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): August 10, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

On August 10, 2017, KemPharm, Inc., or the Company, issued a press release announcing preliminary results of KP415.109, a Phase 1 trial designed to assess the relative pharmacokinetics, or PK, of three different formulations of KP415 vs. a methylphenidate-containing comparator product, or Concerta, at both single and multiple dose conditions. KP415 is the Company's co-lead attention deficit hyperactivity disorder, or ADHD, product candidate.

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 August 10, 2017, the Company announced preliminary results of KP415.109. The Phase 1 clinical trial, or KP415.109, was designed to assess the relative PK of three different co-formulations of the KP415 extended release, or ER, prodrug in combination with immediate release, or IR, d-methylphenidate, or d-MPH, compared with 54mg of Concerta, after oral administration of once-daily doses for seven days under fasted conditions. Forty-eight healthy volunteers (12 per dosing group) were enrolled in and completed this open-label, multiple-dose, parallel-group PK clinical trial. Each co-formulation contained total equivalent amounts of 40 mg d-MPH. PK results were evaluated both on a single-dose basis, after the first day of dosing, and a multiple-dose basis over seven days.

Steady state was reached after a few days of dosing in all groups. The combination of 70% KP415 prodrug, the component with ER characteristics, and 30% IR d-MPH resulted in a mean Day-7 d-MPH trough concentration, or C_{min}; pre-dose on Day-7, of 3.3 ng/mL and a mean Day-7 d-MPH peak concentration, or C_{max}, of 20.9 ng/mL, at a median T_{max} of 1.5 hours.

On Day-7, the mean systemic exposure over the dosing interval, or AUC_{0-24}, for d-MPH was 208 ng•hr/mL for all completers and the mean terminal elimination plasma half-life, or $T_{1/2}$, of d-MPH was 8.9 hr. The mean accumulation ratios, or Day-7/Day-1 ratios, for C_{min}, C_{max} and AUC_{0-24} were 1.31, 1.20 and 1.34, respectively. The combination of the 70%/30% KP415/d-MPH resulted in early peak d-MPH exposure followed by sustained d-MPH exposure, as desired for chronic, once-per-day treatment of ADHD in a pediatric population. Based on previously established PK of MPH-based products, KP415 may show an effect vs. placebo from 0.5 hours to 13 hours as substantial plasma concentrations of active MPH were measured during this time period. This may provide both early onset of action with total duration that may exceed 12.5 hours based on available data.

Plasma concentrations of the inactive, intact KP415 prodrug molecule were measured after oral administration, which may contribute to the ER profile of KP415-derived d-MPH. Intact KP415 did not accumulate after multiple doses, and its mean $T_{1/2}$ on Day-7 was 5.1 hours.

Both treatments were generally well-tolerated and there were no serious adverse events.

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 and characteristics of KP415, the expected timing of the initiation and completion of any clinical trials of KP415 and the expected timing for any submission of a New Drug Application with the U.S. Food and Drug Administration 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; and the FDA approval process under the Section 505(b)(2) regulatory pathway, 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 Annual Report on Form 10-K for the year ended December 31, 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 Announces Preliminary Results from KP415 Pharmacokinetic Single and Multiple Dose Trial" dated August 10, 2017.

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: August 10, 2017

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer

Exhibit Index

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EXHIBIT 99.1

KemPharm Announces Preliminary Results from KP415 Pharmacokinetic Single and Multiple Dose Trial

Phase I Study Results Demonstrated Early Peak Exposure to d-Methylphenidate followed by Sustained Duration in both Single and Multiple Dose Settings

Coralville, IA – August 10, 2017 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced preliminary results of KP415.109, a Phase I trial designed to assess the relative pharmacokinetics (PK) of three different formulations of KP415 vs. a methylphenidate-containing comparator product (Concerta®) at both single and multiple dose conditions. KP415 is KemPharm's co-lead ADHD product candidate.

"We are very pleased to report that our proposed co-formulation of our proprietary extended release (ER) KP415 d-methylphenidate (d-MPH) prodrug together with immediate release (IR) d-MPH demonstrated expected PK parameters in this Phase I trial and is now being readied for further development in a safety and efficacy clinical trial later this year," said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "The trial demonstrated the expected early peak exposure due to the IR d-MPH component of the co-formulation, which was followed by sustained exposure to d-MPH from the ER KP415 prodrug over the course of the day, leading us to believe that our product candidate may have a longer total duration than current methylphenidate-based products. Steady state exposure was reached after a few days with a negligible accumulation of the prodrug and sustained a duration similar that of Concerta after the 12-hour time point."

"There is a clear need for an extended-release methylphenidate product, with the potential benefit of early onset and longer total duration, as a treatment option for patients," said Ann Childress, M.D., an attention deficit hyperactivity disorder (ADHD) expert, and President of the Center for Psychiatry and Behavioral Medicine. "Many patients prefer methylphenidate, but currently must take multiple doses of existing methylphenidate products. That means multiple prescriptions, multiple copays and the inconvenience of multiple daily doses. I am thrilled to see KP415 advance in development."

"Given that this Phase I study performed as anticipated, we remain on schedule to begin the single pivotal efficacy clinical trial of KP415 prior to the end of this year," added Mickle. "Assuming the results of the pivotal trial are positive, we anticipate submitting a New Drug Application (NDA) with the FDA prior to the end of 2018. We are excited for the potential KP415 now has highlighted for us."

Data Presentation

Travis C. Mickle, Ph.D., will present the KP415 Phase I data today at the Canaccord Genuity 37th Annual Growth Conference being held at the InterContinental Boston Hotel, in the New York room at 2:00PM (EDT). The presentation will be webcast and available on the Investor Relations section of the Company's website at http://investors.kempharm.com/.

Summary of the Preliminary Results from Study KP415.109

The Phase 1 clinical trial (KP415.109) was designed to assess the relative pharmacokinetics (PK) of three different co-formulations of the KP415 ER prodrug in combination with IR d-MPH, compared with 54mg of Concerta (ER MPH), after oral administration of once-daily doses for 7-days under fasted conditions. Forty-eight healthy volunteers (12 per dosing group) were enrolled in and completed this open-label, multiple-dose, parallel-group PK clinical trial. Each co-formulation contained total equivalent amounts of 40 mg d-MPH. PK results were evaluated both on a single-dose basis (after the first day of dosing) and a multiple-dose basis over seven days.

Steady state was reached after a few days of dosing in all groups. The combination of 70% KP415 prodrug (the component with extended release (ER) characteristics) and 30% IR d-MPH resulted in a mean Day-7 d-MPH trough concentration (C_{min}; pre-dose on Day-7) of 3.3 ng/mL and a mean Day-7 d-MPH peak concentration (C_{max}) of 20.9 ng/mL, at a median T_{max} of 1.5 hours.

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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 LAT™ (Ligand Activated Therapy) 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 central nervous system disorders. KemPharm's co-lead clinical development candidates are KP415 and KP484, both based on a prodrug of methylphenidate, but with differing extended-release profiles for the treatment of ADHD, and KP201/IR, an acetaminophen-free formulation of the company's immediate release abuse deterrent hydrocodone product candidate, KP201. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com.

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