue for the three and nine months ended September 30, 2017 is $5 thousand and $13 thousand, respectively, of royalty revenue from MainPointe (See Note 3).

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.

NOTE 17 – 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 was 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 within the next several months. 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. Legal fees related to this matter are currently covered by our insurance carrier.

As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of September 30, 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 September 30, 2017 and December 31, 2016, we have accrued approximately $274 thousand and $150 thousand, respectively, of these potential cost sharing reimbursable 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-03 or any successor product candidate, the date by which such studies will be complete and the results will be available and whether LTX-03 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-03 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-03 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;
- 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 and development 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 an additional pseudoephedrine product 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 by neutralizing stomach acid with buffer ingredients but deliver efficacious amounts of drug when taken as a single tablet with a nominal buffer dose. We have completed three clinical studies of various product formulations utilizing the Limitx technology which have demonstrated that maximum drug blood levels (Cmax) are reduced when excess buffer is introduced but exhibits what we believe to be efficacious blood levels when no buffer are used. Studies AP-LTX-400, or Study 400, and AP-LTX-401, or Study 401, were open label, crossover design pharmacokinetic studies in healthy adult subjects of LTX-04 (immediate-release hydromorphone HCl) compared to a marketed comparator, or reference drug. Each of Study 400 and Study 401 demonstrated the Cmax was reduced by 50% to 65% when excessive buffer levels were ingested. Study AP-LTX-300, or Study 300, a parallel design pharmacokinetic buffer dose ranging study of LTX-03 (immediate-release hydrocodone bitartrate and acetaminophen) compared to a reference drug, demonstrated drug

Cmax from LTX-03 in the presence of no buffer ingredient which are expected to provide therapeutic drug levels in the bloodstream for a single dosage, but that due to erratic release of the drug from the over-encapsulated tablets used in the Study, we were unable to reliably identify the precise buffer level for a single Limitx tablet. We plan to conduct another dose ranging study, AP-LTX-301, or Study 301, without using over-encapsulated tablets. We expect to commence Study 301 in the fourth quarter of 2017, with topline results expected in the first quarter of 2018. We believe the results of Study 301 will guide us on the final formulation of LTX-03 tablets, which will combine the hydrocodone micro-particles, acetaminophen and buffer ingredients into a single tablet. We also plan to identify a commercial manufacturer to assist in finalizing the LTX-03 formulation. 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. However, we intend to advance LTX-03 as a lead Limitx product candidate due to its larger market size and its known prevalence of oral excessive tablet abuse.

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.

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. We are also finalizing the formulation of a Loratadine/PSE extended-release combination product utilizing our Impede technology.

Abuse of Prescription Opioid Products and Development of Abuse Deterrent Formulations

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

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

- Oral Manipulated Tablet Abuse (MTA). Extended-release tablets or patches are sometimes crushed, chewed or otherwise physically or chemically manipulated to defeat the extended-release mechanism and provide an immediate-release of the opioid for oral ingestion.

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

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

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

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

Development of our Limitx and Aversion (if recommenced) product candidates will require one or more abuse deterrent studies consistent with FDA's 2015 Guidance. These studies may include in vitro laboratory studies to determine, among other things, syringeability of the formulation, extractability of the opioid, and particle size of the crushed product. It is also expected that development will include human abuse liability studies comparing the abuse liability of our product candidates to currently marketed products. Because our products use known active ingredients in approved dosage strengths, the safety and efficacy of the opioid will need to be established by a series of pharmacokinetic studies demonstrating: (a) bioequivalence to an approved reference drug, (b) food effect of our formulations, and (c) dose proportionality of our formulation. A product candidate that does not achieve satisfactory pharmacokinetic results may require a phase III clinical pain study 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 redirecting our development focus from LTX-04 to a hydrocodone/APAP product candidate utilizing our Limitx Technology (LTX-03).

