

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

September 26, 2012  
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 (17CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17CFR240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-4(c))

### **Item 1.01 Entry into a Material Definitive Agreement.**

On September 26, 2012 we entered into a letter agreement (“Letter Agreement”) with King Pharmaceuticals Research & Development, Inc. (“King”), now a subsidiary of Pfizer, Inc., (collectively “Pfizer”) relating to the License, Development and Commercialization Agreement dated October 30, 2007 (the “License Agreement”) between King and us.

As previously reported, on July 26, 2012 Pfizer provided notice to us of exercise of its right to terminate the license under the License Agreement to three development-stage products (oxycodone hydrochloride with acetaminophen, hydrocodone bitartrate with acetaminophen and an undisclosed third product) using the Company’s Aversion® Technology (the “Returned Products”). Pursuant to the License Agreement, prior to entry into of the Letter Agreement, such termination was to be effective twelve months after such notice.

Pursuant to the termination and the Letter Agreement:

- Pfizer’s license to the Returned Products will immediately terminate. We will no longer be eligible for milestones or royalties relating to the Returned Products.
- We have the right to commence development of the Returned Products. Pfizer will transfer to us requested studies, data, regulatory filings and other information relating to the Returned Products pursuant to a transition process.
- If any of the Returned Products are approved by the U.S. Food and Drug Administration, we can commercialize such Returned Product.
- Certain mu opioids agreed to by us and Pfizer will not be subject to licensing by Pfizer in the future.
- Pfizer retains all rights to OXECTA® (oxycodone hydrochloride) Tablets CII, and product line extensions thereof. Pfizer’s marketing and royalty payment obligations under the License Agreement relating to OXECTA® remain unchanged.

**Item 8.01 Other Events**

On September 26, 2012 we issued a press release relating to the Letter Agreement, which press release is attached hereto as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
10.1	Letter Agreement dated September 24, 2012 (executed September 26, 2012) between Acura Pharmaceuticals Inc. and King Pharmaceuticals Research and Development, Inc. (Certain information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portion.)
99.1	Press Release dated September 26, 2012 Announcing Pfizer's Immediate Return of Development Products.

**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: September 26, 2012

**Exhibit Number**

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**Description**

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10.1	Letter Agreement dated September 24, 2012 (executed September 26, 2012) between Acura Pharmaceuticals Inc., and King Pharmaceuticals Research and Development, Inc. (Certain information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portion.)
99.1	Press Release dated September 26, 2012 Announcing Pfizer's Immediate Return of Development Products.

September 24, 2012

Robert Jones  
Acura Pharmaceuticals, Inc.  
616 N. North Court, Suite 120  
Palatine, IL 60067

**Re:** License, Development and Commercialization Agreement, dated October 30, 2007, by and between Acura Pharmaceutical, Inc. and King Pharmaceuticals Research and Development, Inc. (the "**Agreement**")

Dear Robert:

The purpose of this letter agreement is to memorialize the Parties' (i) termination of the Agreement with respect to certain Products, and (ii) agreement to amend certain post-termination provisions in the Agreement, all as discussed in our recent communications (this "**Letter Agreement**"). All capitalized terms used but not defined herein shall have the meanings set forth in the Agreement.

The Parties hereby acknowledge and agree as follows:

1. **Termination of Certain Products.** The Parties acknowledge and agree that, on July 26, 2012, King provided proper written notice of termination, without cause, of the Agreement with respect to Product B, Product C, and Product D, and any Product Line Extension of Product B, Product C, and Product D (collectively, the "**Returned Products**," and each individually, a "**Returned Product**").
2. **Waiver of Prior Written Notice and Termination Date.** With respect to any Returned Product, Acura further acknowledges and agrees to forever and irrevocably waive the requirement to provide twelve (12) months written notice to Acura prior to terminating the Agreement with respect to such Returned Product as described in Section 16.3. The effective date of termination of the Agreement with respect to the Returned Products shall be the date set forth above (the "**Letter Agreement Effective Date**").
3. **Limited Waiver of Non-Compete.** Notwithstanding King's termination and return of the Returned Products, the Parties acknowledge and agree that the provisions of the covenant not to compete set forth in Section 13.1(a)(i) and (ii) of the Agreement as of the Letter Agreement Effective Date shall continue to apply, provided however, that the covenant not to compete in Section 13.1(a)(i) shall not apply to Product B or to any Product Line Extension of Product B, and the covenant not to compete in Section 13.1(a)(ii) shall not apply to Product C, Product D (or to any Product Line Extension of Product C or Product D) or to any of the Future Products listed on Schedule A. For avoidance of doubt, Acura and its Affiliates may, directly or indirectly, Commercialize Product B, Product C, Product D, and/or any of the Future Products listed on Schedule A or any Product Line Extension of any of the foregoing or grant any right to Third Parties to Commercialize Product B, Product C, Product D, and/or any of the Future Products listed on Schedule A or any Product Line Extension of any of the foregoing in the Territory. For purposes of clarity, the covenant not to compete set forth in Section 13.1(b)(i) of the Agreement shall not apply to the Returned Products or any of the Future Products listed on Schedule A.

