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

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): September 30, 2015**

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**KEMPHARM, INC.**

(Exact name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-36913**  
(Commission File Number)

**20-5894398**  
(IRS Employer  
Identification No.)

**2656 Crosspark Road, Suite 100  
Coralville, IA**

(Address of Principal Executive Offices)

**52241**

(Zip Code)

**Registrant's Telephone Number, Including Area Code: (319) 665-2575**

**Not Applicable**

(Former Name or Former Address, if Changed Since Last Report)

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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 Instructions 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 7.01 Regulation FD Disclosure.**

On September 30, 2015, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release regarding the items described in Item 8.01 below. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in the press release furnished as Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is not incorporated by reference into any of KemPharm’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

**Item 8.01 Other Events.**

On September 30, 2015, KemPharm announced positive results from three distinct studies designed to evaluate the tamper-resistant properties of its lead opioid prodrug KP201/APAP, KemPharm’s prodrug of hydrocodone in combination with acetaminophen, or APAP, compared to a generic hydrocodone bitartrate/APAP product, or HB/APAP. The highlights from these tampering studies included:

- Under all conditions tested (over 1,000 conditions examined), the amount of hydrocodone released from KP201, the active pharmaceutical ingredient, or API, of KP201/APAP, was less than the amount of hydrocodone released from HB/APAP tablets.
- Extraction of KP201 yielded mostly inactive KP201, while hydrocodone was efficiently extracted from HB/APAP under the same conditions.
- Greater than 90% of all conditions tested for extraction yielded no hydrocodone released from KP201.
- Conditions that led to any release of hydrocodone from KP201/APAP required harsh chemicals and usually heat; by comparison, hydrocodone was extracted from HB/APAP tablets with only water.
- Traditional means of preparing a drug for injection were not suitable for KP201/APAP, yielding only inactive KP201, while up to 100% of hydrocodone could be extracted from HB/APAP tablets by the same process.
- Cold water extraction yielded no free hydrocodone from KP201/APAP.
- Smoking or freebasing of KP201/APAP tablets was not possible.
- Smoking of the KP201 API itself after extraction yielded no hydrocodone; by comparison, it was possible to smoke the hydrocodone API.

The first study, KP201.T01, evaluated KP201/APAP for the possibility and potential for individuals to extract the KP201 prodrug from its tablet formulation and convert the extracted KP201 API into active hydrocodone, following a protocol that KemPharm developed with input from the United States Food and Drug Administration, or the FDA. The study evaluated how the abuse-deterrent properties of KP201 could be defeated or compromised, as compared to HB/APAP tablets. The results showed that efforts to extract and hydrolyze KP201/APAP were less efficient compared to HB/APAP tablets. Under the more than 1,000 conditions tested, KP201/APAP released less hydrocodone compared to the hydrocodone released from the HB/APAP tablets in every case, usually only yielding the inactive prodrug, KP201.

A second study, KP201.T02, was designed to determine the properties of KP201 that reduce the likelihood of intravenous, or IV, abuse of KP201/APAP as compared to HB/APAP, based again on a protocol developed by KemPharm with input from the FDA. The study evaluated the amount of KP201, APAP and hydrocodone detected in an extract derived from KP201/APAP tablets that would be suitable for IV abuse. The results showed the traditional means used to prepare a drug for injection were likely not suitable for KP201/APAP. In each condition employed, only inactive KP201 was extracted, if anything at all, while up to 100% of the hydrocodone from HB/APAP tablets could be extracted for injection. Cold water extraction methods typically used to “enrich” or “purify” the hydrocodone from HB/APAP also yielded only inactive KP201 with zero release of hydrocodone from the prodrug. As expected, hydrocodone was readily extracted from HB/APAP tablets by this method.

The final study, KP201.T03, examined the potential to abuse KP201/APAP by smoking. The results demonstrated that KP201/APAP could not be smoked in either tablet or API form. The results also showed that freebasing KP201/APAP was not possible. By contrast, HB/APAP can be prepared as a freebase and also smoked as the API.

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**Item 9.01**

**Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release titled "KemPharm Reports Positive Data Demonstrating Tamper-Resistant Properties of KP201/APAP" dated September 30, 2015.

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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.

**KEMPHARM, INC.**

Date: September 30, 2015

By: /s/ R. LaDuane Clifton  
R. LaDuane Clifton  
Chief Financial Officer

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## Exhibit Index

Exhibit No.

