
**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 9, 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 9, 2016, KemPharm, Inc., or the Company, announced that it has filed with the U.S. Food and Drug Administration, or the FDA, an amendment request to its 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 KemPharm'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.

On June 9, 2016, the Company announced that the FDA provided the Company with a draft label for Apadaz that does not include abuse-deterrent language.

As described above, on June 9, 2016, the Company filed with the FDA an amendment to its NDA for Apadaz. The amendment is focused on providing to the FDA additional information the Company seeks to include in the FDA's current review of the Apadaz NDA. The FDA is reviewing the request and their determination is anticipated to impact the previously announced target action date for Apadaz of June 9, 2016 set by the FDA under the Prescription Drug User Fee Act.

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 expected timing of completion of review, and approval, of the Apadaz NDA by the FDA, and the Company's plans to continue to work with the FDA to complete 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 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 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

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release titled “KemPharm Files NDA Amendment Request with FDA for Apadaz™” dated June 9, 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 9, 2016

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

Exhibit Index

Exhibit No.

Description

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|------|--|
| 99.1 | Press Release titled "KemPharm Files NDA Amendment Request with FDA for Apadaz™" dated June 9, 2016. |
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KemPharm Files NDA Amendment Request with FDA for Apadaz™

Discussions On-going with FDA on Potential Apadaz Product Labeling

Coralville, IA – June 9, 2016 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that it has filed with the U.S. Food and Drug Administration (FDA) an amendment request to its New Drug Application (NDA) for Apadaz™ (benzhydrocodone hydrochloride and acetaminophen), KemPharm's investigational abuse-deterrent product candidate for the short-term management of acute pain.

The amendment is focused on providing to the FDA additional information KemPharm seeks to include in the FDA's current review of the Apadaz NDA. The FDA is reviewing the request and their determination is anticipated to impact the previously announced target action date for Apadaz of June 9, 2016 set by the FDA under the Prescription Drug User Fee Act.

“While the FDA's provided us with a draft label, we feel that additional information could strengthen the draft, with a focus on the section relating to abuse-deterrent product labeling. Our discussions with the FDA have been constructive and we are hopeful that we can agree on an approval pathway that includes abuse-deterrent labeling for Apadaz,” said Travis C. Mickle, Ph.D., President and CEO of KemPharm.

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, attention deficit hyperactivity disorder and other central nervous system 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, and approval, 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 any potential changes to the FDA's proposed labelling for 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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