**[\*\*\*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]**

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4. **Future Product Options.** The Parties acknowledge and agree to forever and irrevocably waive any future obligations and rights with respect to the Future Products listed in Schedule A to this Letter Agreement, and any rights and obligations under Sections 2.1(e), 2.1(f), and 8.6 of the Agreement shall terminate as of the Letter Agreement Effective Date.
5. **Trademarks.** The Parties acknowledge and agree that the definition of Trademarks set forth in Section 1.86 of the Agreement shall no longer include the marks Acurox or Acuracet. For the avoidance of doubt, Acura shall have the exclusive right to the Acurox and Acuracet trademarks and to any domain names incorporating or utilizing Acurox or Acuracet.
6. **Transition.** In connection with the termination of the Agreement with respect to the Returned Products, the Parties acknowledge and agree to follow certain activities to support the transition of the Returned Products all in accordance with Section 16.7(b) of the Agreement, as described in Schedule B to this Letter Agreement (the “**Transition Plan**”), which Transition Plan shall constitute Acura’s request under Section 16.7(b). The Parties acknowledge and agree that the Joint Steering Committee (or a subcommittee thereof) shall facilitate the implementation of the Transition Plan, provided that the Transition Plan and its implementation may not be amended without the mutual written consent of Acura and King. King will commence delivering the items specified in the Transition Plan as soon as they become available, but final delivery of the Transition Plan in no event shall be later than ninety (90) days from the Letter Agreement Effective Date. With respect to the clinical supplies and samples specified in the Transition Plan, King will deliver to Acura, FOB shipping point, freight collect.
7. **Licenses.** To facilitate Acura’s continued development of the Returned Products, King hereby grants to Acura: at no cost (1) a fully paid-up non-exclusive license under King Sole Inventions relating to any Returned Product or the Aversion technology to develop, manufacture, use, sell offer for sale and import Returned Products inside the Territory including the right to grant sublicenses and (2) a right to reference and use all regulatory data from Product A inside the Territory for products listed on Schedule A, Product B, Product C and Product D and any Product Line Extensions of the foregoing.

\*\*\*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]

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8. **Publicity.** Neither party will originate any publicity, press release, or other public announcement or make any comment, written or oral, relating to this Letter Agreement without the advance written consent of the other Party (except as has been previously consented), unless such announcement is required by law or the regulations of a national securities exchange. A Party required by law, rule or regulation or the regulation of a national securities exchange to make such an announcement will give the other Party an opportunity to review the form or content of such announcement and make comments upon it in advance. Either Party may issue a press release in the form substantially similar to Schedule C to this Letter Agreement. The Parties acknowledge that Acura will file a Form 8-K with the Securities and Exchange Commission regarding this Letter Agreement and will be attaching a redacted copy of the Letter Agreement to such 8-K (or a Form 10-Q or 10-K as appropriate) requesting confidential treatment of certain information and the 8-K and redacted copy will be treated as a public announcement as described herein.
9. **Confidentiality.** The terms of this Letter Agreement and the Schedules attached hereto shall be deemed Confidential Information of Disclosing Party.

Except as explicitly set forth in this Letter Agreement, no amendment or modification to the Agreement is hereby made.

Sincerely,

**KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC.**

By: /s/ Robert B. Lamm

Name: Robert B. Lamm

Title: Vice President

Accepted and agreed as of the date first set forth above.

