

ACURA PHARMACEUTICALS, INC  
Form 10-Q  
November 27, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2018**

**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**



Yes " No þ

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 November 26, 2018: 21,033,528

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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)**

	September 30, 2018	December 31, 2017
Assets:		
Cash and cash equivalents	\$ 18	\$ 2,220
Royalty receivable	108	71
Prepaid expenses and other current assets	249	275
Refundable retainer deposits	80	-
Total current assets	455	2,566
Income tax receivable	135	135
Property, plant and equipment, net (Note 6)	623	679
Intangible asset, net of accumulated amortization of \$931 and \$776 (Note 3)	1,069	1,224
Total assets	\$ 2,282	\$ 4,604
Liabilities:		
Accounts payable	\$ 781	\$ 3
Accrued expenses (Note 7)	950	939
Accrued interest	781	700
Other current liabilities	15	41
Sales returns liability	254	254
Debt, net of discounts (Note 8)	1,016	2,694
Total current liabilities	3,797	4,631
Accrued interest to related party	39	-
Debt to related party, net of discounts	2,115	-
Total liabilities	5,951	4,631
Commitments and contingencies (Note 15)		
Stockholders' deficit:		
Common stock - \$.01 par value per share; 100,000 shares authorized, 21,034 and 20,796 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	210	208

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Additional paid-in capital	380,351	380,145
Accumulated deficit	(384,230 )	(380,380 )
Total stockholders' deficit	(3,669 )	(27 )
Total liabilities and stockholders' deficit	\$ 2,282	\$ 4,604

See accompanying notes to unaudited consolidated financial statements.

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

	<b>Three months Ended</b>		<b>Nine months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
<b>Revenues:</b>				
License fee revenue	\$ -	\$ -	\$ -	\$ 2,500
Collaboration revenue	-	-	-	59
Royalty revenue	73	83	347	226
Product sales, net	-	-	-	107
Total revenues, net	73	83	347	2,892
<b>Cost and expenses:</b>				
Cost of sales	-	-	-	128
Research and development	549	1,077	1,676	2,808
Selling, marketing, general and administrative	543	1,068	2,332	3,427
Total cost and expenses	1,092	2,145	4,008	6,363
Operating loss	(1,019 )	(2,062 )	(3,661 )	(3,471 )
Interest expense, net (Note 8)	(76 )	(138 )	(189 )	(473 )
Loss before income taxes	(1,095 )	(2,200 )	(3,850 )	(3,944 )
Provision for income taxes	-	-	-	-
Net loss	\$ (1,095 )	\$ (2,200 )	\$ (3,850 )	\$ (3,944 )
<b>Loss per share:</b>				
Basic	\$ (0.05 )	\$ (0.12 )	\$ (0.18 )	\$ (0.27 )
Diluted	\$ (0.05 )	\$ (0.12 )	\$ (0.18 )	\$ (0.27 )
<b>Weighted average shares outstanding:</b>				
Basic	21,168	16,686	21,101	14,147
Diluted	21,168	16,686	21,101	14,147



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

	<b>Common Stock Number of Shares</b>	<b>Par Value</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
Balance at January 1, 2018	20,796	\$ 208	\$ 380,145	\$ (380,380 )	\$(27 )
Net loss	-	-	-	(3,850 )	(3,850)
Non-cash share-based compensation	-	-	174	-	174
Net distribution of common stock pursuant to restricted stock unit award plan	238	2	32	-	34
Balance at September 30, 2018	21,034	\$ 210	\$ 380,351	\$ (384,230 )	\$(3,669)

See accompanying notes to unaudited consolidated financial statements.

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

	<b>Nine months Ended</b>	
	<b>September 30,</b>	
	2018	2017
Cash Flows from Operating Activities:		
Net loss	\$ (3,850 )	\$ (3,944 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	56	68
Provision for sales returns	-	49
Non-cash share-based compensation	174	353
Capitalized debt discount	(103 )	-
Amortization of debt discount and deferred debt issue costs	59	79
Amortization of intangible asset	155	155
Gain on disposal of machinery & equipment	-	(3 )
Change in assets and liabilities:		
Trade accounts receivable	-	23
Collaboration revenue receivable	-	79
Royalty receivable	(37 )	(15 )
Inventory	-	103
Prepaid expenses and other current assets	26	(174 )
Refundable retainer deposits	(80 )	-
Accounts payable	778	50
Accrued expenses	11	187
Accrued interest	120	135
Other current liabilities	6	17
Sales returns liability	-	(50 )
Net cash used in operating activities	(2,685 )	(2,888 )
Cash Flows from Investing Activities:		
Proceeds from transfer of equipment to licensee	-	103
Proceeds from transfer of inventory to licensee	-	206
Net cash provided by investing activities	-	309
Cash Flows from Financing Activities:		
Issuance of common stock	-	4,000
Proceeds from distribution of restricted stock units	2	-
Proceeds from loan maturing January 2, 2020	2,200	-
Principal payments on loan maturing December 1, 2018	(1,719 )	(1,815 )
Net cash provided by financing activities	483	2,185
Net decrease in cash, cash equivalents, and restricted cash	(2,202 )	(394 )
Cash, cash equivalents, and restricted cash at beginning of period	2,220	5,181

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Cash and cash equivalents at end of period	\$ 18	\$ 4,787
Supplemental disclosure of cash flow information:		
Cash interest payments on loan maturing December 1, 2018	\$ 112	\$ 262

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

	September 30,	
	2018	2017
Cash	\$ 18	\$ 2,284
Cash equivalents	-	2,503
Total cash and cash equivalents cash show in the consolidated statements of cash flows	\$ 18	\$ 4,787

Supplemental disclosures of noncash investing and financing activities:

Nine months Ended September 30, 2018

The imputed interest on the below market rate element of the related party \$2.2 million loan amounted to \$103 1 thousand recorded as a benefit to interest income 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.

Nine months Ended September 30, 2017

1. There are no supplemental disclosure activities

See accompanying notes to unaudited consolidated financial statements.

**ACURA PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**SEPTEMBER 30, 2018 AND SEPTEMBER 30, 2017**

**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 a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Limitx™ Technology is intended to address methods of product tampering associated with opioid abuse by retarding the release of active drug ingredients when too many tablets are accidentally 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 into methamphetamine.

Our Limitx Technology is in development with immediate-release tablets containing hydrocodone bitartrate and acetaminophen as the lead product candidate due to its large market size and its known prevalence of oral excessive tablet abuse.

Our Aversion Technology has been licensed to 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 our Impede Technology in the United States and Canada to commercialize our Nexafed products. (See Note 3).

*Basis of Presentation 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, 2017. 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 nine month period ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

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 September 30, 2018, we had cash and refundable retainer deposits of \$98 thousand, working capital deficit of \$3.3 million and an accumulated deficit of \$384.2 million. We had a loss from operations of \$3.7 million and a net loss of \$3.9 million for the nine months ended September 30, 2018. We have suffered recurring losses from operations and have not generated positive cash flows from operations. We had a loss from operations of \$5.2 million and a net loss of \$5.7 million for the year ended December 31, 2017. We anticipate operating losses to continue for the foreseeable future.

To date, we have borrowed a total of \$4.15 million from John Schutte, a principal of MainPointe and our largest shareholder, including \$150 thousand received on November 21, 2018. As of November 26, 2018 we had cash of \$150 thousand. With the net proceeds to the Company resulting from the loans from Mr. Schutte, we expect our cash will only be sufficient to fund operations into early December 2018.

These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. We must seek sources to raise additional financing and seek to enter into license or collaboration agreements with third parties relating to our technologies. The Company is exploring a variety of capital raising and other transactions to provide additional funding to continue operations. These include potential private offerings of common stock to accredited and/or institutional investors and licensing transactions with pharmaceutical company partners for our proprietary technologies, including Limitx. We are actively seeking a licensing partner for our Limitx Technology, with the objective of receiving an upfront license fee, development milestone payments and royalties on the net sales of products utilizing the Limitx Technology, similar to the Egalet Agreement. We are also exploring licensing or selling select assets and intellectual property in an effort to raise capital and reduce operating expenses. Finally, the Company continues to evaluate the potential for a strategic transaction which may involve the Company being acquired in a merger or asset purchase transaction. No assurance can be given that we will be successful in completing any one or more of such transactions on acceptable terms, if at all, or if completed, that such transactions will provide payments to the Company sufficient to fund continued operations. In the absence of the Company's completion of one or more of such transactions, there will be substantial doubt about the Company's ability to continue as a going concern within one year after the date these financial statements are issued, 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, 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 balance sheets is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its funding requirements on a continuous basis, to maintain existing financing and to succeed in its future operations. The Company's financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

## **NOTE 2 – RECENT ACCOUNTING PRONOUNCEMENTS**

### New accounting standards which have been adopted on or before September 30, 2018

#### *Revenue from Contracts with Customers*

The Company adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to its accounting policy for revenue recognition. The Company used the modified retrospective method and the cumulative effect of initially applying Topic 606 would be recognized

as an adjustment to the opening accumulated deficit at January 1, 2018. Accordingly, comparative information has not been adjusted and continues to be reported under the previous accounting standards. The implementation of Topic 606 had no financial impact (See Note 4).

