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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

Or

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

For the transition period from ___ to____

Commission File Number 1-10113

Acura Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

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

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

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 (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes o No þ

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this charter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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, a smaller reporting company, or an emerging growth company.

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	ACUR	OTC Pink

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practical date:
Common Stock, $0.01 par value Shares outstanding as of September 27, 2019: 21,300,192

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2019

Unless otherwise indicated or the context otherwise requires, references to the "Company", "we", "us" and "our" refer to Acura Pharmaceuticals Inc. and its subsidiary. The Acura logo is our trademark and Acura Pharmaceuticals is our registered trademark. All other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this Quarterly Report on Form 10-Q, appear with the trade name, trademark or service mark notice and then throughout the remainder of this Quarterly Report on Form 10-Q without the trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

Item 1. Financial Statements

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

	March 31, 2019	December 31, 2018
Assets:		
Cash	$ 95	$ 91
Royalty receivable	56	137
Prepaid expenses and other current assets	98	166
Income tax receivable	67	67
Total current assets	316	461
Income tax receivable	68	68
Property, plant and equipment, net (Note 6)	589	606
Intangible asset, net of accumulated amortization of $1,034 and $983 (Note 3)	966	1,017
Total assets	$ 1,939	$ 2,152
Liabilities:		
Accounts payable	$ 640	$ 605
Accrued expenses (Note 7)	594	596
Accrued interest to related party (Note 8)	190	-
Other current liabilities	6	11
Sales returns liability	223	223
Debt to related party, net of discounts (Note 8)	4,647	-
Total current liabilities	6,300	1,435
Debt to related party, net of discounts (Note 8)	-	4,224
Accrued interest to related party (Note 8)	-	110
Total liabilities	6,300	5,769
Commitments and contingencies (Note 15)		
Stockholders' deficit:		
Common stock - $0.01 par value per share; 100,000 shares authorized, 21,300 and 21,034 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	213	210
Additional paid-in capital	380,436	380,395
Accumulated deficit	(385,010)	(384,222)
Total stockholders' deficit	(4,361)	(3,617)
Total liabilities and stockholders' deficit	$ 1,939	$ 2,152

See accompanying notes to unaudited consolidated financial statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited; in thousands except per share amounts)

	Three months Ended March 31,	
	2019	2018
Revenues:		
Royalty revenue	$ 67	$ 198
Expenses:		
Research and development	313	650
General and administrative	437	943
Total expenses	750	1,593
Operating loss	(683)	(1,395)
Interest expense, net (Note 8)	(105)	(99)
Loss before income taxes	(788)	(1,494)
Provision for income taxes	-	-
Net loss	$ (788)	$ (1,494)
Net loss per share:		
Basic	$ (0.04)	$ (0.07)
Diluted	$ (0.04)	$ (0.07)
Weighted average number of shares outstanding:		
Basic	21,493	21,034
Diluted	21,493	21,034

See accompanying notes to unaudited consolidated financial statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENT OF CHANGES IN ACCUMULATED STOCKHOLDERS' DEFICIT
(Unaudited; in thousands)

	Common Stock		Additional		
	Number of Shares	Par Value	Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2019	21,034	$ 210	$ 380,395	$ (384,222)	$ (3,617)
Net loss	-	-	-	(788)	(788)
Non-cash share-based compensation	-	-	29	-	29
Net distribution of common stock pursuant to restricted stock unit award plan	266	3	12	-	15
Balance at March 31, 2019	21,300	213	380,436	$ (385,010)	$ (4,361)

See accompanying notes to unaudited consolidated financial statements.

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

	Three months Ended March 31,	
	2019	2018
Cash Flows from Operating Activities:		
Net loss	$ (788)	$ (1,494)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	17	20
Non-cash share-based compensation	29	62
Capitalized debt discount	(9)	-
Amortization of debt discount and deferred debt issue costs	32	17
Amortization of intangible asset	51	52
Change in assets and liabilities:		
Royalty receivable	81	(121)
Prepaid expenses and other current assets	68	159
Accounts payable	35	413
Accrued expenses	(1)	(122)
Accrued interest on loan	-	45
Accrued interest on related party loans	80	-
Other current liabilities	5	4
Net used in operating activities	(399)	(965)
Cash Flows from Financing Activities:		
Proceeds from distribution of restricted stock units	3	2
Proceeds from related party loans	400	-
Principal payments on loan	-	(483)
Net cash provided by (used in) financing activities	403	(481)
Net increase (decrease) in cash and cash equivalents	4	(1,446)
Cash and cash equivalents at beginning of period	91	2,220
Cash and cash equivalents at end of period	$ 95	$ 774
Supplemental disclosure of cash flow information:		
Cash interest payments on loan	$ -	$ 36

See accompanying notes to unaudited consolidated financial statements.

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

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

	March 31, 2019	March 31, 2018
	(in thousands)	
Cash	$ 95	$ 772
Cash equivalents	-	2
Total cash and cash equivalents shown in the consolidated statements of cash flows	$ 95	$ 774

See accompanying notes to unaudited consolidated financial statements.

ACURA PHARMACEUTICALS, INC.
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2019 AND MARCH 31, 2018

NOTE 1 – OPERATIONS AND BASIS OF PRESENTATION

Principal Operations

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the "Company", "Acura", "We", "Us" or "Our") is an innovative drug delivery company engaged in the research, development and commercialization of technologies and products intended to address safe use of medications. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Limitx™ Technology is intended to minimize the risks and side effects associated with overdose by retarding the release of active drug ingredients when too many tablets are accidently or purposefully ingested. Our Aversion® Technology is intended to address methods of product tampering associated with opioid abuse by incorporating gelling ingredients and irritants into tablets to discourage abuse by snorting and provide barriers to abuse by injection. Our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine tablets into methamphetamine.

- Our Limitx Technology is in development with immediate-release tablets containing hydrocodone bitartrate and acetaminophen (also known as LTX-03) as the lead product candidate due to its large market size and its known prevalence of oral excessive tablet abuse and overdose. The technology is designed to retard the release of active opioid drug when too many tablets are accidentally 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. US commercialization rights to LTX-03 are licensed to Abuse Deterrent Pharmaceuticals LLC (See Note 16).

- Our Aversion Technology has been licensed to Zyla Life Sciences or Zyla (formerly known as Egalet Corporation) for use in Oxaydo® Tablets (oxycodone HCl, CII), and is the first approved immediate-release oxycodone product in the United States with abuse deterrent labeling. Oxaydo is currently approved by the FDA for marketing in the United States in 5mg and 7.5mg strengths (See Note 3).

- Our Impede Technology is used in Nexafed® Tablets (30mg pseudoephedrine HCl) and Nexafed® Sinus Pressure + Pain Tablets (30/325mg pseudoephedrine HCl and acetaminophen). We have licensed to MainPointe Pharmaceuticals, LLC (MainPointe), our Impede Technology in the United States and Canada to commercialize these Nexafed products (See Note 3).

Basis of Presentation, Liquidity and Substantial Doubt in 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, 2018. 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 month period ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019.

The going concern basis of presentation assumes that we will continue in operation one year after the date these financial statements are issued and we will be able to realize our assets and discharge our liabilities and commitments in the normal course of business. As of March 31, 2019, we had cash of $95 thousand, working capital deficit of $6.0 million and an accumulated deficit of $385 million. As of September 27, 2019 we had cash of approximately $600 thousand. We had a loss from operations of $0.7 million and a net loss of $0.8 million for the three months ended March 31, 2019. We have suffered recurring losses from operations and have not generated positive cash flows from operations. We had a loss from operations of $3.92 million and a net loss of $3.84 million for the year ended December 31, 2018. We anticipate operating losses to continue for the foreseeable future.

From January 1, 2019 and through June 27, 2019, we borrowed an aggregate of $650 thousand from Mr. Schutte and issued various promissory notes to him with the same terms and conditions from the previous loans. On June 28, 2019 the aggregate principal of the promissory notes was $5.0 million and the accrued interest was $274 thousand. On June 28, 2019 we borrowed $726 thousand from Mr. Schutte, bringing the aggregate principal of the loans and accrued interest to $6.0 million, and consolidated the loans into a single promissory note with a fixed interest rate of 7.5%, maturity date of July 1, 2023, granted conversion rights into 37.5 million shares of our common stock at a price of $0.16 per share, issued a warrant for 10.0 million common shares having an exercise price of $0.01 per share, and granted a security interest in all of the Company's assets.

On June 28, 2019, we entered into License, Development and Commercialization Agreement (the "Agreement") with Abuse Deterrent Pharma, LLC (AD Pharma) and the $6.0 million promissory note, the common stock purchase warrant and the security agreement were all assigned and transferred by Mr. Schutte to AD Pharma (See Subsequent Event - Note 16). AD Pharma has the right to terminate the agreement for "convenience". Should AD Pharma exercise their right to terminate the Agreement, we would need to raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations. In light of AD Pharma's right to terminate the Agreement "upon convenience", our auditors have included in their report relating to our 2018 financial statements a "going concern" explanatory paragraph as to substantial doubt of our ability to continue as a going concern.

In view of the matters described above, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying consolidated 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.

Also, the required monthly license payments by AD Pharma cease at November 2020 at which time the Company will need to have additional capital to fund operations until such time as LTX-03 is approved and royalty payments commence. To fund further operations beyond December 2020, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies or explore a variety of capital raising and other transactions to provide additional funding. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, there will be substantial doubt about the Company's ability to continue as a going concern and the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

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

NOTE 2 – RECENT ACCOUNTING PRONOUNCEMENTS

New accounting standards which have been adopted on or before March 31, 2019

Leases

In February 2016, the FASB issued ASU 2016-02, *Leases* (ASC 842), 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. The classification of the lease will affect the pattern of expense recognition in the income statement such that 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 standard also requires disclosures to help investors and other financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. In July 2018, the FASB issued ASU No. 2018-10, "Codification Improvements to Topic 842, Leases" (ASU 2018-10), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, "Leases (Topic 842)-Targeted Improvements" (ASU 2018-11), which addressed implementation issues related to the new lease standard. These and certain other lease-related ASUs have generally been codified in ASC 842. ASC 842 supersedes the lease accounting requirements in Accounting Standards Codification Topic 840, Leases (ASC 840).

The Company adopted ASC 842 using the modified retrospective transition approach as of the effective date, which allows the Company to not adjust the comparative periods presented. The Company has elected to adopt the package of transition practical expedients and, therefore, has not reassessed whether existing or expired contracts contain a lease or the lease classification for existing or expired. The Company did not elect the practical expedient to use hindsight for leases existing at the adoption date. Upon adoption, operating leases was to be reported on the balance sheet as a gross-up of assets and liabilities, however the Company has elected, as an accounting policy, to not recognize ROU assets and lease liabilities for all short-term leases that have a lease term of 12 months or less. The adoption of the ASC 842 did not have an impact on the Company’s financial statements as has no leases with term of more than 12 months.

