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): June 28, 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 8.01 Other Events.

On June 28, 2016, KemPharm, Inc., or the Company, announced results from a Phase 1 proof-of-concept trial of KP511, the Company's prodrug of hydromorphone. In the trial, the Company observed comparable hydromorphone exposure between 4 mg Dilaudid™ Oral Liquid and an equimolar 8 mg dose of KP511. The Company is developing KP511 as an abuse-deterrent, extended-release (ER) formulation for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatments are inadequate (KP511/ER).

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K, the contents of which are incorporated herein by reference. The information contained in this Current Report on Form 8-K speaks only as the date hereof. While the Company may elect to update the information in this Current Report on Form 8-K in the future, the Company disclaims any obligation to do so except to the extent required by applicable law.

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 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 features and characteristics of KP511 and the timelines surrounding potential clinical trials for KP511 and the submission of an NDA for KP511/ER. 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 Quarterly Report on Form 10-Q for the quarter ended March 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's Prodrug of Hydromorphone, KP511, Demonstrates Comparable Oral Pharmacokinetics to Hydromorphone in Phase 1 Trial" dated June 28, 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: June 28, 2016

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release titled "KemPharm's Prodrug of Hydromorphone, KP511, Demonstrates Comparable Oral Pharmacokinetics to Hydromorphone in Phase 1 Trial" dated June 28, 2016.

EXHIBIT 99.1

KemPharm's Prodrug of Hydromorphone, KP511, Demonstrates Comparable Oral Pharmacokinetics to Hydromorphone in Phase 1 Trial

KP511 clinical data consistent with preclinical animal data

Coralville, IA – June 28, 2016 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced results from a Phase 1 proof-of-concept trial (KP511.101) with KP511, KemPharm's prodrug of hydromorphone. In the trial, KemPharm observed comparable hydromorphone exposure between 4 mg Dilaudid™ Oral Liquid and an equimolar 8 mg dose of KP511. KemPharm is developing KP511 as an abuse-deterrent, extended-release (ER) formulation for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatments are inadequate (KP511/ER).

"We are pleased that KP511 continues to confirm our Ligand Activated Therapy (LAT) prodrug approach by delivering human pharmacokinetic data consistent with our preclinical animal model. The data from the Phase 1, proof-of-concept trial suggest that oral administration of KP511 in solution efficiently releases hydromorphone with a pharmacokinetic profile that is similar to Dilaudid Oral Liquid. This represents an important developmental milestone in the advancement of KP511 as an abuse-deterrent, ER pain therapeutic," stated Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "The next steps are to finalize the clinical program for KP511/ER and the anticipated trials that will be used to assess tamper and extraction resistance, intranasal and intravenous abuse potential, as well as the potential to limit oral abuse and/or overdose."

KemPharm plans to seek approval of KP511/ER under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act with an anticipated New Drug Application (NDA) submission as early as 2018. In May, KemPharm was granted "Fast Track" designation by the U.S. Food and Drug Administration (FDA) for KP511.

KP511 Phase 1 Proof-of-Concept Trial Results

The Phase 1 proof-of-concept trial was designed to assess the bioavailability of 4 mg, 8 mg and 16 mg doses of KP511 compared with 4 mg of Dilaudid Oral Liquid (equivalent to 8 mg of KP511) after oral administration under fasted conditions. Twenty-four (24) healthy volunteers were enrolled in this single dose, four treatment, four period, four sequence pharmacokinetic trial.

In the trial, KP511 effectively released the active hydromorphone into the bloodstream while no intact prodrug was found in the systemic circulation of any subject. The equivalent doses, 8 mg of KP511 and 4 mg of Dilaudid Oral Liquid, were bioequivalent with regard to overall hydromorphone exposure (AUClast and AUCinf). Peak exposure (Cmax) was approximately 19% lower for KP511. Similar reductions of approximately 15% and 17%, respectively, in dose-adjusted peak hydromorphone exposure were observed for the 4 mg and 16 mg doses of KP511 with dose-linear Cmax values across all three doses. Median time to peak exposure (Tmax) was 0.5 hours for all treatments. These results were consistent with previously collected preclinical data. In the trial, KP511 demonstrated a similar safety profile as Dilaudid and was well-tolerated with only adverse events reported that are typical for oral opioids.

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 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.

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