

ACURA PHARMACEUTICALS, INC

FORM 8-K (Current report filing)

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act Of 1934

March 16, 2017
Date of Report (Date of earliest event reported)

ACURA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

State of New York
(State of Other Jurisdiction
of Incorporation)

1-10113
(Commission File Number)

11-0853640
(I.R.S. Employer
Identification Number)

616 N. North Court, Suite 120
Palatine, Illinois 60067
(Address of principal executive offices) (Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01 Entry into a Material Definitive Agreement.

License, Commercialization and Option Agreement with MainPointe Pharmaceuticals, LLC

On March 16, 2017, Acura Pharmaceuticals, Inc. (“we” or the “Company”) entered into a License, Commercialization and Option Agreement (the “Agreement”) with MainPointe Pharmaceuticals, LLC, a Kentucky limited liability company (“MainPointe”) to commercialize Nexafed® and Nexafed® Sinus Pressure + Pain in the United States and Canada. Nexafed® and Nexafed® Sinus Pressure + Pain utilize our Impede technology and are currently marketed by us in the United States. Our Impede technology is directed at minimizing the extraction and conversion of pseudoephedrine, or PSE, into methamphetamine. Under the terms of the Agreement we are transferring existing inventory and equipment relating to such products to MainPointe and licensing our Impede technology intellectual property rights to MainPointe for such products as well as certain future PSE-containing products. MainPointe is responsible for all development, manufacturing and commercialization activities with respect to products covered by the Agreement.

On signing, MainPointe paid us an upfront licensing fee of \$2.5 million plus approximately \$425,000 for inventory and equipment being transferred. We will receive a 7.5% royalty on 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 territory beyond the United States and Canada to the European Union (and the United Kingdom), Japan and South Korea for payments of \$1 million, \$500,000 and \$250,000, respectively. In addition, MainPointe has the option to add to the Agreement certain additional products, or Option Products, containing PSE and utilizing the Impede technology for a fee of \$500,000 per product (for all product strengths). If the territory has been expanded prior to the exercise of a product option, the option fee will be increased to \$750,000 per product. If the territory is expanded after the payment of the \$500,000 product option fee, a one-time \$250,000 fee will be due for each product. If a third party is interested in developing or licensing rights to an Option Product, MainPointe must exercise its option for that product or its option rights for such product will terminate.

The 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 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.

A press release regarding the Agreement is attached as Exhibit 99.1.

The inclusion of a description of the Agreement under Item 1.01 of this Current Report on Form 8-K shall not be deemed an acknowledgement that the Agreement is a material agreement not made, or deemed not to be made, in the ordinary course of our business.

Amendment to Loan Agreement with Oxford Finance

On March 16th, 2017, we, and our subsidiary, Acura Pharmaceutical Technologies, Inc. (“APT”, and together with Acura, the “Borrowers”) and Oxford Finance LLC (“Oxford” or the “Lender”), as collateral agent and as lender, entered into an amendment dated as of March 15, 2017 (the “Amendment”) to the Loan and Security Agreement (the “Loan Agreement”) dated December 27, 2013, as previously amended, pursuant to which the Lender made a term loan to us in the principal amount of \$10.0 million (the “Term Loan”). Pursuant to the Amendment, (i) the Borrowers granted the Lender a security interest in their intellectual property, subject to the rights of existing licensees; (ii) the Lender consented to the terms of our Agreement with MainPointe (as described above); and (iii) with respect to the fiscal year ended December 31, 2016 only, the Lender waived the requirement that we receive an unqualified opinion from our auditor with respect to our audited financial statements.

Item 2.01 Completion of Acquisition or Disposition of Assets.

Item 1.01 is incorporated by reference.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The Section of Item 1.01 entitled “Amendment to Loan Agreement with Oxford Finance” is incorporated herein by reference.