*Scope of Modification Accounting, Stock Based Compensation*

In May 2017, the FASB issued ASU No. 2017-09 which provides guidance as to how an entity should apply modified accounting in Topic 718 when changing the terms and conditions of its share-based payment awards. The guidance clarifies that modification accounting will be applied if the value, vesting conditions or classification of the award changes. The ASU is effective for annual reporting periods, including interim periods within those annual periods, beginning after December 15, 2017 but early adoption is permitted. The Company adopted this new standard on January 1, 2018 which did not have a material impact on the Company's financial statements.



*Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments*

In August 2016, the FASB issued ASU 2016-15 which clarifies existing guidance on how companies present and classify certain cash receipts and cash payments in the statement of cash flows by addressing specific cash flow issues in an effort to reduce diversity in practice, including guidance on debt prepayment or extinguishment costs and contingent consideration payments made after a business combination. This update is effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this new standard on January 1, 2018 which did not have a material impact on the Company's financial statements.

*Intra-Entity Transfers of Assets Other than Inventory*

In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*. ASU 2016-16 eliminates from Topic 740, Income Taxes, the recognition exception for intra-entity asset transfers other than inventory so that an entity's financial statements reflect the current and deferred tax consequences of those intra-entity asset transfers when they occur. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2017 but early adoption is permitted. The Company adopted this new standard on January 1, 2018 which did not have a material impact on the Company's financial statements.

New accounting standards which have not been adopted on or before September 30, 2018

*Fair Value Measurements*

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. This standard is effective for fiscal years beginning after December 15, 2019, including interim reporting periods within those years, with early adoption permitted. The Company is currently evaluating the impact that the standard will have on the financial statements and related footnote disclosures.

*Leases*

In February 2016, the FASB issued ASU 2016-02, Leases, which establishes a comprehensive new lease accounting model. The new standard will require most leases (with the exception of leases with terms of one year or less) to be recognized on the balance sheet as a lease liability with a corresponding right-of-use asset. Leases will be classified as an operating lease or a financing lease. Operating leases are expensed using the straight-line method whereas financing leases will be treated similarly to a capital lease under the current standard. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2018 but early adoption is permitted. The new standard must be presented using the modified retrospective transition method existing at or entered into after the beginning of the earliest comparative period presented in the financial statements, but it does not require transition accounting for leases that expire prior to the date of initial application. Upon adoption, operating leases will be reported on the balance sheet as a gross-up of assets and liabilities. The Company is currently evaluating the impact that the standard will have on the financial statements and related footnote disclosures.

### **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.

#### ***Egalet Agreement covering Oxaydo***

In April 2014, we terminated an agreement with Pfizer and the return to us of Aversion Oxycodone (formerly known as Oxecta®) and all Aversion product rights in exchange for a one-time termination payment of \$2.0 million. Our termination payment of \$2.0 million has been recorded in our 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 Pfizer agreement was terminated. The recoverability of the Aversion intangible asset is contingent upon future Egalet royalty revenues. We have recorded amortization expense of \$155 thousand in each of the nine month periods ending September 30, 2018 and 2017. Annual amortization of the patent for its remaining life through 2021 is expected to approximate \$208 thousand each year or \$52 thousand per quarter.

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

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

Egalet paid us a \$5.0 million license fee upon signing of the Egalet Agreement and on October 9, 2015, paid us a \$2.5 million milestone in connection with the first commercial sale of Oxaydo. We will be entitled to a one-time \$12.5 million sales-based milestone payment when worldwide Oxaydo net sales reach \$150 million in a calendar year. We are receiving from Egalet a stepped royalty at percentage rates ranging from mid-single digits to double-digits based on Oxaydo net sales during each calendar year (excluding net sales resulting from our co-promotion efforts). In any calendar year of the agreement in which net sales exceed a specified threshold, we will receive a double digit royalty on all Oxaydo net sales in that year (excluding net sales resulting from our co-promotion efforts). If we exercise our co-promotion rights, we will receive a share of the gross margin attributable to incremental Oxaydo net sales from our co-promotion activities. Egalet’s royalty payment obligations commence on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA’s Orange Book remains with respect to Oxaydo). Royalties will be reduced upon the entry of generic equivalents, as well as for payments required to be made by Egalet to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Egalet Agreement expires upon the expiration of Egalet’s royalty payment obligations in all countries. Either party may terminate the Egalet Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Egalet Agreement, subject to applicable cure periods, or in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws. We also may terminate the Egalet Agreement with respect to the U.S. and other countries if Egalet

materially breaches its commercialization obligations. Egalet may terminate the Egalet Agreement for convenience on 120 days prior written notice, which termination may not occur prior to the second anniversary of Egalet's launch of Oxaydo. Termination does not affect a party's rights accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations (but not expiration), the Egalet Agreement provides for the transition of development and marketing of Oxaydo from Egalet to us, including the conveyance by Egalet to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Egalet's supply of Oxaydo for a transition period.

On October 31, 2018, Egalet issued a press release and filed a SEC Form 8-K announcing its filing for voluntary pre-arranged plan of reorganization under Chapter 11 of the United States Bankruptcy Code in the District of Delaware. As Egalet's announcement is very recent, at this time it is uncertain as to the impact on our license agreement with them, but we do anticipate a delay in the Egalet's payment of their third quarter 2018 royalty payment to us until the first quarter 2019, assuming no objections or changes to their Chapter 11 proceedings. Our royalty receivable is \$80 thousand at September 30, 2018 and remains unreserved for collectability at this time as we monitor the proceedings. We have recognized royalty revenue under the Egalet license agreement of \$70 thousand and \$330 thousand for the three and nine month periods ending September 30, 2018.

***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.

#### ***Terminated Bayer Agreement Covering Methamphetamine Resistant Pseudoephedrine-containing Product***

In June 2015, we and Bayer entered into a License and Development Agreement (the "Bayer Agreement") granting Bayer an exclusive worldwide license to our Impede Technology for use in an undisclosed methamphetamine resistant pseudoephedrine-containing product (the "Bayer Licensed Product") and providing for the joint development of such product utilizing our Impede Technology for the U.S. market. In June 2017, we received Bayer's notice of termination of the Bayer Agreement pursuant to its convenience termination right exercised prior to the Company's completion of its product development obligations under the Bayer Agreement. We have received reimbursement of certain of our development costs under the Bayer Agreement. Following Bayer's termination of the Bayer Agreement the Bayer Licensed Product is now subject to MainPointe's option rights under the MainPointe Agreement.

#### **NOTE 4 – REVENUE FROM CONTRACTS WITH CUSTOMERS**

##### ***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 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 Stockholder's 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 September 30, 2018.

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.



### *Net Product Sales*

Prior to the licensing the Nexafed products to MainPointe in March 2017, we sold our Nexafed products in the United States to wholesale pharmaceutical distributors as well as directly to chain drug stores. Our Nexafed products were sold subject to the right of return usually for a period of up to twelve months after the product expiration. Both products had an initial shelf life of twenty-four months from the date of manufacture, which shelf life had been extended to thirty-six months for Nexafed product supplied to us during 2016 from one of the Company's contract manufacturers. We recognized revenue from our Nexafed products sales when the price was fixed and determinable at the date of sale, title and risk of ownership were transferred to the customer, and returns could be reasonably estimated, which generally occurred at the time of product shipment. ASC 606 did not change the practice under which the Company previously recognized the product revenue from sales of the Nexafed products, which was at the time the product was shipped to a customer. As a result of the Company's license agreement with MainPointe completed in March 2017, the Company no longer sold the Nexafed products. There was no impact from the recognition of revenue for Nexafed product sales under the adoption of ASC 606.

### *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 Egalet 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 Egalet. 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 September 30, 2018	Nine months Ended September 30, 2018
	(in thousands)	
Egalet	\$ 70	\$ 330
MainPointe	3	17
Royalty revenues	\$ 73	\$ 347

*Contract Balance and Performance Obligations*

The Company's reported contract assets and contract liability balances under the license and collaboration agreements at either September 30, 2018 or December 31, 2017 was \$0 thousand. 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 September 30, 2018 or December 31, 2017.

