# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

### **CURRENT REPORT**

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

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

# KEMPHARM, INC.

(Exact name of Registrant as Specified in Its Charter)

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

**52241** (Zip Code)

(Address of Principal Executive Offices)

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

#### Not Applicable

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

| 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 sions (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))   |

#### Item 7.01 Regulation FD Disclosure.

On December 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 December 30, 2015, KemPharm announced plans to initiate development of KP746, a recently identified oral prodrug of oxymorphone. Based on preclinical studies of KP746, KemPharm believes that the prodrug may offer enhanced bioavailability at typical therapeutic doses and abuse-deterrent features in comparison to standard oxymorphone. Specifically, based on preclinical studies, KemPharm believes KP746 may be highly tamper-resistant and may be stable under conditions that can potentially defeat many other abuse-deterrent technologies, suggesting greatly reduced intranasal bioavailability and minimal to no release of oxymorphone when administered intravenously.

#### **Caution Concerning Forward Looking Statements**

This Current Report 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 21 E 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 regarding the clinical development of KP746. 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; and risks related to the drug discovery and the regulatory approval process. 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. 333-208633) filed with the Securities and Exchange Commission on December 18, 2015, and KemPharm's other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligat

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press Release titled "KemPharm Expands Pain Therapy Pipeline with Discovery of KP746" dated December 30, 2015.

## 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: December 30, 2015 By: /s/ R. LaDuane Clifton

R. LaDuane Clifton Chief Financial Officer **Exhibit Index** 

Exhibit No. Description

Press Release titled "KemPharm Expands Pain Therapy Pipeline with Discovery of KP746" dated December 30, 2015.

99.1



# KemPharm, Inc. Expands Pain Therapy Pipeline with Discovery of KP746

Novel Prodrug of Oxymorphone Adds New Asset to KemPharm's Advancing Abuse-Deterrent Product Portfolio

Coralville, IA – December 30, 2015 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, announced today plans to initiate development of KP746, a recently identified, first-in-class oral prodrug of oxymorphone. Oxymorphone, marketed under the brand name Opana®, is a commonly prescribed medication for the management of pain in patients where an opioid analgesic is appropriate. KP746 has the potential to be the first approved prodrug of oxymorphone.

Based on preclinical studies of KP746, we believe that the prodrug may offer enhanced bioavailability at typical therapeutic does and abuse-deterrent features in comparison to standard oxymorphone. Specifically, based on preclinical studies, KemPharm believes KP746 may be highly tamper-resistant and may be stable under conditions that can potentially defeat many other abuse-deterrent technologies, suggesting greatly reduced intranasal bioavailability and minimal to no release of oxymorphone when administered intravenously.

KP746 applies KemPharm's Ligand Activated Therapy (LAT) platform technology, adding to its pipeline of opioid prodrug product candidates, which includes KP201/APAP and KP201/IR (prodrugs of hydrocodone with and without acetaminophen), KP511/ER (a prodrug of hydromorphone), and KP606/IR (a prodrug of oxycodone). In addition, KemPharm is developing KP415, a prodrug of methylphenidate with controlled release (CR) features, for managing ADHD.

Travis C. Mickle, Ph.D., President and CEO of KemPharm, stated, "We are very pleased to introduce KP746 to our advancing pipeline of opioid prodrug candidates as we seek to enhance our clinical-stage product portfolio while progressing KP201/APAP through regulatory review and potential commercialization. Oxymorphone is a commonly prescribed opioid analgesic, which, while effective at treating the symptoms of pain, has been found to have the potential for abuse and misuse similar to other opioids. Like our other opioid prodrug candidates, KP746 has features that may deter tampering and abuse on the molecular level, potentially limiting opioid exposure when misused either intranasally, intravenously, orally, or when subjected to various physical and chemical manipulation techniques commonly used by opioid abusers."

#### **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 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; the impact of competitive products and technological changes; and the FDA approval process under the Section 505(b)(2) regulatory pathway. 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. 333-208633) filed with the Securities and Exchange Commission on December 18, 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 forwardlooking statements, whether as a result of new information, future events or otherwise.

###

For KemPharm, Inc.: Gordon K. "Rusty" Johnson 321-939-3416 info@kempharm.com Media / Investor Contacts:
Jason Rando / Joshua Drumm, Ph.D.
<u>Tiberend Strategic Advisors, Inc.</u>
212-375-2665 / 2664
<u>jrando@tiberend.com</u>
jdrumm@tiberend.com