This Report contains forward-looking statements about Nexafed products and Impede technology. However, substantial risks and uncertainties exist in the process of commercialization and further development and regulatory review with respect to such further development. There can be no assurance that Nexafed® and Nexafed® Sinus Pressure + Pain or that other products utilizing Impede® technology will prove to be commercially successful or that they will be developed in other strengths or for other countries. Accordingly, investors in the Company should recognize that there is no assurance that the Company will receive any of the royalties described above or any payments for exercising an option for the additional products or territories. Furthermore that the Company may not be able to continue in business or fund its continuing operations without additional capital, whether raised through strategic transactions or in the capital markets or through receipt of royalty payments. Currently royalties received are not sufficient to sustain our operations. For further discussion of these and other risks and uncertainties, see the Company’s Annual Report on Form 10-K for the year ended December 31, 2015, under the heading “Risks Factors”, and its most recent quarterly report on Form 10-Q and its other public disclosures filed with the U.S. Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of the Registrant dated March 16th, 2017.

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release of the Registrant dated March 16, 2017



**Acura Pharmaceuticals and MainPointe Pharmaceuticals
Announce Deal for Nexafed® Products**

Expands Commercialization of Acura's Methamphetamine-Resistant Pseudoephedrine Products

PALATINE, IL, March 16, 2017: Acura Pharmaceuticals, Inc. (OTCQB: ACUR) and MainPointe Pharmaceuticals, LLC today announced that they have entered into a License Agreement (the "Agreement") to have MainPointe exclusively market NEXAFED and NEXAFED Sinus in the US and Canada. The pseudoephedrine-containing NEXAFED brand products utilize Acura's IMPEDE® Technology which disrupts the extraction and conversion of the pseudoephedrine into the illicit drug, methamphetamine. MainPointe will assume all manufacturing and commercialization activities from Acura.

"MainPointe is an emerging OTC pharmaceutical company that brings added leverage to our NEXAFED business", commented Bob Jones, Acura's President and CEO. "With additional products in distribution and new customer contacts, MainPointe is well positioned to expand on the US pharmacy distribution achieved by Acura over the past several years".

"Conversion of pseudoephedrine products into methamphetamine remains an acute problem in many communities", said John Schutte, MainPointe's Chairman and CEO. "The NEXAFED products have proven to be a success in curbing this costly problem and we look forward to driving this business forward".

The Agreement provided for an upfront cash payment of \$2.5 million to Acura. Acura is eligible to receive a royalty 7.5% based on commercial sales by MainPointe.

About Acura Pharmaceuticals

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address medication abuse and misuse, utilizing its proprietary LIMITX™, AVERSION® and IMPEDE® Technologies. LIMITX contains ingredients that are intended to reduce or limit the rate or extent of opioid release when multiple tablets are ingested. AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages if the product is snorted. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

OXAYDO® (oxycodone HCl immediate-release tablets) which incorporates the AVERSION Technology, is FDA approved and marketed in the U.S. by our partner Egalet Corporation.

NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products, utilize the IMPEDE Technology.

Forward-Looking Statements

Certain statements in this press release 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;
- the expected results of clinical studies relating to LTX-04 or any successor product candidate, the date by which such study results will be available and whether LTX-04 or any successor product candidate will ultimately receive FDA approval;
- whether LIMITX will retard the release of opioid active ingredients as dose levels increase;
- whether we will be able to reformulate LTX-04 or any successor product candidate to provide an efficacious level of drug when one or two tablets are taken;
- whether we will be able to reformulate LTX-04 or any successor product candidate to improve its abuse deterrent performance;
- whether the extent to which products formulated with the LIMITX technology deter abuse will be determined sufficient by the FDA to support approval or labelling describing abuse deterrent features;
- whether our LIMITX technology can be expanded into extended-release formulations;
- our and our licensee’s ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
- our and our licensee’s ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of, timing of commercial launch and competitive environment for any of our products;
- expectations regarding potential market share for our products;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
- 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;
- the ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development process to meet over-the-counter (“OTC”) Monograph standards, as applicable;
- the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates;
- changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;
- whether the FDA will agree with our analysis of our clinical and laboratory studies;
- whether further studies of our product candidates will be required to support FDA approval;
- whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and whether we will be able to promote the features of our abuse discouraging technologies; and
- whether Oxaydo or our Aversion and LIMITX product candidates will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede technology product candidates will disrupt the processing of pseudoephedrine into methamphetamine.

In some cases, you can identify forward- looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “indicates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our filings with the Securities and Exchange Commission.

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