**NOTE 6 – PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment at September 30, 2018 and December 31, 2017 are summarized as follows:

	September 30, 2018	December 31, 2017
	(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	(1,889)	(1,833)
Net property, plant and equipment	\$623	\$ 679

We do not have leasehold improvements nor do we have capitalized leases. Costs of betterments are capitalized while maintenance costs and repair costs are charged to operations as incurred. When a depreciable asset is retired from service, the cost and accumulated depreciation will be removed from the respective accounts.

#### NOTE 7 – ACCRUED EXPENSES

Accrued expenses at September 30, 2018 and December 31, 2017 are summarized as follows:

	September 30, 2018	December 31, 2017
	(in thousands)	
Cost sharing expenses under license agreement	\$ 443	\$ 328
Other fees and services	32	36
Payroll, payroll taxes and benefits	53	70
Professional services	100	149
Financed insurance premiums	187	-
Clinical, non-clinical and regulatory services	116	326
Property taxes	15	16
Franchise taxes	4	14
Total	\$ 950	\$ 939

## NOTE 8 – DEBT

### *Fully Paid Loan due December 1, 2018*

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 and November 21, 2018, we borrowed \$1.8 million and \$150 thousand, respectively from John Schutte. We used \$1.5 million from the October 5, 2018 loan proceeds to fully pay-off the debt outstanding under the Oxford Loan Agreement. (See Note 16). 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 is 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 \$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%.

*Loan due January 2, 2020*

We borrowed \$1.5 million and \$0.7 million during the second and third quarters 2018, respectively, and have borrowed an aggregate \$2.2 million as of September 30, 2018 from John Schutte, a related-party, and issued four promissory notes (the Schutte Notes), in that aggregate principal amount 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 are unsecured until all obligations to Oxford are satisfied at which time we are required to grant a security interest to Mr. Schutte in all of our assets. Because we believe the promissory notes' rate of interest is below current market rates for us, we imputed interest on the below market rate element of the loans using the 10.16% interest rate under the Oxford Loan Agreement which has amounted to \$103 thousand as of September 30, 2018. We recorded the \$74 thousand and \$29 thousand as a benefit to interest income in the three month periods ended June 30, 2018 and September 30, 2018, respectively, 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.

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. In addition, Mr. Schutte and Oxford entered into a subordination agreement, approved by us and our subsidiary, pursuant to which Mr. Schutte subordinated the Schutte Notes to our obligations to Oxford under the Oxford Loan Agreement. The Schutte Notes may be prepaid at any time in whole or in part, however while Oxford's loan is outstanding such prepayment will require Oxford's consent.

On October 5, 2018 and November 21, 2018, we borrowed \$1.8 million and \$150 thousand, respectively from John Schutte. We used \$1.5 million from the October 5, 2018 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. (See Note 16.)

Our debt at September 30, 2018 is summarized below (in thousands):

Debt	Current	Long-term	Total
Loan Due December 1, 2018			
Balance at Jan. 1, 2018	\$2,740	\$ -	\$2,740
Principal payments	(1,719)	-	(1,719)
Balance at Sept. 30, 2018	\$1,021	\$ -	\$1,021
Loan Due January 2, 2020			
Balance at Jan. 1, 2018	\$-	\$ -	\$-
Borrowings	-	2,200	2,200
Balance at Sept. 30, 2018	\$-	\$ 2,200	\$2,200
<b>Debt Discount</b>	<b>Current</b>	<b>Long-term</b>	<b>Total</b>
Balance at Jan. 1, 2018	\$ (32 )	\$ -	\$(32 )
Additions	-	(103 )	(103)
Amortization expense	28	18	46
Balance at Sept. 30, 2018	\$ (4 )	\$ (85 )	\$(89 )
<b>Deferred Debt Issuance Costs</b>	<b>Current</b>	<b>Long-term</b>	<b>Total</b>
Balance at Jan. 1, 2018	\$ (14 )	\$ -	\$(14 )
Amortization expense	13	-	13
Balance at Sept. 30, 2018	\$ (1 )	\$ -	\$(1 )
Debt, net at Sept. 30, 2018	\$ 1,016	\$ 2,115	\$3,131

Our debt interest expense for the three and nine months ended September 30, 2018 and 2017 consisted of the following (in thousands):

	Three months Ended		Nine months Ended	
	September 30,	September 30,	September 30,	September 30,
	2018	2017	2018	2017
Interest expense:				

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Term loan – due December 1, 2018	\$ 49	\$ 116	\$ 194	\$ 397
Term loans – due January 2, 2020	29	-	37	-
Debt discount	22	15	46	52
Debt issue costs	3	8	13	27
Financed insurance premiums	2	-	2	-
Total interest expense	\$ 105	\$ 139	\$ 292	\$ 476
Less: imputed interest income on related party loan	(29 )	-	(103 )	-
Less: interest income	-	(1 )	-	(3 )
Total interest expense, net	\$ 76	\$ 138	\$ 189	\$ 473

**NOTE 9 – RELATED PARTY TRANSACTIONS**

In July 2017, we completed a \$4.0 million private placement with John 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 will receive a 7.5% royalty on sales of licensed products. MainPointe also has options to expand the territory and products covered for additional sums. Included in the reported revenue for the nine month period ending September 30, 2018 is \$17 thousand of royalty revenue from MainPointe. (See Note 3).

As part of the closing of the Transaction, the Company, Essex Woodlands Health Ventures V, L.P. (“Essex”) and Galen Partners III, L.P. (“Galen”) amended and restated the existing Voting Agreement 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. Galen has not designated a director and lost that right in December 2017 when it disposed of its shares. Investor has not designated a director as of the date of filing of this Report. 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.

During the second and third quarters of 2018, we borrowed \$1.5 million and \$0.7 million, respectively, from John Schutte and issued promissory notes aggregating \$2.2 million principal amount to him. (See Note 8).

On October 5, 2018 and November 21, 2018, we borrowed \$1.8 million and \$150 thousand, respectively from John Schutte. (See Note 16).

#### **NOTE 10 – COMMON STOCK WARRANTS**

We had no activity in our warrants for either the nine months ended September 30, 2018 or 2017. Our warrants consisted of the following (in thousands except price data):

	September 30, 2018		2017	
	<b>WAvg</b>		<b>WAvg</b>	
	<b>Number</b>	<b>Exercise</b>	<b>Number</b>	<b>Exercise</b>
		<b>Price</b>		<b>Price</b>
Outstanding, Jan. 1,	1,843	\$ 0.59	60	\$ 2.52
Issued	-	-	1,783	0.53
Exercised	-	-	-	-
Expired	-	-	-	-
Modification	-	-	-	-
Outstanding, Sept. 30,	1,843	\$ 0.59	1,843	\$ 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 debt. The carrying amounts of these financial instruments, other than our 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 total share-based compensation expense recognized in the Company’s results of operations from all types of issued instruments comprised the following (in thousands):

<b>Three months Ended</b>		<b>Nine months Ended</b>	
<b>September 30,</b>		<b>September 30,</b>	
<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>

Total Stock Compensation				
Research and development costs:				
Stock options	\$ 9	\$ 38	\$ 33	\$ 106
Restricted stock units	7	-	21	-
Subtotal	\$ 16	\$ 38	\$ 54	\$ 106
General and administrative costs:				
Stock options	\$ 14	\$ 52	\$ 67	\$ 158
Restricted stock units	18	35	69	119
Subtotal	\$ 32	\$ 87	\$ 136	\$ 277
Total	\$ 48	\$ 125	\$ 190	\$ 383

Included in the table's reported totals for general and administrative costs is share-based compensation expense from the mark-to-market accounting of a portion of the RSUs granted to our directors is approximately \$5 thousand benefit and \$5 thousand for the three month periods ended September 30, 2018 and 2017, respectively and approximately \$15 thousand and \$30 thousand for the nine month periods ended September 30, 2018 and 2017, respectively.

