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): October 21, 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 October 21, 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 October 21, 2015, KemPharm reported top-line results from the KP201.A02 intranasal human abuse liability clinical trial**.** This trial was a phase 1 type clinical trial in 42 healthy, non-dependent recreational drug abusers, to determine the exposure, abuse potential, and safety of crushed intranasal (IN) KP201/APAP relative to crushed IN Norco® (hydrocodone bitartrate/APAP). To highlight:

- IN KP201/APAP exhibited significant pharmacokinetic differences from IN Norco® due primarily to a significant increase in time to achieve peak exposure (T_{max})($p = 0.0001$) and lower peak hydrocodone exposure (C_{max}) for KP201/APAP ($p = 0.0027$).
- IN KP201/APAP did not result in greater hydrocodone exposure and produced a similar pharmacokinetic profile compared to both KP201/APAP and Norco® taken orally.
- Hydrocodone exposure through peak drug effect showed a statistically significant reduction for IN KP201/APAP vs. IN Norco®:
    - 0-0.5 hour: 50.1% reduction ($p = 0.0044$);
    - 0-1.0 hour: 29.1% reduction ($p = 0.0005$); and
    - 0-2.0 hours: 14.9% reduction ($p = 0.0003$).
- Based on this reduced exposure to hydrocodone, drug liking through peak effect (2.0 hours) was significantly lower for IN KP201/APAP vs. IN Norco® ($p<0.0001$).
- Mean peak drug liking (E_{max}) was lower for KP201/APAP, both IN (75.9) and oral (76.9), compared to that of Norco® (79.0, IN; 77.9, oral), though liking scores were statistically similar for all treatments, which KemPharm believes was potentially due to the effects of APAP.
- Median peak drug liking was lowest for IN KP201/APAP (74) and highest for IN Norco® (80).
- Time to peak drug liking IN KP201/APAP was delayed (1.8 hours) compared to IN Norco® (1.0 hour), and was similar based on similar pharmacokinetics, to KP201/APAP and Norco® taken orally (2.0 hours for both).
- As seen in the KP201.A03 trial, ease of insufflation scores suggest that KP201/APAP is more difficult to snort than IN Norco®, indicating that both KP201 by itself and KP201/APAP are likely difficult to "snort."

In summary, data from the KP201.A02 intranasal human abuse liability trial confirmed that KP201/APAP may be able to limit hydrocodone exposure as compared to Norco® when both are administered intranasally. Liking scores were not significantly different, which KemPharm believes was potentially due to the effects of APAP. These results reaffirm the key properties of KP201/APAP that were observed in the prior oral human abuse liability trial (KP201.A01) and intranasal human abuse liability trial (KP201.A03). KemPharm plans to present the full human abuse liability data package as part of its 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) as early as by the end of 2015. Post-NDA filing, KemPharm plans to conduct additional trials with KP201 to further explore the overdose protective properties of KP201 at high oral doses as exhibited in the KP201.A01 oral human abuse liability trial.

This randomized, double-blind, double-dummy, placebo-controlled, single-dose, two-part, five-way crossover trial, with 46 subjects enrolled and 42 subjects completed, was designed to determine the exposure, abuse potential, and safety of equivalent doses of both crushed IN and intact (oral) KP201/APAP as compared to both crushed IN and intact (oral) Norco® in opioid-experienced, non-dependent subjects. KP201/APAP demonstrated a lower Cmax, and a delay in Tmax, as well as a decrease in exposure to hydrocodone (AUC0-2h), especially in the early time points typically associated with an increased safety risk. Liking data for all treatments were similar, which KemPharm believes was potentially due to the effects of APAP. KP201, both with and without APAP, showed a high difficulty of snorting in both KP201.A02 and KP201.A03 trials even though both were administered as a fine powder. Adverse events were similar across all treatments.

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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “KemPharm, Inc. Completes Human Abuse Liability Program for KP201/APAP” dated October 21, 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: October 21, 2015

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release titled “KemPharm, Inc. Completes Human Abuse Liability Program for KP201/APAP” dated October 21, 2015.