**ACURA PHARMACEUTICALS, INC.**

By: /s/ Robert B. Jones

Name: Robert B. Jones

Title: President and Chief Executive Officer

**\*\*\*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.**

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SCHEDULE A

List of mu opioids\* for which Pfizer forever and irrevocably waives any future obligations and rights with respect to the Future Products

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***	***
***	***
***	***
***	***
***	***

\* Includes all pharmaceutically acceptable salts thereof.

\*\*\*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.

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SCHEDULE B

**1. Definitions (all including Acura's Aversion® Technology):**

Product B (oxycodone/APAP/niacin)	Product B-LE (oxycodone/APAP)
Product C (hydrocodone/APAP/niacin)	Product C-LE (hydrocodone/APAP)
Product D [***]	Product D-LE [***]

*\* Denotes High Priority Items for early transfer, if possible*

**2. Products B, C and D (products with niacin)**

[\*\*\*]

**3. Product B-LE**

[\*\*\*]

**Product C-LE [\*\*\*]**

**Product D-LE [\*\*\*]**

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SCHEDULE C

Form of Release

**Acura Pharmaceuticals Announces Earlier Return of Development Products**

Palatine, IL - (XXXXXXX, YY, 2012) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today a letter agreement with Pfizer Inc. providing for the termination of Pfizer's license to Acura's AVERSION Technology used in three developmental opioid products as of [date as inserted in the agreement] and the transfer of those products back to Acura. On July 26, 2012 Acura was notified by Pfizer of its intention to terminate the license to the three development products which carried a 12 month notice period under the terms of the companies' 2007 license agreement.

The developmental products being returned to Acura are oxycodone hydrochloride with acetaminophen, hydrocodone bitartrate with acetaminophen and a third previously unnamed opioid, all of which utilize Acura's AVERSION technology. The AVERSION Technology utilizes a proprietary mixture of inactive ingredients to discourage tampering of a product for abusive purposes.

"We are pleased that Pfizer agreed to an earlier return of these development products for development by Acura", said Bob Jones, President and Chief Executive Officer of Acura Pharmaceuticals.

**\*\*\*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been separately filed with the Commission.]**

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### **Acura Pharmaceuticals Announces Earlier Return of Development Products**

Palatine, IL - (September 26, 2012) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today a letter agreement with Pfizer Inc. providing for the termination of Pfizer's license to Acura's AVERSION Technology used in three developmental opioid products as of September 26, 2012 and the transfer of those products back to Acura. On July 26, 2012 Acura was notified by Pfizer of its intention to terminate the license to the three development products which carried a 12 month notice period under the terms of the companies' 2007 license agreement.

The developmental products being returned to Acura are oxycodone hydrochloride with acetaminophen, hydrocodone bitartrate with acetaminophen and a third previously unnamed opioid, all of which utilize Acura's AVERSION technology. The AVERSION Technology utilizes a proprietary mixture of inactive ingredients to discourage tampering of a product for abusive purposes. "We are pleased that Pfizer agreed to an earlier return of these products for development by Acura", said Bob Jones, President and Chief Executive Officer of Acura Pharmaceuticals.

#### **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 AVERSION<sup>®</sup> and IMPEDE<sup>™</sup> technologies. In June 2011, the U.S. Food and Drug Administration approved OXECTA<sup>®</sup> which incorporates the AVERSION technology. The Company has a development pipeline of additional AVERSION technology products including other opioids and its IMPEDE technology for pseudoephedrine hydrochloride products.

The trademark OXECTA<sup>®</sup> is owned by Pfizer Inc.

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## **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 and our licensee’s ability to successfully launch and commercialize our products and technologies including Oxecta® Tablets and Nexafed® Tablets, the price discounting that may be offered by Pfizer for Oxecta®, the ability of us or our licensee’s to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, expectations regarding potential market share for our products and the timing of first sales, our ability to enter into additional license agreements for our other product candidates, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability of our patents to protect our products from generic competition, and 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 to meet over-the-counter, or 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 product candidates, whether the FDA will agree with our analysis of our clinical and laboratory studies and how it may evaluate the results of these studies or 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 will be able to promote the features of our abuse discouraging technologies, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede technology 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,” “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.

## **Contact:**

### **for Acura Investor Relations**

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847-705-7709

### **for Acura Media Relations**

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