

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

October 13, 2016
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 Agreement with KemPharm Inc.

On October 13, 2016, Acura Pharmaceuticals, Inc. (“we” or the “Company”) and KemPharm Inc., a Delaware corporation (“KemPharm”) entered into a License Agreement (the “Agreement”) pursuant to which we are licensing our Aversion® technology to KemPharm for use in development and commercialization of three of KemPharm’s prodrug candidates throughout the world. KemPharm has also been granted an option to extend the Agreement to cover two additional prodrug candidates. KemPharm is responsible for all development, manufacturing and commercialization responsibilities, although we may provide initial technical assistance.

Upon execution of the Agreement KemPharm paid to us an upfront payment of \$3.5 million. If KemPharm exercises its option to use our Aversion Technology with more than the three product candidates, then KemPharm will pay us up to \$1.0 million for each additional product candidate. 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 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 Agreement expires upon the expiration of KemPharm’s royalty payment obligations in all countries. Either party may terminate the Agreement in its entirety if the other party materially breaches the Agreement, subject to applicable cure periods. Acura and KemPharm may terminate the 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 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 Agreement provides for termination of our license grant to KemPharm.

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 October 13, 2016, 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 (the “Second Amendment”) to the Loan and Security Agreement (the “Loan Agreement”) dated December 27, 2013, as previously amended, between Borrowers and Lender pursuant to which the Lender made a term loan to us in the in the principal amount of \$10.0 million (the “Term Loan”). Pursuant to the Second Amendment, (i) the requirement that Borrowers maintain a \$2.5 million cash balance reserve until such time as they repaid \$5 million in principal of the Term Loan, has been modified so that the \$2.5 million cash balance reserve remains in place until Borrowers raise an additional \$6.0 million (excluding payments received under the KemPharm Agreement) through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions, provided that at least \$3.0 million of such amount must be raised through the issuance of Acura’s equity securities, and (ii) the Lender consented to the terms of our Agreement with KemPharm (as described above).

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 the Agreement between the Company and KemPharm. However, substantial risks and uncertainties exist in the process of pharmaceutical product development and commercialization. There can be no assurance that KemPharm’s prodrug products using our Aversion technology will be successfully developed or prove to be commercially successful. Accordingly, investors in the Company should recognize that there is no assurance that the Company will receive any of the royalties or product option fees described above in Item 1.01. 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>
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99.1	Joint Press Release of the Registrant and KemPharm dated October 18, 2016.
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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.

ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens
Peter A. Clemens
Senior Vice President & Chief Financial Officer

Date: October 18, 2016

EXHIBIT INDEX

Exhibit Number

Description

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KemPharm Announces Licensing Agreement with Acura Pharmaceuticals for Aversion® Abuse-Deterrent Technology

Agreement focused on KemPharm's current and in-development IR Opioid Pipeline

Coralville, IA and Palatine, IL – Oct. 18, 2016 – KemPharm, Inc. (NASDAQ:KMPH), a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, and Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) today announced that they have entered into a License Agreement (the “Agreement”) whereby Acura will provide its proprietary Aversion® Technology to KemPharm to use with its current and in-development immediate release (IR) opioid product candidates. Aversion® Technology is a patented composition of commonly used active and inactive pharmaceutical ingredients providing abuse deterrent features (ADF) and benefits for orally administered pharmaceutical drug products.

The Agreement provided for an upfront cash payment of \$3.5 million to Acura at execution and grants KemPharm development and commercialization rights for up to three IR product candidates containing two of KemPharm's opioid prodrugs. Additional payments are provided in the Agreement should KemPharm exercise its option to use Acura's Aversion® Technology with more than the three products. Acura is eligible to receive a royalty at a low single-digit rate based on commercial sales by KemPharm of all products developed under the Agreement. KemPharm will solely own the intellectual property resulting from any new product development.

