
**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): September 24, 2015

KEMPHARM, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36913
(Commission File Number)

20-5894398
(IRS Employer
Identification No.)

**2656 Crosspark Road, Suite 100
Coralville, IA**

(Address of Principal Executive Offices)

52241
(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))
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Item 7.01 Regulation FD Disclosure.

On September 24, 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, Inc.’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 September 24, 2015, KemPharm announced that it has initiated the development of an acetaminophen-free, or APAP-free, formulation of its immediate release hydrocodone product, KP201. Based on current development timelines, KemPharm anticipates human proof-of-concept, or PoC, data for APAP-free KP201 in 2016, with a potential New Drug Application, or NDA, filing in 2017. KemPharm also announced an update to its product candidate pipeline as follows:

Pain			
Hydrocodone (IR)	KP201/APAP	Clinical	NDA-Filing Q4 2015
Hydrocodone (IR)	KP201/IR (APAP-free)	Preclinical	Human PoC data 2016 NDA-Filing 2017
Hydromorphone (ER)	KP511/ER	Preclinical	Human PoC data 2016 NDA-Filing 2018
Oxycodone (ER)	KP606/ER	Preclinical	Human PoC data 2017 NDA-Filing 2019
ADHD			
Methylphenidate (CR)	KP415	Preclinical	Human PoC data 2016 NDA-Filing 2019

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 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 timing of filing of KemPharm’s anticipated NDAs with the United States Food and Drug Administration, the expected timing of completion of additional clinical trials and the availability of human PoC data related thereto. 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.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “KemPharm Expands its Abuse-Deterrent Opioid Pipeline with New Acetaminophen-Free, Immediate Release Hydrocodone and Immediate Release Oxycodone Prodrug Product Candidates” dated September 24, 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: September 24, 2015

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

Exhibit Index

Exhibit No.

Description

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KemPharm Expands its Abuse-Deterrent Opioid Pipeline with New Acetaminophen-Free, Immediate Release Hydrocodone and Immediate Release Oxycodone Prodrug Product Candidates

Provides Updates on Clinical Development Pipeline and Anticipated NDA Filings

Coralville, IA – September 24, 2015 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, announced today that KemPharm has initiated the development of an acetaminophen (APAP)-free formulation of its immediate release (IR) hydrocodone product, KP201, adding to its hydrocodone prodrug pipeline of product candidates. KemPharm expects this highly differentiated product candidate to feature the same abuse-deterrent properties demonstrated by KP201/APAP, KemPharm's most advanced product candidate, in the most recent clinical trial, KP201.A03. In addition, the Company announced it has initiated the development of an IR formulation of its oxycodone prodrug, KP606.

Product Development Strategy

Pain			
Hydrocodone (IR)	KP201/APAP	Clinical	NDA-Filing Q4 2015
Hydrocodone (IR)	KP201/IR (APAP-free)	Clinical	NDA-Filing 2017
Hydromorphone (ER)	KP511/ER	Preclinical	NDA-Filing 2018
Oxycodone (IR)	KP606/IR	Preclinical	NDA-Filing 2019
ADHD			
Methylphenidate (CR)	KP415	Preclinical	NDA-Filing 2019

Based on current development timelines, KemPharm anticipates a potential New Drug Application (NDA) filing for acetaminophen-free KP201 in 2017. KP201/IR would be the first IR, acetaminophen-free hydrocodone option available to physicians. In response to the favorable oral exposure data from the KP201.A01 trial, KemPharm is also preparing additional high strengths of both KP201/APAP and KP201/IR (APAP-free) to provide physicians additional flexibility and choices for pain management.

These programs add to KemPharm's pipeline of opioid prodrug product candidates, which includes KP511/ER, an extended release (ER) formulation of its prodrug of hydromorphone, and KP606/IR, a new IR formulation of the Company's prodrug of oxycodone. In addition, KemPharm is developing KP415, a prodrug of methylphenidate with controlled release (CR)

features, for managing ADHD. KemPharm continues to build a pipeline of discovery stage candidates and expects additional preclinical candidates to be announced by year-end.

Travis C. Mickle, Ph.D., President and CEO of KemPharm, stated, "Adding acetaminophen-free KP201 to our pipeline represents a significant opportunity to extend our hydrocodone prodrug pipeline of product candidates and could potentially provide patients and physicians with a prescription opioid product that is currently not available. Further, we expect to rapidly develop KP201/IR (APAP-free), which could highlight the value of our LAT prodrug technology, specifically as it relates to the speed with which we may be able to advance our multiple product candidates from early- to late stage clinical development. Beginning with KP201/IR (APAP-free) as early as 2017, we anticipate filing at least one new NDA each year through 2019, potentially bringing multiple highly differentiated and potentially safer products to the market over the next several years."

Dr. Mickle concluded, "The Company understands the importance of immediate release products in the treatment of pain and believes that creating abuse deterrent and safer IR products is important for prescribers and patients. The addition of KP201/IR (APAP-free) and our IR oxycodone prodrug, KP606/IR, highlights KemPharm's focus and progress in this important area."

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.

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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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For KemPharm, Inc.:

Gordon K. "Rusty" Johnson
319-665-2575
info@kempharm.com

Media / Investor Contacts:

Jason Rando / Joshua Drumm, Ph.D.
[Tiberend Strategic Advisors, Inc.](http://TiberendStrategicAdvisors.com)
212-375-2665 / 2664
jrando@tiberend.com
jdrumm@tiberend.com