NOTE 3 – LICENSE AND COLLABORATION AGREEMENTS

The Company’s revenues are comprised of amounts earned under its license and collaboration agreements, royalties, and until March 2017 did previously include the Nexafed products’ net product sales. Revenue recognition occurs when a customer obtains control of promised goods or services in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services based on a short-term credit arrangement.

Zyla 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 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. We have recorded annual amortization expense of $208 thousand for each of the years 2018 and 2017. Annual amortization of the patent for the years 2019 through 2021 is expected to approximate $208 thousand each year and $52 thousand be quarter.

In January 2015, we and Zyla US, Inc. and Zyla Ltd., each a subsidiary of Zyla Corporation, or collectively Zyla, entered into a Collaboration and License Agreement (the “Zyla 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 Zyla Agreement, we transferred the approved New Drug Application, or NDA, for Oxaydo to Zyla and Zyla 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 Zyla Agreement, we and Zyla have formed a joint steering committee to coordinate commercialization strategies and the development of product line extensions. Zyla is responsible for the fees and expenses relating to the Oxaydo NDA and product line extensions of Oxaydo, provided that Zyla 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. Zyla will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States. Zyla is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Zyla will have final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Zyla may develop Oxaydo for other countries and in additional strengths, in its discretion.

Zyla paid us a $5.0 million license fee upon signing of the Zyla 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 sales-based milestone payment when worldwide Oxaydo net sales reach $150 million in a calendar year. We are receiving from Zyla 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. Zyla'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 Zyla to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Zyla Agreement expires upon the expiration of Zyla's royalty payment obligations in all countries. Either party may terminate the Zyla Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Zyla 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 Zyla Agreement with respect to the U.S. and other countries if Zyla materially breaches its commercialization obligations. Zyla may terminate the Zyla Agreement for convenience on 120 days prior written notice, which termination may not occur prior to the second anniversary of Zyla'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 Zyla Agreement provides for the transition of development and marketing of Oxaydo from Zyla to us, including the conveyance by Zyla to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Zyla's supply of Oxaydo for a transition period.

MainPointe Agreement covering Nexafed products

In March 2017, we and MainPointe entered into the MainPointe Agreement, pursuant to which we granted MainPointe an exclusive license to our Impede technology to commercialize both of our Nexafed and Nexafed Sinus Pressure + Pain product ("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. 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

In October 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.

NOTE 4 – REVENUE FROM CONTRACTS WITH CUSTOMER

Adoption of ASC Topic 606, Revenue from Contracts with Customers

The Company adopted ASC Topic 606 on January 1, 2018 applying the modified retrospective method to all contracts that were not completed as of January 1, 2018. While the While the timing of future revenues under ASC Topic 606 may differ from the Company's historical accounting practices under ASC Topic 605, the cumulative effect recorded through the Consolidated Statement of Stockholders' Deficit was zero because there was no change in timing or measurement of revenues for open contracts at January 1, 2018.

Under ASC 606, revenue is recognized when, or as, performance obligations under terms of a contract are satisfied, which occurs when control of the promised service is transferred to a customer. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring services to a customer ("transaction price"). The Company will then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied. When determining the transaction price of the contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. None of the Company's licenses and collaboration agreements contained a significant financing component at March 31, 2019.

The Company's existing license and collaboration agreements may contain a single performance obligation or may contain multiple performance obligations. Those which contain multiple performance obligations will require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised services underlying each performance obligation.

The Company's existing license and collaboration agreements contain customer options for the license of additional products and territories. We determined the option's standalone selling prices based on the option product's potential market size in the option territory as compared to the currently licensed product and U.S. territory. Some of our existing license and collaboration agreements contain a license to the technology as well as licenses to tradenames or trademarks. The Company determined that the licenses to the tradenames or trademarks were immaterial in context of the contract.

Sales-based Milestones and Royalty Revenues

The commercial sales-based milestones and sales royalties earned under the license and collaboration for Oxaydo and sales royalties earned under the license for the Nexafed products, are recorded in the period of the related sales by Zyla and MainPointe. Payments of sales-based milestones are generally due within 30 days after the end of a calendar year. Payments of royalties are generally due within 45 days after the end of a calendar quarter.

License and Collaboration Agreement Revenues

The achievement of milestones under the Company's license and collaboration agreements will be recorded during the period the milestone's achievement becomes probable, which may result in earlier recognition as compared to the previous accounting standards. The license fee of an option product or option territory under the Company's license and collaboration agreements will be recorded when the option is exercised and any obligations on behalf of the Company, such as to transfer know-how, has been fulfilled, which may result in later recognition as compared to the previous accounting standards.

Disaggregation of Total Revenues

The Company has two licenses for currently marketed products containing its technologies; the Nexafed products containing the Impede Technology to MainPointe and Oxaydo containing the Aversion Technology to Zyla. All of the Company's royalty revenues are earned from these two licenses and from the licensee's sale of products in the U.S.

Royalty revenues by licensee are summarized below:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Zyla	$ 55	$ 190
MainPointe	12	8
Royalty revenues	$ 67	$ 198

Contract Balance and Performance Obligations

The Company's reported contract assets and contract liability balances under the license and collaboration agreements at either March 31, 2019 or December 31, 2018 was $0.00. Contract assets may be reported in future periods under prepaid expenses or other current assets on the balance sheet. Contract liabilities may be reported in future periods consisting of deferred revenue as presented on the balance sheet.

NOTE 5 - RESEARCH AND DEVELOPMENT ACTIVITIES

Research and Development ("R&D") costs include internal R&D activities, external Contract Research Organization ("CRO") services and their clinical research and investigative sites, and other activities. Internal R&D activity costs can include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, formulation work, depreciation, salaries, benefits, insurance and share-based compensation expenses. CRO activity costs can include preclinical laboratory experiments and clinical trial studies. Other activity costs can include regulatory consulting, regulatory legal counsel, cost of acquiring, developing and manufacturing pre-clinical trial materials, costs of manufacturing scale-up, and cost sharing expenses under license agreements. Internal R&D costs and other activity costs are charged to expense as incurred. We make payments to CROs based on agreed upon terms and may include payments in advance of a study starting date. Payments in advance will be reflected in the financial statements as prepaid expenses. We review and charge to expense the amounts for CRO costs and clinical trial study costs 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 to us. The accrued CRO costs are subject to revisions by us as the study progresses towards completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known to us. We did not have any remaining obligations under cancelable arrangements, nor did we have any prepaid CRO costs or prepaid clinical trial study expenses at March 31, 2019 or December 31, 2018.

NOTE 6 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at March 31, 2019 and December 31, 2018 are summarized as follows:

	March 31, 2019	December 31, 2018
	(in thousands)	
Building and improvements	$ 1,273	$ 1,273
Scientific equipment	598	598
Computer hardware and software	107	107
Machinery and equipment	275	275
Land and improvements	162	162
Other personal property	70	70
Office equipment	27	27
Total	2,512	2,512
Less: accumulated depreciation	(1,923)	(1,906)
Net property, plant and equipment	$ 589	$ 606

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. Depreciation expense was $17 thousand and $20 thousand for the three month period ended March 31, 2019 and 2018, respectively. The Company leases administrative office space in Palatine, Illinois on a month to month basis at the rate of approximately $2 thousand per month.

NOTE 7 - ACCRUED EXPENSES

Accrued expenses at March 31, 2019 and December 31, 2018 are summarized as follows:

	March 31, 2019	December 31, 2018
	(in thousands)	
Cost sharing expenses under license agreement	$ 269	$ 237
Other fees and services	26	36
Payroll, payroll taxes and benefits	22	6
Professional services	178	132
Financed premiums on insurance policies	29	102
Clinical, non-clinical and regulatory services	44	63
Property taxes	9	7
Franchise taxes	17	13
Total	$ 594	$ 596

NOTE 8 – DEBT

Fully Paid Loan

In December 2013, we entered into a Loan and Security Agreement (the "Oxford 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"). On October 5, 2018 we borrowed $1.8 million from Mr. Schutte and used $1.5 million from the loan proceeds to fully pay-off the debt outstanding under the Oxford Loan Agreement. All security interests of Oxford with respect to the Oxford Term Loan have been released.

The Oxford Term Loan accrued 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 was due and payable in full on December 1, 2018. As security for its obligations under the initial Oxford 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. Upon the execution of the Oxford 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.

In January 2015, we and Oxford amended the Oxford Loan Agreement providing for the exercise price of the Warrants to be 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.

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 Oxford Loan Agreement. Combined with the Company's own expenses and a $100 thousand consulting placement fee, the Company incurred a total $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 Term Loan using the loan's effective interest rate of 10.16%. In October 2018, we negotiated and settled the Oxford Loan for $1.5 million and recognized a gain of $296 thousand.

Related Party Loans

We have borrowed an aggregate of $4.75 million as of March 31, 2019 (and additional amounts aggregating $250 thousand during the period April 1, 2019 through June 27, 2019) from Mr. Schutte, a related-party, and issued various promissory notes (the Schutte Notes) to him. The Schutte Notes bear interest at prime plus 2.0%, and mature on January 2, 2020, at which time all principal and interest is due, and was unsecured until all obligations to Oxford were satisfied at which time we were required to grant a security interest to Mr. Schutte in all of our assets. Because we believe the Schutte Notes' rate of interest is below current market rates for us, we impute interest on the below market rate element of the loans using the 10.16% interest rate under the Oxford Loan Agreement and this has aggregated to $181 thousand as of March 31, 2019. We recorded these benefits to interest income in the period we received the loan, with a corresponding like amount as debt discount against the principal amount of the loan. The debt discount will be amortized to interest expense over the term on the loans. At March 31, 2019, the unamortized debt discount balance is $103 thousand and the accrued interest balance is $190 thousand.

The events of default under the Schutte Notes are limited to bankruptcy defaults and failure to pay interest and principal when due on January 2, 2020. The Schutte Notes may be prepaid at any time in whole or in part.

Included in the $4.750 million loan outstanding from Mr. Schutte as of March 31, 2019 is a borrowing of $1.8 million completed on October 5, 2018 where we used $1.5 million of these loan proceeds to fully pay-off the debt outstanding under the Oxford Loan Agreement and therefore, all our assets are pledged as collateral under the Schutte Notes, including our intellectual property.

On June 29, 2019 we borrowed an additional $726 thousand from Mr. Schutte and consolidated the loans in a single note along with the accrued interest (See Subsequent Event - Note 16).

