# 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): May 5, 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**<br>**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 May 5, 2016, KemPharm, Inc., or the Company, announced that the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) recommended approval of Apadaz™ (benzhydrocodone hydrochloride and acetaminophen), for its proposed indication of the management of acute pain that requires an opioid and voted against inclusion of abuse deterrent labeling for the product.

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.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release titled "Statement Regarding FDA Advisory Committee Meeting on KemPharm's Abuse-Deterrent Product Candidate Apadaz™" dated May 5, 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: May 5, 2016

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

**Exhibit Index**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release titled “Statement Regarding FDA Advisory Committee Meeting on KemPharm’s Abuse-Deterrent Product Candidate Apadaz™” dated May 5, 2016. |

**EXHIBIT 99.1**

# Statement Regarding FDA Advisory Committee Meeting on KemPharm's Abuse-Deterrent Product Candidate Apadaz™

**Coralville, IA – May 5, 2016 –** KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) reviewed and voted on Apadaz™ (benzhydrocodone hydrochloride and acetaminophen), KemPharm's investigational abuse-deterrent product candidate for the short-term management of acute pain.

The Committee determined by a vote of 16 to 4 in that Apadaz should be approved for its proposed indication of the management of acute pain that requires an opioid and voted 18 to 2 against inclusion of abuse deterrent labeling for the product.

"We continue to believe in the value of our prodrug technology as a platform for developing prescription opioids with abuse-deterrent properties," said Travis C. Mickle, Ph.D., President and CEO of KemPharm. "While it is inevitable that there will be different points of view when evaluating new molecular entities with abuse-deterrent properties, we will continue to work collaboratively with the FDA to complete the review process of Apadaz."

Apadaz is an abuse-deterrent, immediate release (IR) fixed-dose combination product candidate composed of benzhydrocodone hydrochloride (HCl), a prodrug of hydrocodone and benzoic acid, and acetaminophen (APAP). The FDA will consider, but is not bound by, the advisory committees' recommendations as it continues its review of Apadaz. A target action date of June 9, 2016, has been set by the FDA under the Prescription Drug User Fee Act (PDUFA).

**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.

**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 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 timing of completion of review, of the Apadaz NDA by the FDA, KemPharm's plans to continue to work with the FDA to complete the review process of Apadaz, and that the FDA will consider the advisory committees' recommendations as it continues it priority review of Apadaz. 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; 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. 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and in 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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