### ***Stock Option Award Plans***

We maintain various stock option plans. A summary of our stock option plan activity during the nine month periods ending September 30, 2018 and 2017 is shown below (in thousands except price data):

<b>Nine months Ended</b>				
<b>September 30,</b>				
	2018		2017	
	<b>Weighted</b>		<b>Weighted</b>	
	<b>Number</b>	<b>Average</b>	<b>Number</b>	<b>Average</b>
	<b>of</b>	<b>Exercise</b>	<b>of</b>	<b>Exercise</b>
	<b>Options</b>	<b>Price</b>	<b>Options</b>	<b>Price</b>
	<b>(000's)</b>		<b>(000's)</b>	
Outstanding, Jan. 1,	1,494	\$ 12.33	1,397	\$ 13.57
Granted	-	-	185	0.31
Exercised	-	-	(1 )	0.92
Forfeited or expired	(166 )	1.77	(87 )	6.48
Outstanding, Sept. 30,	1,328	\$ 8.64	1,494	\$ 12.33
Options exercisable	1,313	\$ 8.73	1,176	\$ 15.46

The following table summarizes information about nonvested stock options outstanding at September 30, 2018 (in thousands except price data):

	<b>Number of</b>	<b>Weighted</b>
	<b>Options Not</b>	<b>Average</b>
	<b>Exercisable</b>	<b>Fair Value</b>
Outstanding, Jan. 1, 2018	270	\$ 0.46
Granted	-	-
Vesting	(251 )	0.44
Forfeited	(4 )	0.41
Outstanding, Sept. 30, 2018	15	\$ 0.77

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 September 30, 2018 and 2017 was \$0 thousand. The total remaining unrecognized compensation cost on unvested option awards outstanding at September 30, 2018 was \$12 thousand, and is expected to be recognized in operating expense in varying amounts over the 2 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”). Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. Our non-employee director awards allow for non-employee directors, at their election, to receive payment in cash, instead of stock, for up to 40% of each RSU award. The portion of the RSU awards subject to cash settlement are recorded as a liability in the Company’s balance sheet as they vest and are being marked-to-market each reporting period until they are distributed. The cash settlement liability for vested RSU awards was \$15 thousand and \$41 thousand at September 30, 2018 and December 31, 2017, respectively.

The compensation cost to be incurred on a granted RSU 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 to expense and recorded to additional paid-in capital over the vesting period of the RSU award. The total remaining unrecognized compensation cost on unvested RSU awards outstanding at September 30, 2018 was \$11 thousand, and is expected to be recognized in operating expense over the two months remaining in the requisite service period.

A summary of the award activity under the RSU Plans as of September 30, 2018 and 2017, and for each of the nine month periods then ended consisted of the following:

	Nine months Ended September 30,			
	2018		2017	
	(in thousands)			
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, Jan. 1	462	262	91	91
Granted	267	-	238	-
Distributed	(262 )	(262 )	(67 )	(67 )
Vested	-	200	-	178
Forfeited or expired	(8 )	-	-	-
Outstanding, Sept. 30	459	200	262	202

#### ***2017 Restricted Stock Unit Award Plan***

Our 2017 RSU Plan was approved by 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. As of September 30, 2018, approximately 1.0 million shares are available for award under the 2017 RSU Plan.

Information about the awards under the 2017 RSU Plan is as follows:

In December 2017, we awarded 200 thousand RSUs to our employees. Such RSU awards will vest 100% after one full year of service. Distributions of the vested RSU awards to the employees will be made in three equal installments on the first business day of each of January 2020, 2021, and 2022 or earlier upon a qualifying change of control.

In January 2018, we awarded approximately 67 thousand RSUs to each of our 4 non-employee directors which also allow for them to receive payment in cash, instead of stock, for up to 40% of each RSU award. Such awards vest 25% at the end of each calendar quarter in 2018. Settlement of this RSU award will occur on January 2, 2019, the first business day of the year after vesting. The portion of the RSU awards which are subject to cash settlement are also subject to marked-to market accounting and the liability recorded in the Company's balance sheet as an estimate for such cash settlement was \$15 thousand at September 30, 2018.

#### ***2014 Restricted Stock Unit Award Plan***

Our 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 September 30, 2018, approximately 3 thousand shares are available for award under the 2014 RSU Plan.

Information about the awards under the 2014 RSU Plan during 2017 and 2018 is as follows:

In January 2017, we awarded approximately 60 thousand RSUs to each of our 4 non-employee directors which also allow for them to receive payment in cash, instead of stock, for up to 40% of each RSU award. Such awards vest 25% at the end of each calendar quarter in 2017. The portion of the RSU awards which are subject to cash settlement are also subject to marked-to market accounting and the liability recorded in the Company's balance sheet as an estimate for such cash settlement was \$41 thousand at December 31, 2017. The RSU award was settled on January 2, 2018.

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

In January 2017, 1 thousand RSUs from the May 2014 award and 66 thousand RSUs from the January 2016 award were distributed. There were 1 thousand RSUs from the May 1 2014 award and 22 thousand RSUs from the January 2016 award which remained deferred until a future distribution date, which occurred on January 1, 2018. Of the 67 thousand RSUs distributed, 49 thousand RSUs were settled in common stock and 18 thousand RSUs were settled in cash.

In January 2018, all outstanding 262 thousand RSUs from the 2014 RSU Plan were distributed. Of the approximately 262 thousand RSUs distributed, 238 thousand RSUs were settled in common stock and 24 thousand RSUs were 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. On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the “Act”) was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017 and requiring adjustment to 2017 deferred taxes.

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 \$169 million gross Federal NOLs at September 30, 2018 (of which approximately \$168 million were generated prior to 2018). Because we believe the ability for us to use the Federal NOLs generated prior to January 1, 2018 to offset future taxable income is severely limited, as prescribed under Internal Revenue Code (“IRC”) Section 382, we have estimated and recorded an amount for the likely limitation to our deferred tax asset. The amount we recorded thereby reduced the aggregate estimated benefit of the Federal NOLs generated prior to January 1, 2018 to approximately \$1.0 million. We believe the gross Federal NOL benefit we generated prior to January 1, 2018 to offset future 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 January 1, 2018 and Federal NOLs generated after December 31, 2017 can be carried forward indefinitely. Future common stock transactions may cause another qualifying event under IRC 382 which may further limit our utilization of our NOLs.

The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At both September 30, 2018 and December 31, 2017, 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 2018 or 2017 as the Company reported a net loss for each of the nine 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 (in thousands except per share data):

	<b>Three months Ended</b>		<b>Nine months Ended</b>	
	<b>September 30,</b> 2018	<b>September 30,</b> 2017	<b>September 30,</b> 2018	<b>September 30,</b> 2017
EPS – basic and diluted				
Numerator: net loss	\$ (1,095 )	\$ (2,200 )	\$ (3,850 )	\$ (3,944 )
Denominator (weighted):				
Common shares	21,034	16,544	21,033	14,103
Vested RSUs	134	142	68	44
Basic and diluted weighted average shares outstanding	21,168	16,686	21,101	14,147
EPS – basic and diluted	\$ (0.05 )	\$ (0.12 )	\$ (0.18 )	\$ (0.27 )
Excluded securities (non-weighted):				
Common shares issuable:				
Stock options – vested and nonvested	1,328	1,494	1,328	1,494
Nonvested RSUs	259	60	259	60
Common stock purchase warrants	1,843	1,843	1,843	1,843
Total excluded common shares	3,430	3,397	3,430	3,397

## **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.

In the lawsuits filed to date, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by us. We discontinued manufacture and distribution of generic metoclopramide more than 20 years

ago. In addition, we believe the June 23, 2011 decision by the U.S. Supreme Court in *PLIVA v. Mensing* (“*Mensing* decision”) holding that state tort law failure to warn claims against generic drug companies are pre-empted by the 1984 Hatch-Waxman Act Amendments and federal drug regulations will assist us in favorably resolving these cases.

In New Jersey, Generic Defendants, including Acura, filed dispositive motions based on the *Mensing* decision, which the Court granted with a limited exception. In June 2012, the New Jersey trial court dismissed all of the New Jersey cases pending against us with prejudice.

In Pennsylvania, the trial court proceedings were stayed on January 12, 2017. On June 15, 2017, the Court entered an Order approving a stipulation which dismisses nearly all of the individual cases against us based upon lack of product identification without prejudice and provides for these cases to be dismissed finally, with prejudice, as of June 15, 2018. We expect that the Court will finally dismiss the Pennsylvania-based litigation against us with prejudice in 2018. Legal fees related to this matter are currently covered by our insurance carrier.

In California, on May 24, 2016, the Court entered an Order approving a stipulation which stays the individual cases against us and provides for an agreed upon dismissal protocol for all cases where is a lack of product identification. On January 13, 2017, the Court also entered a general stay of this entire litigation. To date, none of these plaintiffs have confirmed they ingested any of the generic metoclopramide manufactured by us. Therefore, we expect that the lawsuits filed against us will be dismissed voluntarily with prejudice later in 2018. Legal fees related to this matter are currently covered by our insurance carrier.