Our debt at March 31, 2019 is summarized below (in thousands):

Debt to Related Party	Current	Long-term	Total
Loans			
Balance at Jan. 1, 2019	$ -	$ 4,350	$ 4,350
Classification	4,350	(4,350)	-
Principal borrowings	400	-	400
Balance at Mar. 31, 2019	$ 4,750	$ -	$ 4,750

Debt Discount, net	Current	Long-term	Total
Balance at Jan. 1, 2019	$ -	$ (126)	$ (126)
Classification	(126)	126	-
Additions	(9)	-	(9)
Amortization expense	32	-	32
Balance at Mar. 31, 2019	$ (103)	$ -	$ (103)
Debt to Related Party, net at Mar 31, 2019	$ 4,647	$ -	$ 4,647

Our debt interest expense for the three months ended March 31, 2019 and 2018 consisted of the following:

	Three Months Ended March 31,	
Interest expense:	2019	2018
Fully paid term loan	$ -	$ 82
Related party term loans	80	-
Debt discount	32	12
Debt issue costs	-	5
Financed insurance premiums	2	-
Total interest expense	$ 114	$ 99
Less: imputed interest income on related party loans	(9)	-
Total interest expense, net	$ 105	$ 99

NOTE 9 – RELATED PARTY TRANSACTIONS

In July 2017, we completed a $4.0 million private placement with Mr. Schutte (sometimes referred to as 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 $309 thousand for transferred inventory and equipment. The Company is receiving 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 royalty revenue for the three months ended 2019 and 2018 is $12 thousand and $8 thousand, respectively of royalty revenue from MainPointe (See Note 3).

As part of the closing of the Transaction, the Company and Essex Woodlands Health Ventures V, L.P. (“Essex”) and Galen Partners III, L.P. (“Galen”) amended and restated the existing Voting Agreement including such 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, and the parties to such agreement would vote for such persons. 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. Investor has not designated a director as of the date of filing of this Report. Galen had not designated a director and lost that right in December 2017 when it disposed of its shares of common stock in the Company. Once such shareholder no longer holds such securities, the additional forfeited seat would become a seat for an independent director to thereafter be nominated to the Board of Directors from time to time by the then current directors and as applicable, to be elected by the directors to fill the vacancy created by the forfeited seat or submitted to the vote of shareholders at the Company’s next annual meeting. An independent director has not been named to fill the seat forfeited by Galen.

During the period April 1, 2019 through June 27, 2019 we borrowed an aggregate of $250 thousand from Mr. Schutte. On June 28, 2019 we borrowed $726 thousand from Mr. Schutte and consolidated the loans in a single note along with the accrued interest (See Subsequent Event - Note 16.)

NOTE 10 - COMMON STOCK WARRANTS

Our warrant activity for the three months ended March 31, 2019 and 2018 consisted of the following (in thousands except price data):

	Three Months Ended March 31,			
	2019		2018	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, Jan. 1	1,842	$ 0.59	1,842	$ 0.59
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Modification	-	-	-	-
Outstanding, Mar. 31	1,842	$ 0.59	1,842	$ 0.59

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. These warrants contain a cashless exercise feature (See Note 8).

As part of our July 2017 private placement transaction with John Schutte, 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 (See Note 9). 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 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 - SHARE-BASED COMPENSATION EXPENSE

Share-based Compensation

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

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

Our share-based compensation expense recognized in the Company's results of operations from non-cash and cash-portioned instruments issued to our employees and directors comprised the following (in thousands):

	Three Months Ended March 31,	
	2019	2018
Research and development expense:		
Stock options	$ 2	$ 13
Restricted stock units	4	7
Subtotal	$ 6	$ 20
General and administrative expense:		
Stock options	3	34
Restricted stock units	26	22
Subtotal	$ 29	$ 56
Total	$ 35	$ 76

Stock Option Award Plans

We maintain various stock option plans. A summary of our stock option plan activity during the three month periods ending March 31, 2019 and 2018 is shown below:

	Three Months Ended March 31,			
	2019		2018	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, Jan. 1	1,560	$ 7.38	1,494	$ 12.33
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited or expired	(32)	(28.06)	(12)	(32.50)
Outstanding, Mar. 31	1,528	$ 6.88	1,482	$ 12.17
Options exercisable	1,296	$ 8.09	1,235	$ 14.49

The following table summarizes information about nonvested stock options outstanding at March 31, 2019 (in thousands except price data):

	Number of Options Not Exercisable	Weighted Average Fair Value
Outstanding, Jan. 1, 2019	232	$ 0.10
Granted	-	-
Vested	-	-
Forfeited	-	-
Outstanding, Mar. 31, 2019	232	$ 0.10

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.

The intrinsic value of the option awards which were vested and outstanding at each of March 31, 2019 and 2018 was $0 thousand. The total remaining unrecognized compensation cost on unvested option awards outstanding at March 31, 2019 was $15 thousand, and is expected to be recognized in operating expense in varying amounts over the 8 months remaining in the requisite service period.

Restricted Stock Unit Award Plans

We have two Restricted Stock Unit Award Plans for our employees and non-employee directors; a 2017 Restricted Stock Unit Award Plan (the "2017 RSU Plan") and a 2014 Restricted Stock Unit Award Plan (the "2014 RSU Plan"). The 2017 RSU Plan was approved by our shareholders in November 2017 and permits the grant of up to 1.5 million shares of our common stock pursuant to awards under the 2017 RSU Plan. The 2014 RSU Plan was approved by shareholders in May 2014 and permits the grant of up to 400 thousand shares of our common stock pursuant to awards under the 2014 RSU Plan. As of March 31, 2019 there are approximately 219 thousand shares available for award under the 2017 RSU Plan and there are no remaining shares available for award under the 2014 RSU Plan.

Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. The RSU awards to our non-employee directors allow for them to receive payment in cash upon the RSU award's distribution, instead of an exchange into our common stock, for up to 40% of each RSU award. The portion of the RSU award subject to cash settlement is recorded as a liability in the Company's balance sheet and to either general and administrative expense or research and development expense while being marked-to-market each reporting period until the award is distributed. The liability was $6 thousand and $11 thousand at March 31, 2019 and December 31, 2018, respectively.

The compensation cost to be incurred by the Company on a granted RSU award without a cash settlement option 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 over the vesting period of the RSU award to either general and administrative expense or research and development expense and recorded as additional paid-in capital.

A summary of the grants under the RSU Plans as of March 31, 2019 and 2018, and for the three month period then ended consisted of the following (in thousands):

	Three Months Ended March 31,			
	2019		2018	
	(in thousands)			
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, Jan. 1	951	459	462	262
Granted	333	-	267	-
Distributed	(267)	(267)	(262)	(262)
Vested	-	83	-	66
Forfeited or expired	-	-	-	-
Outstanding, Mar. 31	1,017	275	467	66

Information about the award activity under the RSU Plans is as follows:

- In December 2017, we awarded 200 thousand RSUs to employees and such RSU awards were fully vested on December 31, 2018. Distribution of these awards and the exchange into common stock will occur in one third amounts on each of January 1, 2020, 2021 and 2022. The employees have the option to pay the par value of the common stock and settle payroll withholding taxes in shares of common stock they would otherwise be receiving resulting in a net share settlement.
- In January 2017, we awarded approximately 60 thousand RSUs to each of our non-employee directors. Such awards vested 25% at the end of each calendar quarter during 2017. In January 2018, these awards were distributed and they were exchanged into 214 thousand shares of our common stock while 24 thousand RSUs were settled in cash. There were also 24 thousand RSUs exchanged into common stock from prior year awards.
- In January 2018, we awarded approximately 67 thousand RSUs to each of our non-employee directors. Such awards vested 25% at the end of each calendar quarter during 2018. In January 2019, these awards were distributed and they were exchanged into 267 shares of our common stock.
- In December 2018, we awarded 492 thousand RSUs to employees and such RSU awards will vested in full on December 31, 2019. Distribution of these awards and the exchange into common stock will occur in one third amounts on each of January 1, 2021, 2022 and 2023. The employees have the option to pay the par value of the common stock and settle payroll withholding taxes in shares of common stock they would otherwise be receiving resulting in a net share settlement.
- In January 2019, we awarded approximately 83 thousand RSUs to each of our non-employee directors. Such awards vest 25% at the end of each calendar quarter during 2019. These awards will be distributed and exchanged into common stock will occur in one third amounts on each of January 2020 and up to 40% of the award can be settled in cash.

NOTE 13 – 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.

Deferred tax assets reflect the tax effects of net operating losses (“NOLs”), tax credit carryovers, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The most significant item of our deferred tax assets is derived from our Federal NOLs. We have approximately $171.8 million gross Federal NOLs at December 31, 2018 (of which approximately $167.7 million were generated prior to 2018). Because we believe the ability for us to use these NOLs generated prior to January 1, 2018 to offset any future taxable income is severely limited as prescribed under Internal Revenue Code (“IRC”) Section 382, we had estimated and recorded an amount for the likely limitation to our deferred tax asset in the fourth quarter of 2017, thereby reducing the aggregate estimated benefit of the Federal NOLs available to us of approximately $1.0 million at December 31, 2017. We believe the gross Federal NOL benefit we generated prior to January 1, 2018 to offset taxable income is less than $150 thousand annually. As prescribed under Internal Revenue Code, any unused Federal NOL benefit from the annual limitation can be accumulated and carried forward to the subsequent year and will expire if not used in accordance with the NOL carried forward term of 20 years or 2037, if generated before 2018 and Federal NOLs generated after 2017 can be carried forward indefinitely. Future common stock transactions, such as the exercise of common stock purchase warrants or the conversion of debt into common stock, may cause another qualifying event under IRC 382 which may further limit our utilization of our NOLs (See Subsequent Event - Note 16).

The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At both March 31, 2019 and December 31, 2018, all our remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of 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.

NOTE 14 – NET LOSS PER SHARE

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 12). Diluted EPS is based on the treasury stock method and computed based on the same number of shares used in the basic share calculation and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and stock warrants, assuming the exercise of all in-the-money stock options and warrants. Common stock equivalents are excluded from the computation where their inclusion would be anti-dilutive. No such adjustments were made for 2019 or 2018 as the Company reported a net loss for the three month periods, and including the effects of the common stock equivalents in the diluted EPS calculations would have been antidilutive. The weighted-average common shares outstanding diluted computation is not impacted during any period where the exercise price of a stock option or common stock warrant is greater than the average market price.