Description

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99.1	Press Release titled "KemPharm Reports Positive Data Demonstrating Tamper-Resistant Properties of KP201/APAP" dated September 30, 2015.
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## KemPharm Reports Positive Data Demonstrating Tamper-Resistant Properties of KP201/APAP

*Results Indicate that Prodrug Design of KP201/APAP Significantly Hinders Traditional Means of Abuse, Including Extraction, Injection and Smoking*

**Coralville, IA – September 30, 2015** – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today reported positive results from three distinct studies designed to evaluate the tamper-resistant properties of its lead opioid prodrug KP201/APAP, KemPharm's prodrug of hydrocodone in combination with acetaminophen (APAP) compared to a generic hydrocodone bitartrate/APAP product (HB/APAP). The studies were designed based on feedback from the U.S. Food and Drug Administration (FDA). KemPharm believes that, together with the positive data from KemPharm's previous human abuse liability trials, these results may support FDA Category 1 abuse-deterrent language in the KP201/APAP product label, if approved by the FDA.

### Highlights from the Tampering Studies:

- **Under all conditions tested (over 1,000 conditions examined), the amount of hydrocodone released from KP201, the active pharmaceutical ingredient (API) of KP201/APAP, was less than the amount of hydrocodone released from HB/APAP tablets.**
  - Extraction from KP201/APAP yielded mostly inactive KP201, while hydrocodone was efficiently extracted from HB/APAP under the same conditions.
  - Greater than 90% of all conditions tested for extraction yielded no hydrocodone released from KP201/APAP.
  - Conditions that led to any release of hydrocodone from KP201/APAP required harsh chemicals and usually heat; by comparison, hydrocodone was extracted from HB/APAP tablets with only water.
  - Traditional means of preparing a drug for injection were not suitable for KP201/APAP, yielding only inactive KP201, while up to 100% of hydrocodone could be extracted from HB/APAP by the same process.
  - Cold water extraction yielded no free hydrocodone from KP201/APAP.
  - Smoking or freebasing of KP201/APAP tablets was not possible.
  - Smoking of the KP201 API itself after extraction yielded no hydrocodone; by comparison, it was possible to smoke the hydrocodone API.
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Travis C. Mickle, Ph.D., President and CEO of KemPharm, stated, “These results demonstrate the unique characteristics of our prodrug technology, showing that KP201 appears to remain intact in its inactive prodrug form even when being subjected to various chemical manipulation techniques used commonly by opioid abusers. Importantly, we believe these results may support favorable product labeling for KP201/APAP, if approved by the FDA. KP201 has demonstrated intranasal, and KP201/APAP has demonstrated oral, abuse-deterrent and safety properties that we believe further differentiates our product candidate when compared to the immediate-release opioid products currently available.”

The first study, KP201.T01, evaluated KP201/APAP for the possibility and potential for individuals to extract the KP201 prodrug from its tablet formulation and convert the extracted KP201 API into active hydrocodone, following a protocol that KemPharm developed with input from the FDA. The study evaluated how the abuse-deterrent properties of KP201 could be defeated or compromised, as compared to HB/APAP tablets. The results showed that efforts to extract and hydrolyze KP201/APAP were less efficient compared to HB/APAP tablets. Under the more than 1,000 conditions tested, KP201/APAP released less hydrocodone compared to the hydrocodone released from the HB/APAP tablets in every case, usually only yielding the inactive prodrug, KP201.

A second study, KP201.T02, was designed to determine the properties of KP201 that reduce the likelihood of intravenous (IV) abuse of KP201/APAP as compared to HB/APAP, based again on a protocol developed by KemPharm with input from the FDA. The study evaluated the amount of KP201, APAP and hydrocodone detected in an extract derived from KP201/APAP tablets that would be suitable for IV abuse. The results showed the traditional means used to prepare a drug for injection were likely not suitable for KP201/APAP. In each condition employed, only inactive KP201 was extracted, if anything at all, while up to 100% of the hydrocodone from HB/APAP tablets could be extracted for injection. Cold water extraction methods typically used to “enrich” or “purify” the hydrocodone from HB/APAP also yielded only inactive KP201 with no release of hydrocodone from the prodrug. As expected, hydrocodone was readily extracted from HB/APAP tablets by this method.

The final study, KP201.T03, examined the potential to abuse KP201/APAP by smoking. The results demonstrated that KP201/APAP could not be smoked in either tablet or API form. The results also showed that freebasing KP201/APAP was not possible. By contrast, HB/APAP can be prepared as a freebase and also smoked as the API.

Dr. Mickle also noted, “KemPharm is on track to report data from the second intranasal abuse study of KP201/APAP (KP201.A02) in the coming weeks. We look forward to reporting the results of this study and to filing an NDA for KP201/APAP utilizing the 505(b)(2) pathway as anticipated in the fourth quarter of 2015.”

## **About KemPharm**

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KemPharm is a clinical-stage specialty pharmaceutical company focused on the discovery and development of 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 disorders.

### **Caution Concerning 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 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, without limitation, 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; and, the impact of competitive products and technological changes. 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 Registration Statement on Form S-1 (Registration No. 333-202660) declared effective April 15, 2015, 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.

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