Exhibit 99.1

KemPharm, Inc. Completes Human Abuse Liability Program for KP201/APAP

Results from Second Intranasal Human Abuse Liability Clinical Trial Reaffirm Properties of KP201/APAP

Conference Call and Live Audio Webcast Scheduled for Today at 5:00 p.m. ET

Coralville, IA – October 21, 2015 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced the completion of its human abuse liability program of KP201, KemPharm's prodrug of hydrocodone, formulated in combination with acetaminophen (APAP), and reported top-line results from the KP201.A02 intranasal human abuse liability clinical trial. This trial was a phase 1 type clinical trial in 42 healthy, non-dependent recreational drug abusers, to determine the exposure, abuse potential, and safety of crushed intranasal (IN) KP201/APAP relative to crushed IN Norco® (hydrocodone bitartrate/APAP). KemPharm plans to present the full human abuse liability data package as part of its 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) as early as by the end of 2015.

In summary, data from the KP201.A02 intranasal human abuse liability trial confirmed that KP201/APAP may be able to limit hydrocodone exposure as compared to Norco® when both are administered intranasally. Liking scores were not significantly different, which KemPharm believes was potentially due to the effects of APAP. These results reaffirm the key properties of KP201/APAP that were observed in the prior oral human abuse liability trial (KP201.A01) and intranasal human abuse liability trial (KP201.A03).

KP201.A02 Study Highlights

- IN KP201/APAP exhibited significant pharmacokinetic differences from IN Norco® due primarily to a significant increase in time to achieve peak exposure (T_{max})($p = 0.0001$) and lower peak hydrocodone exposure (C_{max}) for KP201/APAP ($p = 0.0027$).
- IN KP201/APAP did not result in greater hydrocodone exposure and produced a similar pharmacokinetic profile compared to both KP201/APAP and Norco® taken orally.
- Hydrocodone exposure through peak drug effect showed a statistically significant reduction for IN KP201/APAP vs. IN Norco®:

    - 0-0.5 hour: 50.1% reduction (p = 0.0044);
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- Based on this reduced exposure to hydrocodone, drug liking through peak effect (2.0 hours) was significantly lower for IN KP201/APAP vs. IN Norco® (p<0.0001).
- Mean peak drug liking (E_{max}) was lower for KP201/APAP, both IN (75.9) and oral (76.9), compared to that of Norco® (79.0, IN; 77.9, oral), though liking scores were statistically similar for all treatments, which KemPharm believes was potentially due to the effects of APAP.
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- As seen in the KP201.A03 trial, ease of insufflation scores suggest that KP201/APAP is more difficult to snort than IN Norco®, indicating that both KP201 by itself and KP201/APAP are likely difficult to "snort."

Travis C. Mickle, Ph.D., President and CEO of KemPharm, stated, "Completion of the second intranasal human abuse liability trial of KP201/APAP is an important milestone for KemPharm as it marks the completion of our current clinical program for KP201/APAP. Overall, we believe that the KP201/APAP human abuse liability program succeeded in demonstrating that the prodrug design of KP201/APAP offers the ability to limit opioid exposure when misused, either intranasally (with and without APAP), intravenously, smoked, or orally at high doses, when compared to non-prodrug formulations. We believe the abuse deterrent attributes of KP201/APAP offer significant improvements compared to other non-abuse-deterrent immediate release formulations and perhaps indicate an overall safer product. If approved by the FDA, KP201/APAP has the potential to be the first immediate release, abuse deterrent hydrocodone/APAP option for acute pain. While the abuse deterrent space continues to produce long-acting opioid options, prescribers currently have essentially no option for prescribing an immediate-release product with these types of abuse deterrent and safety properties."

Dr. Mickle continued, "Based on guidance obtained at our May 2015 pre-NDA meeting with the FDA, we believe the results from the human abuse liability program have the potential to support FDA Category 1 and Category 2 abuse-deterrent language in the KP201/APAP product label."

Lynn Webster M.D., FACPM, FASAM, Pain Specialist and Past President of the American Academy of Pain Medicine, commented, "Prodrugs offer a unique and potentially elegant solution to the problem of prescription opioid abuse in that the technology deters tampering and abuse on the molecular level thereby ensuring that misdirected or excessive opioid exposure is limited. Exposure is the ultimate risk. If exposure can be lowered, as appears to be the case with KP201 alone or with APAP, the risk to the patient or abuser should also be lower."