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

	Three months Ended March 31,	
	2019	2018
	(in thousands except per share data)	
EPS – basic and diluted		
Numerator: net loss	$ (788)	$ (1,494)
Denominator:		
Common shares	21,300	21,033
RSUs – vested	193	1
Basic weighted average shares outstanding	21,493	21,034
EPS – basic and diluted	$ (0.04)	$ (0.07)
Excluded securities:		
Common stock issuable:		
RSUs – nonvested	742	401
Stock options – vested and nonvested	1,528	1,482
Common stock warrants	1,842	1,842
Total excluded potentially dilutive shares	4,112	3,725

NOTE 15 – COMMITMENTS AND CONTINGENCIES

Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to us, was 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.

None of the plaintiffs in the lawsuits filed to date have confirmed that they ingested any of the generic metoclopramide manufactured by us. We discontinued manufacture and distribution of generic metoclopramide more than 20 years ago. All of these lawsuits have been effectively dismissed with the exception of less than ten pending Philadelphia cases that we expect will be finally dismissed without the need for any action by us. We expect that the Court will finally dismiss the small number of remaining Pennsylvania-based cases against us with prejudice by the end of the fourth quarter of 2019. Legal fees related to this matter have been covered by our insurance carrier. Based upon the current status and evaluation, we have not accrued for any potential loss related to these matters as of March 31, 2019.

NOTE 16 – SUBSEQUENT EVENTS

Related Party Transaction – Loans

From April 1, 2019 and through June 27, 2019, we borrowed an aggregate of $250 thousand from Mr. Schutte and issued various promissory notes to him with the same terms and conditions from the previous loans. On June 28, 2019 the aggregate principal of the promissory notes was $5.0 million and the accrued interest was $274 thousand. On June 28, 2019 we borrowed $726 thousand from Mr. Schutte, bringing the aggregate principal of the loans and accrued interest to $6.0 million, and consolidated the loans into a single promissory note with a fixed interest rate of 7.5%, maturity date of July 1, 2023, granted conversion rights into 37.5 million shares of our common stock at a price of $0.16 per share, issued a warrant for 10.0 million common shares having an exercise price of $0.01 per share, and granted a security interest in all of the Company’s assets. The $6.0 million promissory note, the common stock purchase warrant and the security agreement were all assigned and transferred by Mr. Schutte to AD Pharma on June 28, 2019. On July 2, 2019 we received the $726 thousand proceeds of the loan.

Related Party Transaction – License, Development and Commercialization Agreement with Abuse Deterrent Pharma, LLC

On June 28, 2019, we entered into a License, Development and Commercialization Agreement (the "Agreement") with Abuse Deterrent Pharma, LLC (“AD Pharma”), a special purpose company representing a consortium of investors that will finance Acura’s operations and completion of development of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura’s patented LIMITx™ technology which addresses the consequences of excess oral administration of opioid tablets, the most prevalent route of opioid overdose and abuse. The Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03. Financial arrangements include:

- Monthly license payments to Acura by AD Pharma of $350,000 up to the earlier of 18 months or FDA’s acceptance of a New Drug Application (“NDA”) for LTX-03;
- Reimbursement by AP Pharma of Acura’s LTX-03 outside development expenses;
- Upon commercialization of LTX-03, Acura receives stepped royalties on sales and is eligible for certain sales related milestones; and
- Acura authorizes MainPointe to assign to AD Pharma the option and the right to add, as an Option Product to the Nexafed® Agreement, a Nexafed® 12-hour dosage (an extended-release pseudoephedrine hydrochloride product utilizing the IMPEDE® Technology in 120mg dosage strength).

AD Pharma may terminate the Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA within 18 months, AD Pharma may terminate the Agreement and take ownership of the intellectual property. On July 2, 2019 we received the first monthly license payment of $350 thousand and have received subsequent monthly license payments in August and September 2019.

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

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

Forward-Looking Statements

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

- our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our Limitx™ and Impede® technologies;
- the expected results of clinical studies relating to LTX-03, a Limitx hydrocodone bitartrate and acetaminophen combination product, 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 the extent to which products formulated with the Limitx Technology deter abuse or overdose will be determined sufficient by the FDA to support approval or labelling describing safety and/or 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 Zyla Life Sciences' or Zyla (formerly known as Egalet Corporation) 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 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 "anticipate," "believe," "continue," "could," "estimate," "expect," "indicate," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "suggest," "target," "will," "would" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to known and unknown 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 2018 Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission and in Item 1A of this Report. 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 an innovative drug delivery company engaged in the research, development and commercialization of technologies and products intended to address safe use of medications. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Limitx™ Technology is being developed to minimize the risk of opioid overdose, our Aversion® Technology is 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 Zyla US, Inc. and Zyla Ltd., each a subsidiary of Zyla Corporation, or collectively Zyla, pursuant to which we exclusively licensed to Zyla 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. Zyla launched Oxaydo in the United States late in the third quarter of 2015. We are not actively developing product candidates utilizing our Aversion Technology.

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. On March 16, 2017, we and MainPointe Pharmaceuticals, LLC, or MainPointe, entered into a License, Commercialization and Option Agreement, or the MainPointe Agreement, pursuant to which we granted MainPointe an exclusive license to our Impede technology 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. MainPointe is controlled by John Schutte, (Mr. Schutte), who became our largest shareholder pursuant to a private placement completed in July 2017.

Our third abuse deterrent technology, Limitx, is designed to retard the release of active drug ingredients when too many tablets are accidentally 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 four clinical studies of various product formulations utilizing the Limitx Technology which have demonstrated proof-of-concept for the Limitx Technology and will allow us to advance a product to development for a New Drug Application, or NDA. Studies AP-LTX-400, or Study 400, and Study AP-LTX-401, or Study 401, both utilizing our LTX-04 hydromorphone formulation demonstrated the mean maximum drug concentration in blood, or Cmax, was reduced in healthy adult fasted subjects by 50% to 65% when excessive buffer levels were ingested or a situation consistent with over-ingestion of tablets. Study AP-LTX-301, or Study 301 demonstrated drug Cmax from LTX-03, a Limitx hydrocodone bitartrate and acetaminophen combination product, in healthy adult fasted subjects trended toward bioequivalence in test formulations A through E and showed an increasing reduction in Cmax for formulations F through H; in which formulations A though H had increasing incremental amounts of buffer starting with no buffer in formulation A. We believe the results of Study 301 demonstrated that LTX-03 is a formulation that optimizes the balance between effective blood levels of drug for pain relief at a single tablet dose while retarding bioavailability of drug when multiple tablets are ingested. The FDA 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, which combines the hydrocodone micro-particles, acetaminophen and buffer ingredients into a single tablet, as our lead Limitx product candidate due to its larger market size and its known prevalence of oral excessive tablet abuse and overdose, and we voluntarily placed the Investigational New Drug Application, or IND, for LTX-04 on inactive status. We submitted an IND for LTX-03 to the FDA in the first quarter of 2018 in order to advance to NDA development, which became effective in April 2018.

On June 28, 2019, we entered into License, Development and Commercialization Agreement with Abuse Deterrent Pharma, LLC, a Kentucky limited liability company ("AD Pharma"), a special purpose company representing a consortium of investors that will finance Acura's operations and completion of development of LTX-03. The Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03.

According to the 2017 CDC Drug Surveillance Report, opioid analgesics are one of the largest prescription drug markets in the United States with 214 million prescriptions dispensed in 2016. Prescription opioids are also the most widely abused drugs with 12 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 194 million prescriptions, of which approximately 95% was attributable to generic products with no known safety features. Immediate-release oxycodone tablets represent approximately 30 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.

The CDC also reported approximately 45,000 suicide deaths in the U.S. in 2016 with poisoning being the third most prevalent route of suicide. Suicides have increased 30% in the U.S. since 1999. More than 54% of suicides had no prior indication of mental health issues. We believe a significant portion of these intentional poisonings included opioid analgesics which are known to induce respiratory depression related to overdose. An analysis of forensic data associated with hydrocodone overdose deaths suggests a median dose of sixteen 10mg hydrocodone tablets was measured in the bloodstream.

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 20167 to 774,000 people up from 440,000 people in 2012. As of March 16, 2017, sales of Nexafed and Nexafed Sinus are covered under the MainPointe Agreement, for which we receive a royalty.

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

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, methamphetamine, 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 abuse deterrent products, such our Aversion (if recommenced) product candidates, will require one or more abuse deterrent studies consistent with the FDA 2015 published guidance for industry on the evaluation and labeling of abuse-deterrent opioids (the "2015 Guidance"). These studies may include in vitro laboratory studies to determine, among other things, syringeability of the formulation, extractability of the opioid, and particle size of the crushed product. It is also expected that development will include human abuse liability studies comparing the abuse liability of our product candidates to currently marketed products. Because our products use known active ingredients in approved dosage strengths, the safety and efficacy of the opioid will need to be established by a series of pharmacokinetic studies demonstrating: (a) bioequivalence to an approved reference drug, (b) food effect of our formulations, and (c) dose proportionality of our formulation. A product candidate that does not achieve satisfactory pharmacokinetic results may require a phase III clinical pain study.

Further development will likely also entail additional safety and/or efficacy assessment as may be identified by the FDA for each specific formulation during the Investigational New Drug application, or IND, or NDA phase of development. In accordance with the FDA's 2015 Guidance, we will likely have a post-approval requirement for each of our products, if approved, to perform an epidemiology study to assess the in-market impact on abuse of our formulation.

Overdose Minimized Opioid Products and Development

A known and FDA labelled side effect of the overdose of opioids is respiratory depression. High doses of opioids can affect the respiratory center of the brain resulting in a slowing and/or shallowing of the breathing which increases carbon dioxide (CO2) in the blood stream. Opioids also impact ancillary CO2 monitoring of the blood preventing the body from taking corrective action. The increased CO2 and resulting decrease in oxygen in the blood systematically shuts down body systems and may result in death.

Abusers as well as legitimate pain patients are at risk of overdose. In some cases, overdose is accidental but anecdotal reports indicate suicide rates among pain patient are increasing presumably due to their inability to access the pain medications they need to manage their condition.

In June 2019, FDA issued a draft for public comment guidance on a Benefit-Risk Assessment Framework for Opioid Analgesic Drugs. The guidance indicates FDA will "consider the public health risks of the [opioid] drug related to misuse, abuse, opioid use disorder, accidental exposure, and overdose in both patients and nonpatients, as well as any properties of the drug that may mitigate such risks". We intend to develop our Limitx Technology products consistent with this pending guidance and perform studies to demonstrate our drug candidates have properties to mitigate the risk of overdose. 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.

Limitx™ Technology

Limitx Technology is intended to address the accidental or intentional consumption of multiple tablets and provide a margin of safety against respiratory depression. We believe these benefits for opioids are consistent with FDA's proposed direction to require all newly approved opioid products to have features of benefits that provide safety or efficacy benefits over existing available opioid therapies.

