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): February 10, 2016

KEMPHARM, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36913**	**20-5894398**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2656 Crosspark Road, Suite 100 **Coralville, IA**	**52241**
(Address of Principal Executive Offices)	(Zip Code)

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

Not Applicable
(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 (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 February 10, 2016, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing that its new drug application, or NDA, for KP201/APAP, its investigational drug candidate for the short-term management of acute pain, has been accepted and granted priority review by the U.S. Food and Drug Administration, or the FDA. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information set forth in this Item 7.01 and 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.

As described above, on February 10, 2016, KemPharm announced that its NDA for KP201/APAP has been accepted and granted priority review by the FDA. In addition, the FDA has set a target action date under the Prescription Drug User Fee Act of June 9, 2016.

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 include statements regarding the expected timing of approval, if at all, of KP201/APAP by the FDA. 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, including without limitation 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 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FDA Grants Priority Review to KemPharm for KP201/APAP NDA" dated February 10, 2016.

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: February 10, 2016

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release titled “FDA Grants Priority Review to KemPharm for KP201/APAP NDA” dated February 10, 2016.

Exhibit 99.1

FDA Grants Priority Review to KemPharm for KP201/APAP NDA

If approved, KP201/APAP could become the first immediate-release hydrocodone combination product with abuse-deterrent properties

Coralville, IA – February 10, 2016 – KemPharm, Inc. (NASDAQ: KMPH) today announced that the New Drug Application (NDA) for KP201/APAP, its investigational drug candidate for the short-term management of acute pain, has been accepted and granted priority review by the U.S. Food and Drug Administration (FDA). In addition, the FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 9, 2016.

KP201/APAP, an immediate release (IR) combination of KemPharm's prodrug of hydrocodone, KP201 (benzhydrocodone hydrochloride), and acetaminophen (APAP), was developed to potentially deter certain common methods of abuse and may also limit excessive opioid exposure in patients and non-medical users compared to currently available hydrocodone combination products. Hydrocodone/acetaminophen products (commonly known by the brand names Vicodin®, Norco® and Lortab®) are among the most prescribed and the most widely abused (non-medical use) medications in the United States.[1,2] Currently there are no abuse-deterrent IR hydrocodone combination products approved by the FDA.

"We believe this milestone brings us one step closer to providing prescribers and patients with a new acute pain treatment option that may deter certain common methods of abuse while providing the same pharmacokinetic and therapeutic effect as currently available immediate-release hydrocodone/APAP medications," said Travis C. Mickle, Ph.D., President and CEO of KemPharm. "Equally important, we are pleased that the FDA has agreed to a priority review of the NDA with a target PDUFA date of June 9th, which is sooner than was previously anticipated. We look forward to working closely with the agency over the coming months as it considers this potential new option for physicians who are treating patients with acute pain."

In the NDA submission, KemPharm requested the FDA to recommend that KP201/APAP be classified as a Schedule III controlled substance. This request is based on what KemPharm believes is the reduced potential for abuse and the potential safety features attributable to lower exposure levels to hydrocodone for KP201/APAP as compared to other hydrocodone/APAP products, which are designated as Schedule II. In addition, based on the results of the human abuse liability program completed for KP201/APAP, as well as feedback from the FDA, KemPharm believes there may be support for Category 1, Category 2 and potentially Category 3 abuse-deterrent language in the KP201/APAP product label, if approved by the FDA.

KemPharm developed KP201/APAP using the Company's proprietary Ligand-Activated Technology (LAT), which creates a new prodrug by chemically attaching one or more molecules, or ligands, to an FDA-approved parent drug. Once administered, human metabolic

processes, such as those in the gastrointestinal tract, separate the ligand from the prodrug and release the parent drug, which can then provide its therapeutic effect.

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 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 include statements regarding the expected timing of approval, if at all, of KP201/APAP by the FDA. 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, including without limitation 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 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.

###

Investor Contacts:
Jason Rando / Joshua Drumm, Ph.D.
Tiberend Strategic Advisors, Inc.
212-375-2665 / 2664
jrando@tiberend.com
jdrumm@tiberend.com

Media Contact:
Jim Heins
Cooney Waters Unlimited
212-886-2221
jheins@cooneywatersunlimited.com

[1] IMS Institute for Healthcare Informatics, Medicine Use and Spending Shifts: A Review of the Use of Medicines in the US. In 2014, April 6, 2015 https://www.imshealth.com/files/web/IMSH%20Institute/Reports/Medicines_Use_and_Spending_Shifts/Medicine-Spending-and-Growth_1995-2014.pdf

[2] National Survey on Drug Use and Health 2014 , Substance Abuse and Mental Health Services Administration, Table 1.89A http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab1-89a