As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of September 30, 2018 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

### ***DES Litigation***

On April 12, 2018, an action was commenced against the Company, as successor to Halsey Drug Company, and over twenty-five other pharmaceutical manufacturers in New York State Supreme Court, New York County, captioned *Cotto et al. v. Abbott Laboratories, Inc., et al* (index 153339/2018). The Complaint contains seven causes of action, including negligence, strict liability, and breach of warranty, wrongful death, among others, in connection with the alleged exposure of the deceased plaintiff in utero to diethylstilbestrol (DES) in approximately 1956 as the result of the ingestion of the drug by her mother. The plaintiffs are the personal representative of the deceased and her two daughters, individually. The plaintiffs were unable to determine which of the defendants produced the DES used by the deceased, but regardless seeks to hold all defendants jointly and severally liable. The Complaint seeks \$10.0 million in compensatory and \$10.0 million in punitive damages on each of five counts and damages in an amount to be determined for wrongful death and additional punitive damages in an unstated amount. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of September 30, 2018. We are presently unable to determine if any potential loss would be covered by any of our insurance carriers.

### ***Purdue Pharma Settlement***

In April 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (collectively, “Purdue”) commenced a patent infringement lawsuit against us and our Oxaydo product licensee Egalet US, Inc. and its parent Egalet Corporation in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue’s U.S. Patent No. 8,389,007 (the “007 patent”). In April 2016, Purdue commenced a second patent infringement lawsuit against us and Egalet in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue’s newly issued U.S. Patent No. 9,308,171 (the “171 Patent”). The actions regarding the 007 Patent and the 171 Patent are collectively referred to as the “Actions”. On April 6, 2016, we filed a petition for Inter Partes Review (the “IPR Review”) with the U.S. Patent and Trademark Office (“USPTO”) seeking to invalidate Purdue’s 007 Patent.

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

The Settlement Agreement also provides that Purdue will not, in the future, assert certain Purdue U.S. patents, including the 007 Patent, the 171 Patent and related technologies (the “Purdue Patents”) against any Acura Settlement Product or Egalet Settlement Product (except generally in an action or interference by Acura or Egalet challenging a Purdue Patent). Acura Settlement Products and Egalet Settlement Products are certain immediate-release and

extended-release products, including Oxaydo. In addition, the Settlement Agreement provides that Purdue will not challenge, with certain exceptions, the Acura/Egalet Patents with respect to the Purdue Settlement Products (as defined below) and that Purdue provides Acura and/or Egalet certain waivers of non-patent marketing exclusivity with respect to Purdue Settlement Products.

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

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

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

### ***Egalet Agreement covering Oxaydo***

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

In accordance with the Egalet Agreement, we and Egalet have formed a joint steering committee to coordinate commercialization strategies and the development of product line extensions. Egalet is responsible for the fees and expenses relating to the Oxaydo NDA and product line extensions of Oxaydo, provided that Egalet will pay a substantial majority of the expenses and we will pay for the remaining fees and expenses relating to (i) annual NDA PDUFA product fees, (ii) expenses of the FDA required post-marketing study for Oxaydo and (iii) expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States. Egalet will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States. Egalet is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Egalet will have final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Egalet may develop Oxaydo for other countries and in additional strengths, in its discretion. At September 30, 2018 we have accrued approximately \$443 thousand of these potential cost sharing reimbursable expenses under the Egalet Agreement.

### **Facility Lease**

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

**NOTE 16 – SUBSEQUENT EVENT**

*Debt Restructure*

On October 5, 2018 we received a \$1.8 million loan from John Schutte, and another \$150 thousand loan on November 21, 2018, which combined with earlier loans received in the second and third quarters of 2018, total \$4.15 million in loans from Mr. Schutte. In connection the recently received two loans aggregating \$1.95 million, we issued two promissory notes, or the Schutte Notes, in each of that principal amount to him. The Schutte Notes bear interest at prime plus 2%, and mature on January 2, 2020, at which time all principal and interest is due. The terms of these notes are the same as the terms for the \$2.2 million loans previously received from Mr. Schutte which are also represented by promissory notes (together with the Schutte Notes, the “Aggregate Schutte Notes”). Events of Default under the Aggregate Schutte Notes include bankruptcy events and failure to pay interest and principal when due.

Using a portion of the proceeds from the \$1.8 million Schutte loan, we made a lump sum payment of \$1.5 million on October 5, 2018 to Oxford Finance to settle, in full, all remaining obligations of the Oxford Loan Agreement. Loans from Mr. Schutte provide that they be secured after our obligations to Oxford Finance have been satisfied in full. As a result of the termination of the Loan Agreement with Oxford Finance, we are now required to secure payment of the Aggregate Schutte Notes with a security interest in our assets and these Notes now become our senior secured debt. The Aggregate Schutte Notes may be prepaid in whole or part at any time.



***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 will be determined sufficient by the FDA to support approval or labelling describing abuse deterrent features;
  - whether our Limitx Technology can be expanded into extended-release formulations;
- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
  - Egalet's ability to continue as a going concern, including consummation of their proposed plan of reorganization filed in their Chapter 11 proceedings;
    - the pricing and price discounting that may be offered by Egalet for Oxaydo;
    - the results of our development of our Limitx Technology;
- our or our licensees' ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
  - the market acceptance of, timing of commercial launch and competitive environment for any of our products;
    - expectations regarding potential market share for our products;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
  - our exposure to product liability and other lawsuits in connection with the commercialization of our products;
    - the increasing cost of insurance and the availability of product liability insurance coverage;
    - the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
  - the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;

- whether the FDA will agree with or accept the results of our studies for our product candidates; the ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development process to meet over-the-counter (“OTC”) Monograph standards, as applicable;
- the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates;
  - changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;
  - whether the FDA will agree with our analysis of our clinical and laboratory studies;
  - whether further studies of our product candidates will be required to support FDA approval;
- whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and whether we will be able to promote the features of our abuse discouraging technologies; and whether Oxaydo or our Aversion and Limitx product candidates will ultimately deter abuse in commercial settings
- and whether our Nexafed products and Impede Technology product candidates will disrupt the processing of pseudoephedrine into methamphetamine.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “indicate,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “suggest,” “would,” and other 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 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 a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Aversion® and Limitx™ Technologies are intended to address methods of abuse associated with opioid analgesics while our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine, or PSE, into methamphetamine. Oxaydo Tablets (oxycodone HCl, CII), which utilizes the Aversion Technology, is the first approved immediate-release oxycodone product in the United States with abuse deterrent labeling. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, or collectively Egalet, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is currently approved by the U. S. Food and Drug Administration, or FDA, for marketing in the United States in 5mg and 7.5mg strengths. Egalet launched Oxaydo in the United States late in the third quarter of 2015.

We launched our first Impede Technology product, Nexafed, into the United States market in December 2012 and launched our Nexafed Sinus Pressure + Pain product in the United States in February 2015. 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, who became our largest shareholder pursuant to a private placement completed in July 2017 and also became a creditor in May 2018.

On June 28, 2017, Bayer Healthcare LLC, or Bayer, terminated a 2015 License and Development Agreement in which we granted Bayer an exclusive worldwide license to our Impede Technology for use in an undisclosed methamphetamine resistant PSE containing product. As a result of the termination, MainPointe has the option to license our Impede Technology with respect to such product in the United States and Canada upon payment of a fee. MainPointe has not yet exercised this option.

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, 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, the results for which were announced in January 2018, 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 while showed an increasing reduction in Cmax for formulations F through H; in which formulations A through 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. Study AP-LTX-300, or Study 300, was inconclusive in its results due to observed issues with drug release from over-encapsulated test product. The FDA has designated the development program for LTX-04 as Fast Track, which is designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. However, we intend to advance LTX-03, 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 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.

We are actively seeking a licensing partner for our Limitx product candidates.

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. 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.

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 2016 to 684,000 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.

On March 23, 2015, we announced preliminary top line results from our pilot clinical study demonstrating bioequivalence of our Nexafed extended release tablets to Johnson & Johnson's Sudafed® 12-hour Tablets. In October 2016, we received FDA recommendations on our meth-resistant testing protocols for our Nexafed extended release tablets which utilizes our Impede 2.0 enhanced meth-resistant technology. Our Impede 2.0 Technology has demonstrated, in the direct conversion, or "one-pot", methamphetamine conversion process performed by an independent pharmaceutical services company, the ability to reduce meth-yields, on average, by 75% compared to Sudafed® Tablets. We can now scale-up our manufacture batch size at a contract manufacturer which will allow us to submit an IND to the FDA for our Nexafed extended release tablets, however, we have not yet committed to that level of development.