Limitx Technology Products in Development

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

Limitx Technology Products	Status
Immediate-release hydrocodone bitartrate with acetaminophen (LTX-03)	Initial buffer dose ranging study completed October 2017 Follow on dose ranging study completed in January 2018 Manufacturing scale-up initiated
Immediate-release oxycodone HCl (LTX-01) & (LTX-02)	Formulation development in process
Immediate-release non-opioid drug (LTX-09)	Formulation development in process
Immediate-release hydromorphone HCI (LTX-04)	Two Phase I exploratory pharmacokinetic studies completed. IND no longer active.

Study 400

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

Study 401, completed in June 2017, 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 301

Study 301 was an open-label, parallel design pharmacokinetic study testing our LIMITx formulation LTX-03 in 72 fasted healthy adult subjects randomized into 9 groups (8 subjects per group). One group swallowed a single Norco® 10/325mg tablet, the marketed comparator or reference drug. The remaining 8 groups swallowed a single LTX-03 tablet with increasing buffering amounts starting with no buffer, LTX-03 formulations A through H, respectively. All 72 subjects completed the study and the doses were generally well tolerated with no serious adverse events. One subject in the Formulation E group was not analyzed due to emesis. LTX-03 is a combination of hydrocodone bitartrate and acetaminophen.

In Study 301 bioequivalence (BE) was examined to generate information for future registration studies. Results demonstrated a trend toward BE for both active ingredients in LTX-03 formulations A through E. Formulation E had BE ratios (log transformed) for hydrocodone of 0.89 and 0.97 for Cmax and Area Under the Curve (AUC), respectively. In this small sample size study both hydrocodone BE confidence intervals were below the acceptable lower BE range of 0.80 at 0.74 and 0.79 for Cmax and AUC, respectively. For acetaminophen, Formulation E's BE Ratios were 1.15 and 1.03 for Cmax and AUC, respectively. While the acetaminophen AUC's met the BE standards, the Cmax upper confidence interval of 1.61 was above the acceptable upper BE range of 1.25. We believe that bioequivalence of this formulation may be achieved by reducing data variability that can be achieved through an adequately powered crossover study design with sufficient numbers of subjects in the study. For LTX-03 Formulations F though H, the higher buffer level tablets, Study 301 demonstrated a progressively increasing reduction in hydrocodone Cmax culminating in a 34% Cmax reduction associated with Formulation H, the highest level evaluated. The Cmax for acetaminophen did not decline in Formulations F through H in Study 301.

We believe that Study 301 identified a formulation that optimizes the balance between providing therapeutic blood levels of drug for pain relief at a single tablet dose while retarding the bioavailability of drug when higher buffer levels are ingested.

We intend to advance LTX-03 to clinical development for a New Drug Application (NDA). Therefore, we submitted an Investigational New Drug Application, or IND with respect to LTX-03, to the FDA in the first quarter of 2018, which became effective in April 2018. We are currently conducting the scale-up of the commercial manufacturing process as to-be-marketed formulations are required for all NDA development work. Among other things, we believe we will have to demonstrate a scientific link between Cmax reductions and a reduction in the risk of respiratory depression.

AD Pharma Agreement covering LTX-03

On June 28, 2019 we announced a License, Development and Commercialization Agreement (the "Agreement") with Abuse Deterrent Pharma, LLC (“AD Pharma”), a special purpose company representing a consortium of investors that will finance Acura’s operations and completion of development of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura’s patented LIMITx™ technology which addresses the consequences of excess oral administration of opioid tablets, the most prevalent route of opioid overdose and abuse. AD Pharma retains commercialization rights from which Acura will receive royalties and potential sales related milestones.

The Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03. Financial arrangements include monthly license payments by AD Pharma of $350,000 up to the earlier of 18 months or FDA’s acceptance of a New Drug Application (“NDA”) for LTX-03 and reimbursement by AP Pharma of Acura’s LTX-03 outside development expenses. Upon commercialization of LTX-03, Acura receives stepped royalties on sales and is eligible for certain sales related milestones.

AD Pharma may terminate the Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA within 18 months, AD Pharma may terminate the Agreement and take ownership of the Limitx intellectual property.

We also granted authority to MainPointe Pharmaceuticals, LLC (MainPointe) to assign to AD Pharma the option and the right to add, as an Option Product to the Nexafed® Agreement, a Nexafed® 12-hour dosage (an extended-release pseudoephedrine hydrochloride product utilizing the IMPEDE® Technology in 120mg dosage strength). 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.

Mr. Schutte is our largest shareholder and directly owns approximately 47.5% of our common stock (after giving effect to the exercise of warrants he holds). Mr. Schutte also controls MainPointe and is an investor in AD Pharma.

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 six issued U.S. patents, which expire between November 2023 and March 2025. Our Aversion Technology products are intended to provide the same therapeutic benefits of the active drug ingredient as currently marketed products containing the same active pharmaceutical ingredient.

Oxaydo Tablets

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

The 2017 market for immediate-release oxycodone products was approximately 30 million dispensed prescriptions or 1.7 billion tablets. The current market is predominately serviced by generic formulations that contain no abuse deterrent features and sell for approximately $0.10 to $0.40 per tablet, depending on strength. Immediate-release opioids are prescribed by a broad cross-section of healthcare providers including primary care physicians, surgeons and pain specialists. We believe Oxaydo, given its differentiated label compared to generic products, can offer an alternative for opioid prescribing physicians concerned with the abuse or diversion for abuse of their prescriptions even at premium pricing to generics

The safety and efficacy of Oxaydo 5mg and 7.5mg tablets was established by demonstrating bioequivalence to commercially available oxycodone immediate-release tablets in the fasted state. Oxaydo differs from oxycodone tablets when taken with a high fat meal though these differences are not considered clinically relevant, and Oxaydo can be taken without regard to food. The FDA-approved label for Oxaydo describes elements unique to our Aversion Technology, which differs from current commercially available oxycodone immediate-release tablets. The label for Oxaydo includes the results from a clinical study that evaluated the effects of nasally snorting crushed Oxaydo and commercially available oxycodone tablets, and limitations on exposing Oxaydo tablets to water and other solvents and administration through feeding tubes. The clinical study evaluated 40 non-dependent recreational opioid users, who self-administered the equivalent of 15mg of oxycodone. After accounting for a first sequence effect, the study demonstrated:

- 30% of subjects exposed to Oxaydo responded that they would not take the drug again compared to 5% of subjects exposed to immediate-release oxycodone;
- subjects taking Oxaydo reported a higher incidence of nasopharyngeal and facial adverse events compared to immediate-release oxycodone;
- a decreased ability to completely insufflate two crushed Oxaydo tablets within a fixed time period (21 of 40 subjects), while all subjects were able to completely insufflate the entire dose of immediate-release oxycodone; and
- small numeric differences in the median and mean drug liking scores, which were lower in response to Oxaydo than immediate-release oxycodone.

Although we believe these abuse deterrent characteristics differentiate Oxaydo from immediate-release oxycodone products currently on the market, consistent with FDA guidance which requires epidemiology studies to support a claim of abuse deterrence, the clinical significance of the difference in drug liking and difference in response to taking the drug again in this study has not been established. There is no evidence that Oxaydo has a reduced abuse liability compared to immediate release oxycodone. We and Zyla have a post-approval commitment with the FDA to perform an epidemiology study to assess the actual impact on abuse of Oxaydo tablets.

Further, the Oxaydo product label guides patients not to crush and dissolve the tablets or pre-soak, lick or otherwise wet the tablets prior to administration. Similarly, caregivers are advised not to crush and dissolve the tablets or otherwise use Oxaydo for administration via nasogastric, gastric or other feeding tubes as it may cause an obstruction. Our laboratory studies demonstrated that the Oxaydo tablet may gel when Oxaydo is exposed to certain solvents, including water.

Zyla Agreement Covering Oxaydo

On January 7, 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, now known as Zyla Life Sciences or Zyla, entered into a Collaboration and License Agreement, or the Zyla Agreement, to commercialize Oxaydo tablets containing our Aversion® Technology. Oxaydo is approved by the FDA for marketing in the United States in 5 mg and 7.5 mg strengths. Under the terms of the Zyla Agreement, we transferred the approved NDA for Oxaydo to Zyla and Zyla is granted an exclusive license under our intellectual property rights for development and commercialization of Oxaydo worldwide, or the Territory, in all strengths, subject to our right to co-promote Oxaydo in the United States.

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

Zyla paid us an upfront payment of $5.0 million upon signing of the Zyla Agreement and a $2.5 million milestone in October 2015 in connection with the launch of Oxaydo. In addition, we will be entitled to a one-time $12.5 million milestone payment when worldwide Oxaydo net sales reach $150.0 million in a calendar year. In addition, we will receive from Zyla a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on Oxaydo net sales during such year (excluding net sales resulting from our co-promotion efforts). In any calendar year in which net sales exceed a specified threshold, we will receive a double digit royalty on all Oxaydo net sales in that year (excluding net sales resulting from our co-promotion efforts). If we exercise our co-promotion rights, we will receive a share of the gross margin attributable to incremental Oxaydo net sales from our co-promotion activities. Zyla's royalty payment obligations commenced on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA's Orange Book remains with respect to the Product). Royalties will be reduced upon the entry of generic equivalents, as well as for payments required to be made by Zyla to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Zyla Agreement expires upon the expiration of Zyla's royalty payment obligations in all countries. Either party may terminate the Zyla Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Zyla 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 Zyla Agreement with respect to the U.S. and other countries if Zyla materially breaches its commercialization obligations. Zyla may terminate the Zyla Agreement for convenience on 120 days prior written notice, which termination may not occur prior to the second anniversary of Zyla'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 Zyla Agreement provides for the transition of development and marketing of Oxaydo from Zyla to us, including the conveyance by Zyla to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Zyla's supply of Oxaydo for a transition period.

KemPharm Agreement Covering Opioid Prodrugs

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

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

The KemPharm Agreement expires upon the expiration of KemPharm's royalty payment obligations in all countries. Either party may terminate the KemPharm Agreement in its entirety if the other party materially breaches the KemPharm Agreement, subject to applicable cure periods. Acura or KemPharm may terminate the KemPharm Agreement with respect to the U.S. and other countries if the other party challenges the patents covering the licensed products. KemPharm may terminate the KemPharm Agreement for convenience on ninety (90) days prior written notice. Termination does not affect a party's rights accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations (but not expiration), the KemPharm Agreement provides for termination of our license grant to KemPharm.

Aversion Technology Development Opioid Products

We have suspended further development of our Aversion hydrocodone/APAP product candidate, in order to focus our time and available resources on the development of our Limitx technology product candidates. We currently have 6 additional opioids at various stages of formulation development using the Aversion Technology which are not being actively developed.

