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 14, 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.)**
2500 Crosspark Road, Suite E126 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 14, 2016, KemPharm, Inc., or the Company, issued a press release announcing the results of its Phase I proof-of-concept clinical trial of KP415, the Company's prodrug, extended release, or ER, d-threo-methylphenidate, or d-MPH, product candidate for the treatment of attention deficit hyperactivity disorder, or ADHD.

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 the Company’s filings under the Securities Act of 1933, as amended, or the Securities Act, 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.

In the press release described above, on December 14, 2016, the Company announced the results of its Phase I proof-of-concept clinical trial of KP415, or KP415.101. KP415.101 was designed to assess the relative pharmacokinetic, or PK, of 32 mg of KP415 compared with 36 mg of Concerta® after oral administration under fasted conditions. Twenty-four healthy volunteers were enrolled in and completed this open-label, single-dose, two-treatment, two-period, cross-over PK clinical trial. Dosing levels in each treatment did not contain equivalent amounts of d-MPH: 36 mg Concerta contains approximately 12% more d-MPH than 32 mg KP415.

After KP415 dosing, the mean peak plasma concentration, or Cmax, of d-MPH was similar to Concerta at a median time to Cmax, or Tmax, of 3 hours for KP415 and 6 hours for Concerta. When the area under curve, was normalized for dose differences of d-MPH content, they were nearly identical between treatments. The mean terminal elimination plasma half-life of d-MPH was 12 hours for KP415 versus 4 hours for Concerta.

Plasma concentrations of the inactive, intact KP415 molecule were measured after oral administration, which may contribute to the early d-MPH levels and the ER profile of KP415-derived d-MPH. Both treatments were generally well-tolerated and there were no serious adverse events.

Data from the study indicated that KP415 demonstrated PK properties that produce earlier d-MPH exposure followed by a slower extended release of d-MPH relative to the comparator, Concerta.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Exchange Act. 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 features, characteristics, development timeline and potential submission of an NDA for KP415. These forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to the Company 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: the Company's financial resources and whether they will be sufficient to meet the Company'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 the Company's intellectual property; risks related to the drug discovery and the regulatory approval process; the impact of competitive products and technological changes; obligations to third parties regarding the potential commercialization or sale of KP415; and the FDA approval process, including without limitation any timelines for related approval. The Company'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 the Company’s business are described in additional detail in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, and the Company’s other Periodic and Current Reports filed with the Securities and Exchange Commission. The Company 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’s KP415, An Investigational Prodrug of D-Methylphenidate, Completes Phase 1 Proof-of-Concept Trial for the Treatment of ADHD” dated December 14, 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: December 14, 2016

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

Exhibit Index

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99.1	Press Release titled “KemPharm’s KP415, An Investigational Prodrug of D-Methylphenidate, Completes Phase 1 Proof-of-Concept Trial for the Treatment of ADHD” dated December 14, 2016.

Exhibit 99.1

KemPharm's KP415, An Investigational Prodrug of D-Methylphenidate, Completes Phase 1 Proof-of-Concept Trial for the Treatment of ADHD

Both Early and Extended Release of the Methylphenidate Prodrug was observed in the KP415.101 Study

Conference Call and Live Audio Webcast with Dr. Scott Kollins Scheduled for Today at 4:30 p.m., ET

Coralville, IA – December. 14, 2016 – KemPharm, Inc. (NASDAQ:KMPH), a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced the results of its Phase 1 proof-of-concept clinical trial of KP415, KemPharm's prodrug, extended release (ER) d-threo-methylphenidate (d-MPH) product candidate for the treatment of attention deficit hyperactivity disorder (ADHD). Data from the study indicated that KP415 demonstrated pharmacokinetic (PK) properties that produced earlier d-MPH exposure followed by a slower extended release of d-MPH relative to the comparator, Concerta®.

"In this study, the PK data suggest several potential clinically beneficial features of KP415, if it is approved, including a relatively rapid increase and higher overall plasma d-methylphenidate levels compared to other formulations," said Scott Kollins, Ph.D., Professor and Vice Chair for Research Strategy and Development and the Director of the Duke University ADHD Program, following his independent review of the data. "Though additional studies will be necessary to evaluate the safety, efficacy and potential benefits of KP415, the data suggest that the prodrug design of this product could allow for once-daily dosing with a potentially improved onset of action. The prodrug design of KP415 may also add the significant benefit of a lower abuse potential, which could be an important public health benefit."

"We are very pleased with the results of the Phase 1 study of KP415, which demonstrated that the prodrug may, if approved, offer ADHD patients a faster onset of action and a durable therapy. These are properties not seen with any currently marketed ADHD products," stated Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "We believe these attributes may differentiate KP415 from currently marketed and development stage methylphenidate products. The methylphenidate portion of the ADHD market, which is estimated at approximately 19.7 million prescriptions and $4.2 billion in sales for 2015, makes KP415 one of our highest priority pipeline candidates. The next phase in KP415's development is the completion of pivotal studies in 2017, leading to a potential New Drug Application (NDA) for KP415 as early as 2018."

Summary of the Preliminary Results from Study KP415.101.

This Phase 1 proof-of-concept clinical trial (KP415.101) was designed to assess the relative pharmacokinetics (PK) of 32 mg of KP415 compared with 36 mg of Concerta® after oral administration under fasted conditions. Twenty-four healthy volunteers were enrolled in and completed this open-label, single-dose, two-treatment, two-period, cross-over PK clinical trial. Dosing levels in each treatment did not contain equivalent amounts of d-MPH: 36 mg Concerta contains approximately 12% more d-MPH than 32 mg KP415.

After KP415 dosing, the mean peak plasma concentration (Cmax) of d-MPH was similar to Concerta at a median time to Cmax (Tmax) of 3 hours for KP415 and 6 hours for Concerta. When the area under curve (AUC) was normalized for dose differences of d-MPH content, they were nearly identical between treatments. The mean terminal elimination plasma half-life (T1/2) of d-MPH was 12 hours for KP415 versus 4 hours for Concerta. The earlier Tmax and the longer T1/2 for d-MPH after KP415 dosing appears to indicate that KP415 as a prodrug of d-MPH has PK properties that produce early d-MPH exposure that may be maintained during the daytime hours, as desired, for an effective ADHD medication while still maintaining extended release of d-MPH throughout the day.

Plasma concentrations of the inactive, intact KP415 molecule were measured after oral administration, which may contribute to the early d-MPH levels and the ER profile of KP415-derived d-MPH. Both treatments were generally well-tolerated and there were no serious adverse events.

Conference Call Information:
KemPharm will host a conference call and live audio webcast on Wednesday, December 14, 2016, at 4:30 p.m., ET. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 39405141

An audio webcast will be accessible via the Investor Relations section of the KemPharm website http://investors.kempharm.com/. An archive of the webcast will remain available for 30 days beginning at approximately 5:30 p.m., ET, on December 14, 2016.

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 Ligand Activated Therapy (LAT) platform technology. KemPharm utilizes its LAT platform technology to generate improved prodrug versions of U.S. Food and Drug Administration (FDA)-approved drugs in the high need areas of pain, ADHD and other central nervous system (CNS) disorders. KemPharm's co-lead clinical development candidates are KP415, an extended-release (ER) prodrug of methylphenidate for the treatment of attention deficit hyperactivity disorder (ADHD), and KP201/IR, an acetaminophen (APAP)-free formulation of the company's immediate release (IR) abuse deterrent hydrocodone product, KP201. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com.

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