In March 2017, we completed a pilot pharmacokinetic study for a 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 5050(b)(2) NDA submission. The Company intends to upgrade this formulation with its Impede 2.0 Technology before determining any advancement in development, however, we have not yet committed to that level of development.

Our objective is to establish, either directly or through third-party licensees, the Nexafed franchise in the United States with multiple product offerings, including both immediate and extended release products utilizing both single and combinations of active ingredients. We aim to make meth-resistant PSE product the standard of care in all U.S. pharmacies. In addition to the MainPointe Agreement, we may license our Impede Technology to commercial partners to extend our internal development resources to develop difficult to formulate products, such as extended-release.

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 Limitx and Aversion (if recommended) 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.



## **Limitx™ Technology**

Limitx Technology is intended to address oral ETA or accidental consumption of multiple tablets and provide a margin of safety during accidental over-ingestion of tablets. Limitx is also expected to exhibit barriers to abuse by snorting and injection.

The FDA's 2015 Guidance singles out immediate-release combination products with acetaminophen as being predominately abused by the oral route and that reducing nasal snorting of these products may not be meaningful. The initial Limitx formulation (LTX-04) utilizes hydromorphone as its sole active ingredient. During 2017 we redirected our development focus from LTX-04 to a hydrocodone/APAP product utilizing our Limitx Technology (LTX-03). In August 2015, April 2016, and May 2017 the United States Patent and Trademark Office, or USPTO, issued to us patents 9,101,636, 9,320,796 and 9,662,393, respectively, covering, among other things, our Limitx Technology.

Development of our Limitx Technology was supported by a \$300 thousand grant by the National Institute on Drug Abuse of the National Institutes of Health for Phase I development, which entailed the development of an optimized formulation of LTX-04 suitable for commercial manufacture and human testing.

*NIDA Disclaimer: Research on LTX-04 was supported by the National Institute On Drug Abuse of the National Institutes of Health under Award Number R44DA037921. The results and content of any such research is solely the responsibility of Acura and does not necessarily represent the official views of the National Institutes of Health.*

The LTX-04 development program was also designated as Fast Track by the FDA for its potential to address an unmet medical need but we have voluntarily placed the IND for LTX-04 on inactive status to pursue development of LTX-03.

## **Limitx Technology Products in Development**

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

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

***Study 400***

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 C<sub>max</sub>, 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 C<sub>max</sub> of 45% and 50% lower than the reference drug for LTX-04S and LTX-04P, respectively. For an 8 tablet dose, the C<sub>max</sub> for LTX-04P was 59% lower than the reference drug. Doses between 1 and 8 tablets had similar reduction in C<sub>max</sub> 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 C<sub>max</sub> 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 C<sub>max</sub> 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 C<sub>max</sub> for a one tablet LTX-04P3 dose was approximately 50% less than the active comparator. The C<sub>max</sub> 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 T<sub>max</sub> (time of C<sub>max</sub>) 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 T<sub>max</sub> which is indicative of a delayed release of drug from LTX-04P3, we concluded the Limitx micro-particles are working as designed in that when we neutralize the stomach acid we are slowing the release of drug and subsequent absorption of drug into the blood stream.

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

### ***Study 300***

Study 300, completed in October 2017, yielded unreliable and inconclusive results due to inconsistent drug release from over-encapsulated test product.

### ***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 C<sub>max</sub> 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 C<sub>max</sub> and AUC, respectively. For acetaminophen, Formulation E's BE

Ratios were 1.15 and 1.03 for C<sub>max</sub> and AUC, respectively. While the acetaminophen AUC's met the BE standards, the C<sub>max</sub> 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 through H, the higher buffer level tablets, Study 301 demonstrated a progressively increasing reduction in hydrocodone C<sub>max</sub> culminating in a 34% C<sub>max</sub> reduction associated with Formulation H, the highest level evaluated. The C<sub>max</sub> 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 commenced the scale-up of the commercial manufacturing process in the second quarter of 2018 as to-be-marketed formulations are required for all NDA development work. We may run additional exploratory studies before manufacturing scale-up is complete to further understand the Limitx Technology.

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

The 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 Egalet have a post-approval commitment with the FDA to perform an epidemiology study to assess the actual impact on abuse of Oxaydo tablets.

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

Egalet has advised that late in the fourth quarter of 2016 it filed a supplemental NDA for Oxaydo with the FDA to support an abuse-deterrent label claim for the intravenous route of abuse. Egalet reported that it submitted a prior approval supplement to support approval of 10 and 15 mg dosage strengths which was accepted by the FDA on April 18, 2017. On June 20, 2017, Egalet announced that it had received a complete response letter from the FDA in response to this prior approval supplement. Egalet has advised that the FDA is requesting more information regarding the effect of food on Oxaydo 15mg and the intranasal abuse-deterrent properties of Oxaydo 10mg and 15mg.



Egalet commenced shipping Oxaydo in October 2015.

### **Egalet Agreement Covering Oxaydo**

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

In accordance with the Egalet Agreement, we and Egalet have formed a joint steering committee to oversee commercialization strategies and the development of product line extensions. Egalet will pay a significant portion of the expenses relating to (i) annual NDA PDUFA 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. Egalet is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Egalet will have final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Egalet may develop Oxaydo for other countries and in additional strengths, in its discretion.

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

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

On October 31, 2018, Egalet issued a press release and filed a SEC Form 8-K announcing its filing for voluntary pre-arranged plan of reorganization under Chapter 11 of the United States Bankruptcy Code in the District of Delaware. As Egalet's announcement is very recent, at this time it is uncertain as to the impact on our license agreement with them, but we do anticipate a delay in the Egalet's payment of their third quarter 2018 royalty payment to us until the first quarter 2019, assuming no objections or changes to their Chapter 11 proceedings.

### **KemPharm Agreement Covering Opioid Prodrugs**

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

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

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

### **Aversion Technology Development Opioid Products**

On April 9, 2015, we announced the indefinite suspension of further development of our Aversion hydrocodone/APAP product candidate, in order to focus our time and available resources on the development of our Limitx Technology product candidates. We currently have 6 additional opioids at various stages of formulation development using the Aversion Technology which are not being actively developed.

### **Abuse of Pseudoephedrine Products**

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

### **Impede 1.0 Technology**

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

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

### Impede 2.0 Technology

We have 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 <sup>1</sup>	Purity <sup>2</sup>
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 %

<sup>1</sup> Total methamphetamine HCl recovered from the equivalent of 100 PSE 30mg tablets divided by the maximum theoretical yield of 2.7 grams.

<sup>2</sup> 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. Prior to the completion of the MainPointe Agreement in March 2017, we previously completed a project to integrate Impede 2.0 Technology into our commercially available Nexafed 30mg tablet while moving supply to an alternate contract manufacturer. We believe MainPointe launched the new formulation into the market in the 3<sup>rd</sup> quarter of 2017.

## **Nexafed Products**

The Nexafed products currently marketed, 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 and 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. However, as meth-resistant products become pervasive, we believe meth cooks will migrate to other, larger selling, PSE containing products.

We have demonstrated that our Nexafed 30mg tablets are bioequivalent to Johnson & Johnson's Sudafed 30mg Tablets when a single 2 tablet dose is administered. Commencing in 2006, the CMEA, required all non-prescription PSE products to be held securely behind the pharmacy counter, has set monthly consumer purchase volume limits, and has necessitated consumer interaction with pharmacy personnel to purchase PSE-containing products. Prior to the MainPointe Agreement completed in March 2017, we capitalized on this consumer-pharmacist interaction at the point of sale by soliciting distribution to pharmacies and educating and encouraging pharmacists to recommend Nexafed to their customers. Under the terms of the MainPointe Agreement, MainPointe controls the marketing and sale of our Nexafed products.

We launched Nexafed commercially in mid-December 2012 into the United States OTC market for cold and allergy products. Prior to the MainPointe Agreement, we distributed our Nexafed products through several regional and national drug wholesalers for redistribution to pharmacies, which included the three largest U.S. drug wholesalers: McKesson, Cardinal Health and AmerisourceBergen and we also shipped directly to the warehouses of certain pharmacy chains. Prior to the MainPointe Agreement, Nexafed was stocked in approximately 13,900 pharmacies or about approximately 21% of the estimated 65,000 U.S. pharmacy outlets. Initial adoption was primarily in independent pharmacies in predominately rural communities with high meth awareness. Chain pharmacies, with more centralized control of the pharmacy operations, began adopting in mid-2013, including Kroger, Publix, Fruth and Bartells. Some pharmacists actively recommended Nexafed to their customers while some replaced all 30mg PSE products, brand and generic, with Nexafed. Rite Aid, the nation's fourth largest pharmacy operator, began purchasing Nexafed in late 2013. In late 2014, Kmart and Kroger initiated chain-wide stocking of Nexafed.