Development of our LTX-04 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 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)	Initial buffer dose ranging study completed October 2017 Follow on dose ranging study expected to commence Q4 2017
Immediate-release oxycodone HCl (LTX-01) & (LTX-02)	Formulation development in process
Immediate-release non-opioid drug (LTX-09)	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.

The topline results from Study 400 demonstrated that a single tablet dose delivered a Cmax of 45% and 50% lower than the reference drug for LTX-04S and LTX-04P, respectively. For an 8 tablet dose, the Cmax for LTX-04P was 59% lower than the reference drug. Doses between 1 and 8 tablets had similar reduction in Cmax compared to the reference. The extent of drug absorption, measure by area under the curve (AUC) was consistent between the Limitx products and the reference.

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. 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 (LTX-04P3). 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 demonstrated that Cmax for a one tablet LTX-04P3 dose was approximately 50% less than the active comparator. The Cmax for the 7 tablet LTX-04P3 dose was 65% below the comparator. Study 401 also included a 7 tablet dose of LTX-04P3 taken simultaneously with an agent known to increase gastric emptying time (i.e. increase retention time of the ingredients in the stomach) which demonstrated an increase in Tmax (time of Cmax) of over 1 hour compared to LTX-04P3 taken without this agent. 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 excessive and is retarding the release of drug even with a single dose. Also, given that manipulating the duration of stomach acidity with a gastric emptying agent produced a significant increase in Tmax which is indicative of a delayed release of drug from LTX-04P3, we concluded the Limitx micro-particles are working as designed in that when we neutralize the stomach acid we are slowing the release of drug and subsequent absorption of drug into the blood stream.

We believe the results from Study 400 and 401 indicate the micro-particle are working as designed but that we used too much buffer for even a single tablet and did not achieve full release of the drug at a 1 tablet dose.

Study 300

Study 300 was a parallel design, open label, pharmacokinetic buffer dose ranging study in 56 in fasted healthy subjects. Study 300 was a single dose of LTX-03 (10mg of hydrocodone bitartrate in Limitx micro-particles and 325mg of acetaminophen) without any buffering capacity compared to the reference drug, Norco®. A buffering component, that contained a fraction of the buffering capacity that we have previously used in testing LTX-04, was included with the LTX-03 active component with an incremental number of buffering units from 0 (no buffer) to 5 buffer doses. All study drug, including the reference, was over-encapsulated to allow dosing multiple Limitx test articles simultaneously to replicate the action of a single tablet dose. The goal of Study 300 was 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 were also analyzed and compared to the positive control.

Study 300 demonstrated rapid release of drug from the micro-particle formulation, providing expected therapeutic drug levels in the bloodstream for a single dose, but that due to erratic release of the drug from the over-encapsulated tablets used in the Study, we were unable to reliably identify the precise buffer level for a single Limitx tablet. A single LTX-03 dose formulated without any buffer achieved a Cmax of hydrocodone of 82% of the reference drug. Comparatively, the Cmax of acetaminophen in LTX-03 from the same non-buffered dose was 63% of the reference drug. The acetaminophen Cmax was 100% of the reference drug across all doses in Study 300 indicating the non-buffered Limitx cohort was apparently unduly affected by the over-encapsulation. We observed the time to maximum blood concentration (Tmax) for the over-encapsulated reference drug as compared to published standards was 60 (183%) minutes and 50 (188%) minutes longer for hydrocodone and acetaminophen, respectively.

We plan to conduct another dose ranging study, AP-LTX-301, or Study 301, without using over-encapsulated tablets. We expect to commence Study 301 in the fourth quarter of 2017, with topline results expected in the first quarter of 2018. We believe the results of Study 301 will guide us on the final formulation of LTX-03 tablets, which will combine the hydrocodone micro-particles, acetaminophen and buffer ingredients into a single tablet. We also plan to identify a commercial manufacturer to assist in finalizing the LTX-03 formulation.

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.