KP201.A02 Intranasal Human Abuse Liability Trial Design and Results:
This randomized, double-blind, double-dummy, placebo-controlled, single-dose, two-part, five-way crossover trial, with 46 subjects enrolled and 42 subjects completed, was designed to determine the exposure, abuse potential, and safety of equivalent doses of both crushed IN and intact (oral) KP201/APAP as compared to both crushed IN and intact (oral) Norco® in opioid-experienced, non-dependent subjects. KP201/APAP demonstrated a lower C_{max}, and a delay in T_{max}, as well as a decrease in exposure to hydrocodone (AUC_{0-2h}), especially in the early time points typically associated with an increased safety risk. Liking data for all treatments were similar, which KemPharm believes was potentially due to the effects of APAP. KP201, both with and without APAP, showed a high difficulty of snorting in both KP201.A02 and KP201.A03 trials even though both were administered as a fine powder. Adverse events were similar across all treatments.

KP201/APAP Human Abuse Liability Program Design and Data Review:
The KP201/APAP human abuse liability program was designed by KemPharm to assess key abuse-deterrence criteria as specified by the FDA. The program included three clinical trials, KP201.A01, KP201.A02 and KP201.A03, as well as three distinct trials designed to evaluate the tamper-resistant properties of KP201/APAP.

Results from the KP201.A01 oral human abuse liability trial, which was designed to measure hydrocodone exposure, drug likability and the safety of KP201/APAP, as compared to Norco®, when taken orally at 4, 8 and 12 tablet dosages, indicated that KP201/APAP resulted in lower exposure to hydrocodone at the two highest dose levels for the trial, as well as lower incidence of hypoxia across the same dosage levels, in each case compared to Norco®, suggesting the potential for improved safety.

Results from the KP201.A02 intranasal human abuse liability trial, which was designed to determine the relative bioavailability, abuse potential, and safety of equivalent doses of crushed and intact KP201/APAP as compared to Norco®, indicated that KP201/APAP, when insufflated, reduces C_{max}, delays T_{max}, and significantly decreases AUC_{0-2h} at early time points typically associated with an increased safety risk.

Data from the KP201.A03 intranasal human abuse liability trial, which was designed to compare the amount of hydrocodone released from KP201 and from hydrocodone bitartrate (HB) (both without APAP) after insufflation, demonstrated a statistically significant reduction in C_{max}, a delay in T_{max}, and a significant decrease in total exposure to hydrocodone (AUC_{last} and AUC_{0-4h}) especially at early time points typically associated with increased drug liking, abuse and safety. Secondary endpoints related to drug liking, pupillometry and ease of snorting also showed significant differences between KP201 and HB, with KP201 demonstrating lower drug liking, less pupil dilation and higher difficulty of snorting than HB.

Lastly, results from three distinct trials designed to evaluate the tamper-resistant properties of KP201/APAP indicated that KP201 remains mostly intact in its inactive prodrug form when being

subjected to various chemical manipulation techniques used commonly by opioid abusers. The trials demonstrated 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. Additionally, KP201/APAP is difficult to prepare for injection and it does not appear to be possible to smoke either KP201 or KP201/APAP.

KemPharm plans to present the FDA with the full KP201/APAP human abuse liability data package as part of its NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for KP201/APAP as early as the end of 2015. KemPharm believes the results from the human abuse liability program may support FDA Category 1 and Category 2 abuse-deterrent language in the KP201/APAP product label. Post-NDA filing, KemPharm plans to conduct additional trials with KP201 to further explore the overdose protective properties of KP201 at high oral doses as exhibited in the KP201.A01 oral human abuse liability trial.

Conference Call Information:
KemPharm will host a conference call and live audio webcast today at 5:00 p.m. ET to review the full KP201/APAP human abuse liability program and results from the KP201.A02 intranasal abuse liability trial.

Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)

An audio webcast will be accessible 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.

Caution Concerning Forward Looking Statements
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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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