In February 2015, we began initial shipments of Nexafed Sinus Pressure + Pain. Prior to the MainPointe Agreement, we were marketing this product consistent with our Nexafed marketing efforts to pharmacists concerned with meth abuse of their products. We are not aware of any branded non-prescription product that contains PSE and acetaminophen believing that brands containing these ingredients have either been discontinued or reformulated with phenylephrine. We expect Nexafed Sinus Pressure + Pain to compete primarily against Advil® Cold and Sinus (PSE/ibuprofen) and to a lesser extent Aleve®-D and Sudafed® Pressure + Pain which are extended-release products.

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

### **MainPointe Agreement covering Nexafed Products**

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

On signing the MainPointe Agreement, MainPointe paid us an upfront licensing fee of \$2.5 million plus approximately \$425 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). 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.

### **Impede Technology Products in Development**

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

<b>Impede Technology Product</b>	<b>Status</b>
Nexafed 30mg with Impede 2.0 Technology	Manufacturing validation complete. We believe MainPointe launched commercial shipments in third quarter of 2017
Immediate-release pseudoephedrine HCl in combination with other cold and allergy active ingredients	Nexafed Sinus Pressure + Pain launched and licensed to MainPointe
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	Final formulation development ready. 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 intends to upgrade this formulation with its Impede 2.0 Technology before determining any advancement in development.

Our objective is to establish, either directly or through third-party licensees, the Nexafed franchise in the United States with multiple product offerings, including both immediate and extended release products utilizing both single and combinations of active ingredients. We aim to make meth-resistant PSE product the standard of care in all U.S. pharmacies. In addition to the MainPointe Agreement, we may license our Impede Technology to commercial partners to extend our internal development resources to develop difficult to formulate products, such as extended-release.

### **Bayer Agreement**

On June 15, 2015, we and Bayer entered into a License and Development Agreement, or the Bayer Agreement, pursuant to which we granted Bayer an exclusive worldwide license to our Impede® Technology for use in an undisclosed methamphetamine resistant pseudoephedrine-containing product and providing for the joint development of such product using our Impede Technology for the U.S. market. We received reimbursement of certain our development expenses, and were entitled to success-based development and regulatory milestone payments, and low mid-single digit royalties on the net sales of the developed product. On June 28, 2017, we received Bayer's written notice terminating the Bayer Agreement. Bayer exercised its convenience termination right prior to the completion of our development obligations under the Bayer Agreement, which we believe is as a result of Bayer's de-prioritization of development of the methamphetamine resistant PSE-containing product contemplated in the Agreement. As a result of the termination, MainPointe has the option to license such product in the U.S. and Canada upon payment to us of \$500 thousand, (additional amounts would be due for expansion of the territory – See “–MainPointe Agreement covering Nexafed Products”, above), together with royalty of 7.5% of net sales of such product, under the MainPointe Agreement.

**U.S. Market Opportunity for Impede PSE Products**

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

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

<sup>1</sup> Branded product only. Does not include store brand sales.

<sup>2</sup> Extended release PSE formulations

The 2014 market for 30mg PSE tablets, including store brands was approximately 470 million tablets or 19 million boxes of 24 tablets. Prior to the MainPointe Agreement, we priced Nexafed at \$4.39 for a box of 24 tablets and Nexafed Sinus Pressure + Pain at \$7.95 for a box 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 that are marketed pursuant to an NDA or ANDA will be subject to a label approved by the FDA. We expect that such a label will require submission of our scientifically derived abuse liability data and we intend to seek descriptions of our abuse liability studies in the FDA approved product label, although there can be no assurance that this will be the case.

## U.S. Market Opportunity for Opioid Analgesic Products

The misuse and abuse of 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 <sup>(1)</sup>	2016 US Prescriptions (Millions) <sup>(2)</sup>	% of Total	
Hydrocodone	90	43	%
Oxycodone	55	26	%
Tramadol	43	21	%
Codeine	15	7	%
4 Others	5	3	%
Total	208	100	%

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

2IMS Health, 2016

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

### **Product Labeling for Abuse-Deterrent Opioid Products**

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

We or our licensee may seek to include descriptions of studies that characterize the abuse-deterrent properties in the label for our Aversion and Limitx Technology products in development. Although the FDA approved label for Oxaydo contains limitations on exposing Oxaydo tablets to water and other solvents and administration through feeding tubes, the FDA approved Oxaydo label does not contain a description of the I.V. injection studies we performed to characterize the abuse deterrent properties of Oxaydo. Egalet has committed to the FDA to undertake epidemiological studies to assess the actual consequences of abuse of Oxaydo in the market. Under the terms of the Egalet Agreement, we share a minority portion of the fees and expenses relating to such FDA required epidemiological studies, provided Egalet 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:

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



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

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

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

<b>Patent No. (Jurisdiction)</b>	<b>Subject Matter</b>	<b>Issued</b>	<b>Expires</b>
8,901,113 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Dec. 2014	Feb. 2032

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9,757,466 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Sep. 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	Sep. 2030
2,775,890 (CAN)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sep. 2030
2,488,029 (EUR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Mar. 2016	Sep. 2030
218533 (ISR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jan. 2016	Sep. 2030
2015274936 (AUS)	Methods and compositions for interfering with extraction or conversion of a drug susceptible to abuse	Sep. 2018	Jun. 2035
13102020.5 (HK)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Oct. 2016	Sep. 2030

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

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

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

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

Reference is made to the Risk Factors contained in our Annual Report on Form 10-K for the year ended December 31, 2017 for a discussion, among other things, of patent applications and patents owned by third parties, including claims that may encompass our Aversion Technology and Oxaydo tablets, and the risk of infringement, interference or opposition proceedings that we may be subject to arising from such patents and patent applications.

### ***Company's Present Financial Condition***

At September 30, 2018, we had cash and refundable retainer deposits of \$98 thousand compared to \$2.2 million of cash and cash equivalents at December 31, 2017. We had an accumulated deficit of approximately \$384.2 million at September 30, 2018. We had loss from operations of \$3.7 million and net loss of \$3.9 million for the nine months ended September 30, 2018 and we had a net loss from operations of \$5.2 million and net loss of \$5.7 million for the year ended December 31, 2017. As of November 26, 2018 after giving effect to an aggregate of \$4.15 million loans from John Schutte including the recently received \$150 thousand loan on November 21, 2018, our cash was approximately \$150 thousand. We expect our current cash will only be able to fund operations into early December 2018.

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

Our losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and sales, marketing and general corporate expenses. Research and development activities include costs of pre-clinical studies, clinical trials, and clinical trial product supplies associated with our product candidates as well as cost sharing expenses of line extension studies and post-marketing studies under the Egalet Agreement. Sales and marketing expenses include costs associated with the Nexafed products advertising incurred prior to our entering into the MainPointe Agreement on March 16, 2017, salaries and other personnel-related costs include the stock-based compensation associated with stock options and restricted stock units granted to employees and non-employee directors.

**Three months Ended September 30, 2018 Compared to Three months Ended September 30, 2017**

	September 30,		Increase (decrease)	
	2018	2017		Percent
	(In thousands)			
<b>Revenues:</b>				
Royalty revenue	\$73	\$83	\$ (10 )	(12 )%
<b>Cost and expenses:</b>				
Cost of sales	-	-	-	-
Research and development	549	1,077	(528 )	(49 )
Sales, marketing, general and administrative	543	1,068	(525 )	(49 )
Total cost and expenses	1,092	2,145	(1,053 )	(49 )
Operating loss	(1,019)	(2,062)	(1,043 )	(51 )
Interest expense, net	(76 )	(138 )	(62 )	(45 )
Loss before income taxes	(1,095)	(2,200)	(1,105 )	(50 )
Provision for income taxes	-	-	-	-
Net loss	\$(1,095)	\$(2,200)	\$ (1,105 )	(50 )%

***Revenue and Cost of Sales***

***Royalty Revenue***

In connection with our agreement with Egalet for Oxaydo tablets, we earn a royalty based on Oxaydo net sales. We recognized \$70 thousand and \$78 thousand of royalty revenue during the three months ended September 30, 2018 and 2017, respectively.

In connection with our agreement with MainPointe for the Nexafed products, we earn a royalty of 7.5% on net sales. We recognized \$3 thousand and \$5 thousand of royalty revenue during the three months ended September 30, 2018 and 2017, respectively.