Abuse of Pseudoephedrine Products

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

Impede 1.0 Technology

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

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

Impede 2.0 Technology

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

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

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

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

We have previously demonstrated in a pilot clinical study the bioequivalence of a formulation of our Nexafed extended release tablets utilizing our Impede 2.0 Technology to Sudafed® 12-hour Tablets.

Nexafed Products and the MainPointe Agreement

Nexafed and Nexafed Sinus Pressure + Pain, consist of immediate release tablets. Nexafed is a 30mg pseudoephedrine tablet which until the third quarter of 2017 incorporated our patented Impede 1.0 technology and commencing in such quarter incorporated our Impede 2.0 technology. Nexafed Sinus Pressure + Pain is a 30/325mg pseudoephedrine and acetaminophen tablet which incorporates our Nexafed 1.0 technology. PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products. While the 30mg PSE tablet is not the largest selling PSE product on the market, we believe it is the most often used product to make meth due to: (a) its relatively low selling price and (b) its simpler formulation provides better meth yields.

We have demonstrated that our Nexafed 30mg tablets are bioequivalent to Johnson & Johnson's Sudafed 30mg Tablets when a single 2 tablet dose is administered. Commencing in 2006, the CMEA, required all non-prescription PSE products to be held securely behind the pharmacy counter, has set monthly consumer purchase volume limits, and has necessitated consumer interaction with pharmacy personnel to purchase PSE-containing products.

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

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

MainPointe has the option to expand the licensed territory beyond the United States and Canada to the European Union (and the United Kingdom), Japan and South Korea for payments of $1.0 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), including the product candidate Loratadine with pseudoephedrine (following termination of the Bayer Agreement).). MainPointe has assigned its option rights to a Nexafed 12-hour formulation to AD Pharma. 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. . On June 28, 2019, we granted authority to MainPointe to assign to AD Pharma the option and the right to add, as an Option Product to the Nexafed® Agreement, a Nexafed® 12-hour dosage (an extended- release pseudoephedrine hydrochloride product utilizing the IMPEDE® Technology in 120mg dosage strength) and waived the $500 thousand option fee.

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

Impede Technology Products in Development

Given the fragmented nature of the PSE market with products containing multiple active ingredients, we have developed additional products for our Nexafed franchise:

Impede Technology Products	Status
Extended-release formulation utilizing Impede 2.0 Technology	Pilot pharmacokinetic testing demonstrated bioequivalence to Sudafed® 12-hour Tablets. Pre-IND meeting held with the FDA No imminent development planned
Extended-release combination products	No imminent development planned
Loratadine with pseudoephedrine	No imminent development planned

In July 2015, we had a pre-IND meeting with the FDA to discuss the results from our pharmacokinetic and meth-resistance testing studies to determine the development path for our extended-release development product. The FDA acknowledged the potential value of the development of risk-mitigating strategies for new formulations of pseudoephedrine products while also recognizing an approved "meth-deterrent" extended release pseudoephedrine product would be novel in the over-the-counter (OTC) setting. The FDA did not make a formal determination whether "meth-resistant" claims would be appropriate but is open to consider such an appropriately worded, evidence-based claim directed to the consumer and/or retailer. As recommended by the FDA, we have submitted additional "meth-resistant" testing information to the FDA for review prior to submitting an IND. In October 2016, we received FDA recommendations on our meth-resistant testing protocols for our Nexafed extended release tablets. We can now scale-up our manufacture batch size at a contract manufacturer which allows us to submit an IND to the FDA for our Nexafed extended release tablets, however, we have not yet committed to that level of development.

In March 2017, we completed a pilot pharmacokinetic study for the PSE and loratadine combination product using our Impede 1.0 technology. The study in 24 healthy adult subjects demonstrated sufficient, but not bioequivalent blood levels of PSE to the comparator while the second active ingredient achieved bioequivalence. Based on the product profile, we believe this formulation can be moved into final development for a 505(b)(2) NDA submission. The Company has upgraded a portion of this formulation with its Impede 2.0 Technology.

U.S. Market Opportunity for Impede PSE Products

PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products. PSE is sold in products as the only active ingredient in both immediate and extended-release products. In addition, PSE is combined with other cold, sinus and allergy ingredients such as pain relievers, cough suppressants and antihistamines. PSE also competes against phenylephrine, an alternate nasal decongestant available in non-prescription products. In 2014, a data service reported approximately $0.7 billion in retail sales of non-prescription products containing PSE. The top retail selling PSE OTC cold/allergy products in 2014 were:

Reference Brand[1]	Brand Company	Active Ingredient(s)	2014 Retail Sales ($ Millions)
Claritin-D	Bayer	PSE & Loraditine[2]	$ 208.0
Allegra-D	Chattem	PSE & Fexofenadine[2]	$ 101.3
Zyrtec-D	Pfizer	PSE & Ceterizine[2]	$ 101.7
Advil Sinus	Pfizer	PSE & Ibuprofen	$ 58.4
Sudafed 12 Hour	J&J	PSE[2]	$ 82.3
Sudafed 30mg	J&J	PSE	$ 70.4

[1] Branded product only. Does not include store brand sales.

[2] Extended release PSE formulations

The 2014 market for 30mg PSE tablets, including store brands was approximately 470 million tablets or 19 million boxes of 24 tablets. MainPointe controls the price of Nexafed and Nexafed Sinus under the terms of the MainPointe Agreement.

The market for cold, sinus and allergy products is highly competitive and many products have strong consumer brand recognition and, in some cases, prescription drug heritage. Category leading brands are often supported by national mass marketing and promotional efforts. Consumers often have a choice to purchase a less expensive store brand. Store brands contain the same active ingredients as the more popular national brands but are not supported by large marketing campaigns and are offered at a lower price. Non-prescription products are typically distributed through retail outlets including drug store chains, food store chains, independent pharmacies and mass merchandisers. The distribution outlets for PSE products are highly consolidated. According to Chain Drug Review, the top 50 drug, food and mass merchandising chains operate approximately 40,000 pharmacies in the U.S., of which 58% are operated by the four largest chains. Stocking decisions and pharmacists recommendations for these chain pharmacies are often centralized at the corporate headquarters.

Product Labeling for Impede Technology Products

Nexafed and Nexafed Sinus Pressure + Pain products are marketed pursuant to the FDA's OTC Monograph regulations, which require that our product have labeling as specified in the regulations. Marketing for the Nexafed products includes advertising the extraction characteristics and methamphetamine-resistant benefits of these products which is supported by our published research studies.

We expect that any of our other Impede Technology products will be marketed pursuant to an NDA or ANDA and will be subject to a label approved by the FDA. We expect that such a label will require submission of our scientifically derived abuse liability data and we intend to seek descriptions of our abuse liability studies in the FDA approved product label, although there can be no assurance that this will be the case.

U.S. Market Opportunity for Opioid Analgesic Products

The misuse and abuse of opioid analgesics continues to constitute a dynamic and challenging threat to the United States and is the nation's fastest growing drug problem. During 2017, the US Government declared opioid abuse as an epidemic and national health emergency. According to the 2017 Centers on Disease Control Drug Surveillance Report, 11.8 million Americans aged 12 and over abused or misused prescription opioids in 2016. Further, this Report calculates that, on average, 115 Americans die every day from an opioid overdose. The majority of drug overdose deaths (66%) involve an opioid. Immediate release, or IR, opioid products comprise the vast majority of this abuse compared with extended release, or ER, opioid products**.**

It is estimated that more than 75 million people in the United States suffer from pain and the FDA estimates more than 61 million people receive a prescription for the opioid hydrocodone annually. For many pain sufferers, opioid analgesics provide their only pain relief. As a result, opioid analgesics are among the largest prescription drug classes in the United States with over 214 million tablet and capsule prescriptions dispensed in 2016 of which approximately 194 million were for IR opioid products and 204 million were for ER opioid products. However, physicians and other health care providers at times are reluctant to prescribe opioid analgesics for fear of misuse, abuse, and diversion of legitimate prescriptions for illicit use.

We expect our Aversion and Limitx Technology opioid products, to compete primarily in the IR opioid product segment of the United States opioid analgesic market. Because IR opioid products are used for both acute and chronic pain, a prescription, on average, contains 66 tablets or capsules. According to IMS Health, in 2016, sales in the IR opioid product segment were approximately $2.7 billion, of which ~98% was attributable to generic products. Due to fewer identified competitors and the significantly larger market for dispensed prescriptions for IR opioid products compared to ER opioid products, we have initially focused on developing IR opioid products utilizing our Aversion and Limitx Technologies. A summary of the IR opioid product prescription data for 2016 is provided below:

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

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

[2] IMS Health, 2016

Despite considerable publicity regarding the abuse of OxyContin® extended-release tablets and other ER opioid products, U.S. government statistics suggest that far more people have used IR opioid products non-medically than ER opioid products. These statistics estimate that nearly four times as many people have misused the IR opioid products Vicodin®, Lortab® and Lorcet® (hydrocodone bitartrate/acetaminophen brands and generics) than OxyContin®.

Product Labeling for Opioid Products Using Our Technologies

In April 2015, the FDA published guidance for industry on the evaluation and labeling of abuse-deterrent opioids. While the 2015 FDA Guidance is non-binding on the FDA, it outlines FDA's current thinking on the development and labeling of abuse-deterrent products. The 2015 FDA Guidance provides for three distinct levels of pre-marketing studies that are potentially eligible for inclusion in the labeling: (1) laboratory-based in vitro manipulation and extraction studies, (2) pharmacokinetic studies, and (3) clinical abuse potential studies. The 2015 FDA Guidance further prescribes additional post-approval or epidemiology studies to determine whether the marketing of a product with abuse-deterrent properties results in meaningful reductions in abuse, misuse, and related adverse clinical outcomes, including addiction, overdose, and death in the post-approval setting, which can also be included in the labeling. FDA notes "the science of abuse deterrence is relatively new. Both the technologies involved and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. For these reasons, FDA will take a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent opioid products".

We or our licensee may seek to include descriptions of studies that characterize the safety features of our technologies in the label for our Aversion and Limitx Technology products in development. Although the FDA approved label for Oxaydo contains limitations on exposing Oxaydo tablets to water and other solvents and administration through feeding tubes, the FDA approved Oxaydo label does not contain a description of the I.V. injection studies we performed to characterize the abuse deterrent properties of Oxaydo. Zyla has committed to the FDA to undertake epidemiological studies to assess the actual consequences of abuse of Oxaydo in the market. Under the terms of the Zyla Agreement, we share a minority portion of the fees and expenses relating to such FDA required epidemiological studies, provided Zyla complies with the sections of the agreement relating thereto. The extent to which a description of the abuse-deterrent properties or results of epidemiological or other studies will be added to or included in the FDA approved product label for our products in development will be the subject of our discussions with the FDA as part of the NDA review process, even after having obtained approval of Oxaydo. Further, because the FDA closely regulates promotional materials, even if FDA initially approves labeling that includes a description of the abuse deterrent properties of the product, the FDA's Office of Prescription Drug Promotion, or OPDP, will continue to review the acceptability of promotional labeling claims and product advertising campaigns for our marketed products.

