
**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 13, 2016

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 June 13, 2016, KemPharm, Inc., or the Company, announced that the U.S. Food and Drug Administration, or the FDA, issued a Complete Response Letter, or CRL, regarding the New Drug Application, or NDA, for Apadaz™ (benzhydrocodone hydrochloride and acetaminophen), the Company's investigational abuse-deterrent product candidate for the short-term management of acute pain.

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.

As described above, the FDA issued a CRL regarding the NDA for Apadaz. The CRL indicated that the review cycle for the Apadaz NDA is complete and the application is not ready for approval in its present form. The Company is currently evaluating the points raised in the CRL and intends to request an End of Review meeting with the FDA to determine the pathway forward for Apadaz.

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 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 Company's plans to work with the FDA to continue the review process 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 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 the review process. 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 fiscal year ended December 31, 2015, and in 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 "FDA Issues Complete Response Letter for Apadaz™ New Drug Application" dated June 13, 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 13, 2016

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

Exhibit Index

Exhibit No.

Description

99.1	Press Release titled "FDA Issues Complete Response Letter for Apadaz™ New Drug Application" dated June 13, 2016.
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FDA Issues Complete Response Letter for Apadaz™ New Drug Application

Coralville, IA – June 13, 2016 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for Apadaz™ (benzhydrocodone and acetaminophen), KemPharm's investigational abuse-deterrent product candidate for the short-term management of acute pain.

The FDA issues CRLs to indicate that the Agency considers the review cycle for an application is complete and that the application is not ready for approval in its present form. Included in the CRL is guidance that describes all specific deficiencies that the FDA has identified in the application. When possible, the FDA recommends actions that the applicant may take to place the application in condition for approval.

“After last week’s amendment request, a Complete Response Letter from the FDA was received for the Apadaz NDA,” said Travis C. Mickle, Ph.D., President and CEO of KemPharm. “We are currently evaluating the points raised in the CRL and intend to request an End of Review meeting with the Agency to determine the pathway forward for Apadaz.”

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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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 KemPharm’s plans to work with the FDA to continue the review process 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 the review process. 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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