### *Expenses*

#### *Research and Development*

Research and development expense (R&D) is primarily for our Limitx Technology development activity. We are continuing the scale-up of the commercial manufacturing process on the IND for LTX-03, as to-be-marketed formulations are required for all NDA development work. We may run additional exploratory studies before manufacturing scale-up is complete to further understand the Limitx Technology. Our submitted IND for LTX-03 to the FDA became effective in April 2018. Included in each of September 30, 2018 and 2017 quarterly results are share-based compensation expenses of \$16 thousand and \$38 thousand, respectively. Excluding the share-based compensation expense, our R&D expenses decreased by approximately \$500 thousand between reporting periods.

*General, Administrative, Selling and Marketing*

In March 2017 we licensed the Nexafed products to MainPointe and beginning thereafter, we reduced and eliminated all selling and marketing types of expenses. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the September 30, 2018 and 2017 quarterly results are share-based compensation expenses of \$32 thousand and \$87 thousand, respectively. Excluding this share-based compensation expense, our selling, marketing, general and administrative expenses decreased by approximately \$500 thousand between reporting periods, resulting primarily from the reduction in patent and general legal activities.

*Interest Expense, net*

During the three months ended September 30, 2018 and 2017, we incurred net interest expense of \$76 thousand and \$138 thousand, respectively, on our debt.

*Income Taxes*

Our results for 2018 and 2017 show no federal or state income tax benefit provisions due to 100% allowances placed against them for the uncertainty of their future utilization.

**Nine months Ended September 30, 2018 Compared to Nine months Ended September 30, 2017**

	September 30,		Increase (decrease)	
	2018	2017		Percent
	(In thousands)			
Revenues:				
License fee revenue	\$-	\$2,500	\$ (2,500 )	(100 )%
Collaboration revenue	-	59	(59 )	(100 )
Royalty revenue	347	226	121	54
Product sales, net	-	107	(107 )	(100 )
Total revenues, net	347	2,892	(2,545 )	(88 )
Cost and expenses:				

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Cost of sales	-	128	(128 )	(100 )
Research and development	1,676	2,808	(1,132 )	(40 )
Sales, marketing, general and administrative	2,332	3,427	(1,095 )	(32 )
Total cost and expenses	4,008	6,363	(2,355 )	(37 )
Operating loss	(3,661)	(3,471)	190	6
Interest expense, net	(189 )	(473 )	(284 )	(60 )
Loss before income taxes	(3,850)	(3,944)	(94 )	(2 )
Provision for income taxes	-	-	-	-
Net loss	\$(3,850)	\$(3,944)	\$(94 )	(2 )%

***Revenue and Cost of Sales***

*License Fees*

In March 2017, the Company entered into a license agreement with MainPointe for a licensing fee of \$2.5 million pursuant to which we granted MainPointe an exclusive license to our Impede Technology to commercialize our Nexafed products in the U.S. and Canada.

*Collaboration Revenue*

Collaboration revenue is derived from development activities under a collaboration agreement we may have with a customer. We had no development activities with a customer during the nine months ended September 30, 2018. We recognized \$59 thousand of collaboration revenue during the nine months ended September 30, 2017.



### *Royalty Revenue*

In connection with our agreement with Egalet for Oxaydo tablets, we earn a royalty based on Oxaydo net sales. We recognized \$330 thousand and \$213 thousand of royalty revenue during the nine months ended September 30, 2018 and 2017, respectively. Included in the 2018 results was a one-time benefit of \$89 thousand on royalty revenue reported to us by Egalet 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 \$17 thousand and \$13 thousand of royalty revenue during the nine months ended September 30, 2018 and 2017, respectively.

### *Net Product Sales and Cost of Sales*

In March 2017 we stopped selling the Nexafed products as we licensed the product line to MainPointe, who is actively manufacturing, distributing, and selling the Nexafed products. We recognized \$107 thousand of net product sales and incurred \$128 thousand of cost of sales on the Nexafed products during the nine months ended September 30, 2017. Our cost of sales on the Nexafed products included third-party manufacturing costs, third-party warehousing and product distribution charges and inventory reserve expenses.

### *Expenses*

#### *Research and Development*

Research and development expense (R&D) is primarily for our Limitx Technology development activity. During the nine months of 2017, our activities were addressing certain excipient issues in our LTX-04 tablet formulation and developing a new, faster releasing micro-particle formulation for LTX-04 and we substantially completed our second pharmacokinetic study, AP-LTX-401. During the nine months of 2018 we announced results for Study 301, submitted an IND for LTX-03 to the FDA in order to advance to NDA development, which became effective in April 2018, and we commenced and the scale-up of the commercial manufacturing process as to-be-marketed formulations are required for all NDA development work. We may run additional exploratory studies before manufacturing scale-up is complete to further understand the Limitx Technology. Included in each of September 30, 2018 and 2017 quarterly results are share-based compensation expenses of \$54 thousand and \$106 thousand, respectively. Excluding the share-based compensation expense, our R&D expenses decreased by approximately \$1.1 million between reporting

periods.

*General, Administrative, Selling and Marketing*

In March 2017 we licensed the Nexafed products to MainPointe and beginning thereafter, we reduced and eliminated all selling and marketing types of expenses. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the September 30, 2018 and 2017 quarterly results are share-based compensation expenses of \$136 thousand and \$277 thousand, respectively. Excluding this share-based compensation expense, our selling, marketing, general and administrative expenses decreased by approximately \$1.0 million thousand between reporting periods, resulting primarily from the reductions in advertising and marketing activities as well as patent and general legal activities.

*Interest Expense, net*

During the nine months ended September 30, 2018 and 2017, we incurred net interest expense of \$189 thousand and \$473 thousand, respectively, on our debt.

*Income Taxes*

Our results for 2018 and 2017 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 September 30, 2018, we had cash and refundable retainer deposits of \$98 thousand compared to cash and cash equivalents of \$2.2 million at December 31, 2017. As of November 26, 2018 after giving effect to an aggregate of \$4.15 million loans from John Schutte, including the recently received \$150 thousand loan on November 21, 2018, our cash was approximately \$150 thousand. We expect our cash will only be able to fund operations into early December 2018.

To fund further operations mid December 2018, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. The Company is exploring a variety of capital raising and other transactions to provide additional funding to continue operations. These include potential private offerings of common stock to institutional investors. The Company is also actively seeking a licensing partner for its Limitx Technology, with the objective of receiving an upfront license fee, development milestone payments and royalties on the net sales of products utilizing the Limitx Technology, similar to the Egalet Agreement and the now terminated Bayer Agreement. The Company is also exploring licensing or selling select assets and intellectual property in an effort to raise capital and reduce operating expenses. Finally, the Company is evaluating the potential for a strategic transaction which may involve the Company being acquired in a merger or asset purchase transaction. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. Our auditors have included in their report relating to our 2017 financial statements a “going concern” explanatory paragraph as to substantial doubt of our ability to continue as a going concern. In the absence of such financing or third-party license or collaboration agreements, there will be substantial doubt about the Company’s ability to continue as a going concern and the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company’s continuing product development efforts will have a material adverse effect on the Company’s financial condition and results of operations.

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

Our future sources of revenue, if any, will be derived from milestone payments and royalties under the Egalet Agreement, the KemPharm Agreement, the MainPointe Agreement and similar agreements 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 A of the Notes to Consolidated Financial Statements, in the Company's 2017 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 2017 Annual Report are also applicable to 2018.

***Item 4. Controls and Procedures***

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

(b) *Changes in Internal Controls over Financial Reporting.* There were no changes in our internal controls over financial reporting during the third fiscal quarter of 2018 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 2017 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 November 26, 2018 we had approximately \$150 thousand of cash and expect such amounts will only be sufficient to fund operations into early December 2018. Our auditors have included in their report relating to our 2017 financial statements a “going concern” explanatory paragraph as to substantial doubt of our ability to continue as a going concern.

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 prior to mid-December 2018, we will be required to scale back and/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.

- 10.39 Promissory Note dated August 2, 2018 issued to John Schutte
- 10.40 Promissory Note dated September 13, 2018 issued to John Schutte
- 31.1 Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
- 31.2 Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
- 32.1 Certification of Periodic Report by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension Schema Document

101.CAL XBRL Taxonomy Extension Calculation Linkbase

101.LAB XBRL Taxonomy Extension Label Linkbase

101.PRE XBRL Taxonomy Extension Presentation Linkbase

101.DEF XBRL Taxonomy Extension Definition Linkbase





*Signatures*

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

November 27, 2018 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