“Acura's Aversion® Technology, an FDA-approved aversive ADF approach without a food effect, and KP201/IR, our priority lead product candidate, together offer significant potential benefits,” stated Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “We believe today's Agreement will help us bridge the regulatory approval process between current abuse deterrence products and the ability of our new molecular entity prodrugs to demonstrate their ADF properties.”

“Based on the strength of our existing data, as well as what we view to be favorable developmental, regulatory and market conditions, we expect this agreement with Acura to allow us to bring a unique prodrug product with the addition of demonstrated aversive barriers to the market in the near term,” Mickle continued. “Access to this technology was contemplated in the guidance for timelines we recently provided for KP201/IR.”

“We are excited to partner with KemPharm who, like us, is committed to address the problem of prescription opioid abuse,” said Bob Jones, President and CEO of Acura. “We believe KemPharm shares our objective of aggressively developing and bringing to the healthcare community new abuse deterrent IR opioid analgesics to treat pain.”

About KemPharm

KemPharm is a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its Ligand Activated Therapy (LAT) platform technology. KemPharm utilizes its LAT platform technology to generate improved prodrug versions of FDA-approved drugs in the high need areas of pain, ADHD and other CNS (central nervous system) disorders

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

Caution Concerning Forward Looking Statements

KemPharm’s Forward Looking Statements

This press release may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as “may,” “will,” “expect,” “project,” “estimate,” “anticipate,” “plan,” “believe,” “potential,” “should,” “continue” or the negative versions of those words or other comparable words. These forward-looking statements include statements regarding the potential development of any product candidates under the Agreement, the expected features and characteristics of KemPharm’s current and in-development opioid product candidates, including those potentially developed under the Agreement, and the related development timelines for KP201/IR. These forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to KemPharm and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, the risks and uncertainties associated with: KemPharm’s financial resources and whether they will be sufficient to meet KemPharm’s business objectives and operational requirements; results of earlier studies and trials may not be predictive of future clinical trial results; the protection and market exclusivity provided by KemPharm’s intellectual property; risks related to the drug discovery and the regulatory approval process; the impact of competitive products and technological changes; and the FDA approval process under the Section 505(b)(2) regulatory pathway, including any timelines for related approval. KemPharm’s forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning KemPharm’s business are described in additional detail in KemPharm’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, and KemPharm’s other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

Acura's 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 Acura's 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:

- Acura's ability to fund or obtain funding for its continuing operations, including the development of its products utilizing our Limitx™ and Impede® technologies;
- whether the extent to which products formulated with the Aversion® technology deter abuse or will be determined sufficient by the FDA to support approval or labeling describing abuse deterrent features;
- Acura's and its licensee's ability to obtain necessary regulatory approvals, successfully launch and commercialize products utilizing its technologies;
- the market acceptance of, timing of commercial launch and competitive environment for any of Acura's products or products utilizing its technologies;
- Acura's exposure to product liability and other lawsuits in connection with the commercialization of products utilizing its technologies;
- the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- the ability of Acura's patents to protect its products from generic competition and its ability to protect and enforce its patent rights in any paragraph IV patent infringement litigation;
- the ability to fulfill the FDA requirements for approving Acura's product candidates or products utilizing its technologies 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 its product candidates and the sufficiency of its development process to meet over-the-counter (“OTC”) Monograph standards, as applicable;
- changes in regulatory requirements;
- adverse safety findings relating to Acura's commercialized products or product candidates in development;
- whether the FDA will agree with Acura's analysis of its clinical and laboratory studies;
- whether further studies of Acura's product candidates will be required to support FDA approval;
- whether or when Acura is able to obtain FDA approval of labeling for its product candidates for the proposed indications and will be able to promote the features of its abuse discouraging technologies; and

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “indicates,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. These statements reflect Acura's 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. Many of these risks are discussed in greater detail in Acura's filings with the Securities and Exchange Commission. Unless required by law, Acura undertakes 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 Acura's silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

For KemPharm, Inc.

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