Patents and Patent Applications

We have the following issued patents covering, among other things, our Limitx Technology:

Patent No. (Jurisdiction)	Subject matter	Issued	Expires
9,101,636 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Aug. 2015	Nov. 2033
9,320,796 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Apr. 2016	Nov. 2033
9,662,393 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	May 2017	Nov. 2033
2,892,908 (CAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Apr. 2016	Nov. 2033
5,922,851 (JAPAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Apr. 2016	Nov. 2033

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

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
7,201,920 (US)	Pharmaceutical compositions including a mixture of functional inactive ingredients and specific opioid analgesics	Apr. 2007	Mar. 2025
7,510,726 (US)	A wider range of compositions than those described in the 7,201,920 Patent	Mar. 2009	Nov. 2023
7,981,439 (US)	Pharmaceutical compositions including any water soluble drug susceptible to abuse	July 2011	Aug. 2024
8,409,616 (US)	Pharmaceutical compositions of immediate-release abuse deterrent dosage forms	Apr. 2013	Nov. 2023
8,637,540 (US)	Pharmaceutical compositions of immediate-release abuse deterrent opioid products	Jan. 2014	Nov. 2023
9,492,443 (US)	Pharmaceutical compositions of immediate-release abuse deterrent opioid products	Nov. 2016	Nov. 2023

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

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
7,476,402 (US)	Pharmaceutical compositions of certain combinations of kappa and mu opioid receptor agonists and other ingredients intended to deter opioid analgesic product misuse and abuse	Jan. 2009	Nov. 2023
8,822,489 (US)	Pharmaceutical compositions of certain abuse deterrent products that contain polymers, surfactant and polysorb 80	July 2014	Nov. 2023
2,004,294,953 (AUS)	Abuse deterrent pharmaceuticals	Apr. 2010	Nov. 2024
2,010,200,979 (AUS)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,547,334 (CAN)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,647,360 (CAN)	Abuse deterrent pharmaceuticals	May 2012	Apr. 2027
175,863 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
221,018 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
1694260 (EUR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024

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

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
8,901,113 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Dec. 2014	Feb. 2032
9,757,466 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Sept. 2017	Feb. 2032
10,004,699 (US)	Methods and compositions for interfering with extraction or conversion of a drug susceptible to abuse	Jun. 2018	Dec. 2035
2010300641 (AUS)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sept. 2030
2,775,890 (CAN)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sept. 2030
2,488,029 (EUR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Mar. 2016	Sept. 2030
218533 (ISR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jan. 2016	Sept. 2030
2015274936 (AUS)	Methods and compositions for interfering with extraction or conversion of a drug susceptible to abuse	Sept. 2018	June 2035
13102020.5 (HK)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Oct. 2016	Sept. 2030

In addition to our issued patents listed above and additional unlisted issued patents, we have filed multiple U.S. patent applications and international patent applications relating to compositions containing abusable active pharmaceutical ingredients as well as applications covering our Impede 1.0 and 2.0 Technologies and filed U.S. patent applications for our Limitx Technology. Except for the rights granted in the Zyla Agreement, the KemPharm Agreement, and the MainPointe Agreement and in the patent infringement settlement agreements described below, we have retained all intellectual property rights to our Aversion Technology, Impede Technology, Limitx Technology and related product candidates.

In 2012 and 2013, we received Paragraph IV Certification Notices from five generic sponsors of ANDAs for a generic drug listing our Oxaydo product as the reference listed drug. The Paragraph IV Notices referred to our 920, 726 and 439 Patents, which cover our Aversion® Technology and our Oxaydo product. We filed suit against each of such generic sponsors, Watson Laboratories, Inc., Par Pharmaceutical, Inc., Impax Laboratories, Inc., Sandoz Inc. and Ranbaxy Inc., in the United States District Court for the District of Delaware alleging infringement of our 726 Patent listed in the FDA's Orange Book. Our litigation against Watson Laboratories was dismissed by us following Watson Laboratories' change of its Paragraph IV Certification to a Paragraph III Certification, indicating it would not launch its generic product until the expiry of our applicable Patents. Our litigation against each of the remaining generic sponsors was settled during the period October 2013 through May 2014 on an individual basis, upon mutual agreement between us and such generic sponsors. None of such settlements impacted the validity or enforceability of our Patents. See "Item 1A. Risk Factors – Generic manufacturers are using litigation and regulatory means to seek approval for generic versions of Oxaydo, which could cause Zyla's sales to suffer and adversely impact our royalty revenue" for a discussion of the settlements and license grants relating to such patent litigation. Notwithstanding the settlement of these prior infringement actions, it is possible that other generic manufacturers may also seek to launch a generic version of Oxaydo and challenge our patents. Any determination in such infringement actions that our patents covering our Aversion Technology and Oxaydo are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents could have a material adverse effect on our operations and financial condition.

In April, 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc., or collectively Purdue, commenced a patent infringement lawsuit against us and our Oxaydo product licensee Zyla in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's U.S. Patent No. 8,389,007, or the 007 Patent. In April 2016, Purdue commenced a second patent infringement lawsuit against us and Zyla in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's then newly issued U.S. Patent No. 9,308,171, or the 171 Patent. The actions regarding the 007 Patent and the 171 Patent are collectively referred to as the "Actions". On April 6, 2016, we filed a petition for Inter Parties Review, or IPR Review, with the USPTO seeking to invalidate Purdue's 007 Patent.

On May 20, 2016, we, Purdue and Zyla entered into a settlement agreement to settle the Actions and the IPR Review. Under the settlement agreement the parties dismissed or withdrew the Actions, requested that the USPTO terminate the IPR Review and exchanged mutual releases. No payments were made by the parties under the settlement agreement.

Reference is made to the Risk Factors contained in our Annual Report on Form 10-K for the year ended December 31, 2018 for a discussion, among other things, of patent applications and patents owned by third parties, including claims that may encompass our Aversion Technology and Oxaydo tablets, and the risk of infringement, interference or opposition proceedings that we may be subject to arising from such patents and patent applications.

Company's Present Financial Condition

At March 31, 2019 and December 31, 2018, we had cash of $0.1 million. We had an accumulated deficit of $385 million at March 31, 2019. We had loss from operations of $0.7 million and net loss of $0.8 million for the three months ended March 31, 2019 and we had a net loss from operations of $3.92 million and a net loss of $3.84 million for the year ended December 31, 2018.

On June 28, 2019, we entered into License, Development and Commercialization Agreement (the Agreement) with Abuse Deterrent Pharma, LLC. The Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03. Financial arrangements include monthly license payments by AD Pharma of $350,000 up to the earlier of 18 months or FDA's acceptance of a New Drug Application (NDA) for LTX-03 and reimbursement by AD Pharma of Acura's LTX-03 outside development expenses. Upon commercialization of LTX-03, Acura receives stepped royalties on sales and is eligible for certain sales related milestones. However, if the NDA application for LTX-03 is not accepted by the FDA within 18 months, AD Pharma may terminate the Agreement and take ownership of the intellectual property.

The Agreement allows AD Pharma to terminate the Agreement "for convenience". Should AD Pharma exercise their right to terminate the Agreement, we would need to raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations. In light of AD Pharma's right to terminate the Agreement "upon convenience", our independent auditors have included in their report relating to our 2018 financial statements a "going concern" explanatory paragraph as to substantial doubt of our ability to continue as a going concern.

Also, the required monthly license payments by AD Pharma cease at November 2020 at which time the Company will need to have additional capital to fund operations until such time as LTX-03 is approved and royalty payments commence. To fund further operations beyond December 2020, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies or explore a variety of capital raising and other transactions to provide additional funding. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, there will be substantial doubt about the Company's ability to continue as a going concern and the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

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

Our future sources of revenue, if any, will be derived from licensing fees, milestone payments and royalties under the AD Pharma Agreement, the Zyla Agreement, the KemPharm Agreement, the MainPointe Agreement and similar agreements which we may enter into for our Limitx products in development with other pharmaceutical company partners, for which there can be no assurance.

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

Three months Ended March 31, 2019 Compared to Three months Ended March 31, 2018

	March 31			
	2019	2018	Increase (decrease)	
	$000's			Percent
Revenues:				
Royalty revenue	$ 67	$ 198	$ (131)	(66)%
Expenses:				
Research and development	313	650	(337)	(52)
General and administrative	437	943	(506)	(54)
Total operating expenses	750	1,593	(843)	(53)
Operating loss	(683)	(1,395)	(712)	(51)
Interest expense, net	(105)	(99)	6	6
Loss before income taxes	(788)	(1,494)	(706)	(47)
Provision for income taxes	-	-	-	-
Net loss	$ (788)	$ (1,494)	$ (706)	(47)%

Revenue

Royalty Revenue

In connection with our agreement with Zyla for Oxaydo tablets, we earn a royalty based on Oxaydo net sales. We recognized $55 thousand and $190 thousand of royalty revenue during the three months ended March 31, 2019 and 2018, respectively. Included in the 2018 results is a one-time benefit of $89 thousand on royalty revenue reported to us by Zyla for the effect of their adoption of ASC 606 on Oxaydo net sales.

In connection with our agreement with MainPointe for the Nexafed products, we earn a royalty of 7.5% on net sales. We recognized $12 thousand and $8 thousand of royalty revenue during the three months ended March 31, 2019 and 2018, respectively.

Expenses

Research and Development

Research and development expense is primarily associated with our Limitx Technology development activity. Included in each of March 31, 2019 and 2018 reported quarterly expenses are share-based compensation expenses of approximately $6 thousand and $20 thousand, respectively. Excluding the share-based compensation expense, our research and development expenses decreased by $323 thousand between reporting periods primarily in the categories of salaries, company insurance premiums and outside clinical and development expenses.

General and Administrative

Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the March 31, 2019 and 2018 quarterly results are share-based compensation expenses of approximately $29 thousand and $56 thousand, respectively. Excluding this share-based compensation expense, our general and administrative expenses decreased by $479 thousand between reporting periods, resulting primarily in the categories of salaries, company insurance premiums, patent and general legal activities, director compensation, and investment and accounting consulting fees.

Interest Expense, net

During the three months ended March 31, 2019 and 2018, we incurred net interest expense on our term loans of $105 thousand and $99 thousand, respectively. The term loan from Oxford having a maturity date of December 1, 2018, was negotiated and settled in October 2018 using loan proceeds from Mr. Schutte.

