# 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**

**Date of Report (Date of earliest event reported): June 11, 2015**

# KEMPHARM, INC.
**(Exact name of registrant as specified in its charter)**

**Delaware**
**(State or other jurisdiction of incorporation)**

| **001-36913** | **20-5894398** |
|---|---|
| **(Commission File No.)** | **(IRS Employer Identification No.)** |

**2656 Crosspark Road, Suite 100**
**Coralville, IA 52241**
**(Address of principal executive offices and zip code)**

**Registrant's telephone number, including area code: (319) 665-2575**

**(Former name or former address, if changed since last report.)**

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:

☐ 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.**

In connection with the press release dated June 11, 2015 described in Item 8.01 below, KemPharm, Inc., or KemPharm, will hold a conference call and webcast on June 11, 2015. Details regarding accessing the conference call and webcast are contained in the press release under the heading "Conference Call Information." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. 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, Inc.'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 June 11, 2015, KemPharm issued a press release with respect to positive data from its oral human abuse liability clinical trial of KP201/APAP, which consists of KP201, KemPharm's prodrug of hydrocodone, combined with acetaminophen, or APAP. The single-center, randomized, double-blind, active- and placebo-controlled, crossover trial, with 71 subjects enrolled and 62 subjects completed, was designed to measure hydrocodone exposure, drug liking and the safety of KP201/APAP, as compared to Norco®, a branded version of generic hydrocodone bitartrate combined with acetaminophen, when taken orally at 4, 8 and 12 tablet dosages, each of which are much greater than the recommended amount, typically 1 to 2 tablets. Each tablet consisted of 7.5 mg hydrocodone bitartrate/325 mg APAP for Norco®, and an equivalent amount of KP201/APAP. In the trial, KemPharm observed that KP201/APAP released less hydrocodone as compared to Norco® at the two highest doses administered, 8 and 12 tablets. In addition, adverse events related to hypoxia trended lower for KP201/APAP at both the 8 and 12 tablet doses. As expected, drug liking was similar for KP201/APAP and Norco® at each equivalent dose level.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release titled "KemPharm, Inc. Reports Positive Data from Oral Human Abuse Liability Clinical Trial of KP201/APAP" dated June 11, 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 hereunto duly authorized.

**KEMPHARM, INC.**

Date: June 11, 2015

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton
Vice President, Finance and Corporate Controller

## EXHIBIT INDEX

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press Release titled “KemPharm, Inc. Reports Positive Data from Oral Human Abuse Liability Clinical Trial of KP201/APAP” dated June 11, 2015. |

**Exhibit 99.1**

**KemPharm, Inc. Reports Positive Data from Oral Human Abuse Liability Clinical Trial of KP201/APAP**

*Company to Host Conference Call and Live Audio Webcast Today at 8:30 a.m. ET*

**Coralville, IA – June 11, 2015 –** KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced positive data from its oral human abuse liability clinical trial of KP201/APAP, the Company's most advanced product candidate. KP201/APAP is an immediate release combination of KP201, the Company's prodrug of hydrocodone, and acetaminophen ("APAP"), which is being developed to provide clinicians and patients a novel abuse-deterrent immediate release prodrug of hydrocodone/APAP, the most commonly prescribed opioid in the United States.

The KP201.A01 oral human abuse liability trial ("KP201.A01") was designed to measure hydrocodone exposure, drug likability and the safety of KP201/APAP, as compared to Norco® (branded version of generic hydrocodone bitartrate combined with acetaminophen), when taken orally at 4, 8 and 12 tablet dosages, each of which are much greater than the recommended amount (1 to 2 tablets). Highlights of the trial results included lower exposure to hydrocodone at the highest dose levels for the trial, as well as lower incidence of hypoxia across the same dosage levels, in each case compared to hydrocodone reference drug, suggesting the potential for improved safety. As expected, liking data was similar at each equivalent dose level.

Travis C. Mickle, Ph.D., President and CEO of KemPharm, stated, "The positive data from the oral human abuse liability clinical trial suggest that the unique prodrug properties of KP201/APAP may offer an improvement in the safety of the drug when taken in high amounts orally. The fact that we saw lower drug exposure at the highest doses compared to the reference drug was better than expected. We are not aware of any other abuse-deterrent opioid in the market or in clinical development that has these inherent molecular properties."

As announced previously, KemPharm's management held a pre-New Drug Application ("NDA") meeting with the FDA for KP201/APAP on May 20, 2015. Based upon the results of this meeting, KemPharm intends to submit an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for KP201/APAP to the U.S. Food and Drug Administration ("FDA") in the second half of 2015.

The KP201.A01 trial is part of a broader human abuse liability program designed by KemPharm to assess key abuse-deterrence criteria as specified by the FDA. Additional components of this program include three nonclinical studies to evaluate the tamper resistance of KP201/APAP (whether the active ingredient can be extracted physically or chemically, abused intravenously or smoked) and two intranasal human abuse liability clinical trials. One of the intranasal studies is designed to assess the relative pharmacokinetics and drug likability of KP201/APAP compared to Norco®. In the second intranasal trial, the amount of hydrocodone released from the active pharmaceutical ingredient ("API"), KP201, is being measured when the API is snorted alone, as compared to hydrocodone bitartrate. Results from these studies are expected in the third quarter of 2015.

Dr. Mickle said, "We believe the data observed in this trial further validate the overall rationale for our prodrug approach to abuse deterrence and the promise for other products in our pipeline, like KP511, which, based on pre-clinical studies, we believe has the ability to reduce the potential for overdose. We believe that the results demonstrated from this particular trial with KP201 may support Category 2 abuse-deterrent labeling for KP201/APAP based on FDA guidance, as well as suggest additional safety improvements that we plan to explore in more detail."

**About the KP201.A01 Oral Human Abuse Liability Trial:**

The single-center, randomized, double-blind, active- and placebo-controlled, crossover trial (KP201.A01), with 71 subjects enrolled and 62 subjects completed, was designed to measure hydrocodone exposure, drug likability and the safety of KP201/APAP, as compared to Norco® (branded version of generic hydrocodone bitartrate combined with acetaminophen), when taken orally at 4, 8 and 12 tablet dosages, each of which are much greater than the recommended amount (1 to 2 tablets). Each tablet consisted of 7.5 mg hydrocodone bitartrate/325 mg APAP for Norco®, and an equivalent amount of KP201/APAP. In the trial, KemPharm observed that KP201/APAP released less hydrocodone as compared to Norco® at the two highest doses administered (8 and 12 tablets). In addition, adverse events related to hypoxia trended lower for KP201/APAP at both the 8 and 12 tablet doses. As expected, drug liking, as measured by $E_{max}$ on the Visual Analogue Scale (VAS), was similar for KP201/APAP and Norco® at each equivalent dose level.

**Conference Call Information:**

KemPharm will host a conference call and live audio webcast today at 8:30 a.m. ET, to discuss the results from its oral human abuse liability clinical trial of KP201/APAP. The conference call can be accessed by dialing (866) 395-2480 toll-free in the U.S., or (678) 509-7538 for participants outside the U.S. The live audio webcast can be accessed via the Investor Relations section of the KemPharm website: http://investors.kempharm.com/. A replay of the call will be available on our website for 30 days.

**About KemPharm:**

KemPharm is a clinical-stage specialty pharmaceutical company focused on the discovery and development of 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. For more information on KemPharm, please visit www.kempharm.com.

**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 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 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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