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): December 15, 2015

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 December 15, 2015, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing that it had submitted a New Drug Application, or 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, or 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.

On December 15, 2015, KemPharm announced that it had submitted an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for KP201/APAP to the FDA and has requested priority review. If priority review is granted, the FDA typically takes action within six months from the date the NDA is accepted for review, potentially allowing for approval as early as the third quarter of 2016. KP201/APAP is an immediate release combination of KemPharm's prodrug of hydrocodone, KP201, and acetaminophen, or APAP, and is being developed for the treatment of acute pain.

KemPharm has requested that KP201/APAP be designated as a Schedule III controlled substance by the Drug Enforcement Administration 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 have been designated as Schedule II controlled substances. 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.

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 timing of acceptance for filing of KemPharm's NDA by the FDA and the expected timing of approval, if any, 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; 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “KemPharm Submits NDA for KP201/APAP and Requests Priority Review from the FDA” dated December 15, 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 15, 2015

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release titled “KemPharm Submits NDA for KP201/APAP and Requests Priority Review from the FDA” dated December 15, 2015.

Exhibit 99.1

KemPharm Submits NDA for KP201/APAP and Requests Priority Review from the FDA

If approved, KP201/APAP may be the first immediate release hydrocodone combination product candidate for the treatment of acute pain designed to address opioid abuse and misuse

Coralville, IA – December 15, 2015 – KemPharm, Inc. (NASDAQ: KMPH), today announced that it has submitted a New Drug Application (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) and has requested priority review. If priority review is granted, the FDA typically takes action within six months from the date the NDA is accepted for review, potentially allowing for approval as early as Q3 2016. KP201/APAP is an immediate release (IR) combination of KemPharm's prodrug of hydrocodone, KP201, and acetaminophen (APAP), and is being developed for the treatment of acute pain.

KemPharm has requested that KP201/APAP be designated as a Schedule III controlled substance by the Drug Enforcement Administration 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 have been 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.

"Submission of the KP201/APAP NDA is a major milestone for KemPharm as we seek FDA approval for our first product candidate based on our proprietary LAT prodrug technology," said Travis C. Mickle, Ph.D., President and CEO of KemPharm. "We believe the data package submitted with the NDA supports the conclusion that KP201/APAP is bioequivalent at therapeutic levels with hydrocodone combination medications currently available, that our prodrug may provide a greater potential to deter abuse by limiting opioid exposure when misused, either intranasally (with and without APAP), intravenously, by smoking, or by oral ingestion at high doses, and that KP201/APAP is tamper-resistant, with KP201 remaining in its inactive prodrug form even when subjected to various physical and chemical manipulation techniques commonly used by opioid abusers."

KP201/APAP is designed to deter certain common methods of abuse and has shown the potential to limit excessive opioid exposure in patients and non-medical users compared to Norco®, which together with Vicodin®, Lortab® and other currently available hydrocodone combination products are among the most prescribed and the most widely abused (non-medical use) medications in the United States.[1,2] If approved, KP201/APAP may offer physicians the first IR hydrocodone-based pain medication designed to address prescription opioid abuse and misuse.

“Non-medical use of prescription pain medications often begins with IR formulations, which progresses toward abuse of more potent long-acting medications and in some cases may lead to heroin use,” said Jeffrey Gudin, MD, Director of Pain and Palliative Care, Englewood Hospital and Medical Center, Englewood, New Jersey. “An IR pain medication with abuse-deterrent features may help interrupt this cascade of opioid abuse. The prodrug design of KP201/APAP in particular may reduce the risk of excessive opioid exposure in both patients with pain and people with substance abuse disorders.”

Dr. Mickle concluded, “If approved, KP201/APAP has the potential to be the first immediate release, abuse deterrent hydrocodone/APAP option for acute pain. We are optimistic about this result and the positive implications it may have for our entire pipeline of prodrug candidates under development.”

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 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. 333-202660) 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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[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