Income Taxes

Our results for 2019 and 2018 show no federal or state income tax benefit provisions due to 100% allowances placed against them for the uncertainty of their future utilization.

Liquidity and Capital Resources

At March 31, 2019 and December 31, 2018, we had cash of $0.1 million. As of September 27, 2019 our cash balance was approximately $600 thousand. Additionally, the License, Development and Commercialization Agreement dated June 28, 2019 (the "Agreement") requires AD Pharma to pay us monthly license payments of $350,000 from July 2019 through November 2020 and pay all outside development costs for LTX-03.

However, the Agreement allows AD Pharma to terminate the Agreement "for convenience". Should AD Pharma exercise their right to terminate the Agreement, we would need to raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations. In light of AD Pharma's right to terminate the Agreement "upon convenience", our independent auditors have included in their report relating to our 2018 financial statements a "going concern" explanatory paragraph as to substantial doubt of our ability to continue as a going concern.

Also, the required monthly license payments by AD Pharma cease at November 2020 at which time the Company will need to have additional capital to fund operations until such time as LTX-03 is approved and royalty payments commence. To fund further operations beyond December 2020, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies or explore a variety of capital raising and other transactions to provide additional funding. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, there will be substantial doubt about the Company's ability to continue as a going concern and the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

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

Our future sources of revenue, if any, will be derived from licensing fees, milestone payments and royalties under the AD Pharma Agreement, the Zyla Agreement, the KemPharm Agreement, the MainPointe Agreement and similar agreements which we may enter into for our Limitx products in development with other pharmaceutical company partners, for which there can be no assurance.

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

Critical Accounting Policies

Note 1 of the Notes to Consolidated Financial Statements, in the Company's 2018 Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company's critical accounting policies described in the 2018 Annual Report are also applicable to 2019.

Item 4. Controls and Procedures

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

(b) *Changes in Internal Controls over Financial Reporting*. There were no changes in our internal controls over financial reporting during the first fiscal quarter of 2019 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

The information required by this Item is incorporated by reference to Note 15, "Commitments and Contingencies," in Part I, Item 1, "Financial Statements."

Item 1A. Risk Factors

Investors in our common stock should consider the following risk factors, in addition to those risk factors set forth in our 2018 Annual Report on Form 10-K:

We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us; if we fail to raise additional funding we will cease operations and/or seek protection under applicable bankruptcy laws.

Our operations to date have consumed substantial amounts of cash. Negative cash flows from our operations are expected to continue over at least the next several years. Our cash utilization amount is highly dependent on the progress of our product development programs, particularly, the results of our preclinical and clinical studies of our Limitx product candidates and the cost, timing and outcomes of regulatory approval for our Limitx product candidates. In addition, the further development of our ongoing clinical trials will depend on upcoming analysis and results of those studies and our financial resources at that time. As of September 27, 2019 our cash balance was approximately $600 thousand. Additionally, the Agreement with AD Pharma calls for monthly license payments of $350,000 from July 2019 through November 2020 and as well as their payment of all outside development costs for LTX-03. We expect these amounts will fund operations through 2020. The monthly payments by AD Pharma cease in November 2020 at which time the Company will need to have additional capital to fund operations until such time as LTX-03 is approved and royalty payments commence. To fund further operations beyond December 2020, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies or explore a variety of capital raising and other transactions to provide additional funding.

We will require future additional capital infusions including public or private financing, strategic partnerships or other arrangements with organizations that have capabilities and/or products that are complementary to our own capabilities and/or products, in order to continue the development of our product candidates. However, there can be no assurances that we will complete any financings, strategic alliances or collaborative development agreements, and the terms of such arrangements may not be advantageous to us. Any additional equity financing will be dilutive to our current stockholders and debt financing, if available, may involve restrictive covenants. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. Our failure to raise capital when needed could materially harm our business, financial condition and results of operations. In the absence of the receipt of additional financing or payments under third-party license or collaborative agreements, we will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. This could result in a complete loss of shareholder value of the Company. Even assuming we are successful in securing additional sources of financing to fund continued operations, there can be no assurance that the proceeds of such financing will be sufficient to fund operations until such time, if at all, that we generate sufficient revenue from our products and product candidate to sustain and grow our operations.

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

Item 6. Exhibits

The exhibits required by this Item are listed below.

10.46	Promissory Note Dated March 25, 2019
31.1	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
31.2	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
32.1	Certification of Periodic Report by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase

Signatures

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

October 1, 2019

ACURA PHARMACEUTICALS, INC.

/s/ Robert B. Jones

Robert B. Jones
Chief Executive Officer

/s/ Peter A. Clemens

Peter A. Clemens
Senior VP & Chief Financial Officer

Exhibit 10.46

PROMISSORY NOTE

FOR VALUE RECEIVED, and subject to the terms and conditions set forth herein, ACURA PHARMACEUTICALS, INC., a New York corporation with offices located at 616 N. North Court, Suite 120, Palatine, Illinois (**"Borrower"**), hereby unconditionally promises to pay to the order of John Schutte c/o MainPointe Pharmaceuticals, LLC, 333 E. Main Street, Louisville, KY 40202 or his assigns (the **"Noteholder"**), the principal amount of **TWO HUNDRED THOUSAND DOLLARS ($200,000)** together with all accrued interest thereon, as provided in this Promissory Note (this "**Note**").

1. Definitions. Unless defined elsewhere in this Note, capitalized terms used herein shall have the meanings set forth in this Section 1.

"**Affiliate**" means as to any Person, any other Person that, directly or indirectly through one or more intermediaries, is in control of, is controlled by, or is under common control with, such Person. For purposes of this definition, "control" of a Person means the power, directly or indirectly, either to (a) vote more than 50% of the securities having ordinary voting power for the election of directors (or persons performing similar functions) of such Person or (b) direct or cause the direction of the management and policies of such Person, whether by contract or otherwise.

"**Person**" means any individual, corporation, limited liability company, trust, joint venture, association, company, limited or general partnership, unincorporated organization, governmental authority or other entity.

"**Prime Rate**" means the rate of interest per annum equal to the prime rate as reported by the *Wall Street Journal.*

2. Loan. On the date hereof Noteholder is funding a loan of $200,000 (the "**Loan**") to Borrower.

3. Payment Dates; Optional Prepayments;

3.1 Payment Dates. The aggregate unpaid principal amount of the Loan together with all accrued and unpaid interest thereon shall be due and payable on January 2, 2020 (the **"Maturity Date")**.

3.2 Optional Prepayments. The Borrower may prepay the Loan in whole or in part at any time or from time to time without penalty or premium by paying the principal amount to be prepaid together with accrued interest thereon to the date of prepayment.

3.3 Payment Mechanics. All payments of interest and principal shall be made in lawful money of the United States of America on the date on which such payment is due by wire transfer of immediately available funds to the Noteholder's account at a bank specified by the Noteholder in writing.

4. Interest. The outstanding principal amount of the Loan shall bear interest at a rate equal to the Prime Rate plus 2% per annum and shall accrue and be payable at the Maturity Date. All computations of interest shall be made on the basis of a 360 day year consisting of 12 months of 30 days.

5. Events of Default. The occurrence and continuance of any of the following shall constitute an "**Event of Default**" hereunder:

5.1 Failure to Pay. The Borrower fails to pay any amount of principal of, or interest on, the Loan when due and such failure continues for 5 days after written notice to the Borrower.

5.2 Bankruptcy. (A) The Borrower commences any case, proceeding or other action (i) under any existing or future law relating to bankruptcy, insolvency, reorganization, or other relief of debtors, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it as bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts or (ii) seeking appointment of a receiver, trustee, custodian, conservator or other similar official for it or for all or any substantial part of its assets, or the Borrower makes a general assignment for the benefit of its creditors; or (B) there is commenced against the Borrower any case, proceeding or other action of a nature referred to in Section 5.2(A) above which (i) results in the entry of an order for relief or any such adjudication or appointment or (ii) remains undismissed, undischarged or unbonded for a period of 60 days.

6. Remedies. Upon the occurrence of any Event of Default and at any time thereafter during the continuance of such Event of Default, the Noteholder may at its option, by written notice to the Borrower declare the entire principal amount of this Note, together with all accrued interest thereon, immediately due and payable, *provided, however* that, if an Event of Default described in Section 5.2 shall occur, the principal of and accrued interest on the Loan shall become immediately due and payable without any notice, declaration or other act on the part of the Noteholder.

7. Miscellaneous.

7.1 Governing Law. This Note, and any claim, controversy, dispute or cause of action (whether in contract or tort or otherwise) based upon, arising out of or relating to this Note and the transactions contemplated hereby and thereby shall be governed by the laws of the State of New York, without giving effect to conflict of law provisions.

7.2 Successors and Assigns. This Note is non-negotiable but may be assigned or transferred by the Noteholder.

7.3 Waiver of Notice. The Borrower hereby waives demand for payment, presentment for payment, protest, notice of payment, notice of dishonor, notice of nonpayment, notice of acceleration of maturity and diligence in taking any action to collect sums owing hereunder.

7.4 Amendments and Waivers. No term of this Note may be waived, modified or amended except by an instrument in writing signed the Noteholder and Borrower. Any waiver of the terms hereof shall be effective only in the specific instance and for the specific purpose given.

7.5 No Waiver; Cumulative Remedies. No failure to exercise and no delay in exercising on the part of the Noteholder, of any right, remedy, power or privilege hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege. The rights, remedies, powers and privileges herein provided are cumulative and not exclusive of any rights, remedies, powers and privileges provided by law.

7.6 Security. This Note is secured. Borrower shall grant a security interest to Noteholder, execute all documents reasonably required by Noteholder and take all action reasonably necessary to secure and perfect Noteholder's security interest in all of Borrower's property including, but not limited to, accounts, inventory, equipment, general intangibles, intellectual property, chattel paper, investment property, instruments, documents, letter of credit rights, insurance proceeds and real estate, excluding agreements that by their terms may not be collaterally assigned and other property that may not be collaterally assigned (such as intent to use trademark applications), in each case without causing a default, termination or right of termination.

IN WITNESS WHEREOF, the Borrower has executed this Note as of March 25, 2019.

ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens
Name: Peter A. Clemens
Title: Senior Vice President & CFO

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

October 1, 2019

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

Exhibit 31.2

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

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

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

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

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

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

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

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

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

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

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

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

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

October 1, 2019

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

Exhibit 32.1

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

In connection with the Quarterly Report of Acura Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert B. Jones, the Chief Executive Officer of the Company, and Peter A. Clemens, Chief Financial Officer certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

October 1, 2019

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

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