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 12, 2017

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.)**
2500 Crosspark Road, Suite E126 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

On September 12, 2017, KemPharm, Inc., or the Company, issued a press release announcing the completion of the Formal Dispute Resolution Request, or FDRR, process with the U.S. Food and Drug Administration, or FDA, for Apadaz™ (benzhydrocodone and acetaminophen). A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Also on September 12, 2017, the Company will conduct a conference call and live audio webcast to discuss these matters.

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.

In the press release described above, on September 12, 2017, the Company announced the completion of the FDRR process with the FDA for Apadaz™. Following detailed discussions with the FDA, the Company has responded to the Complete Response Letter received on June 13, 2016, by submitting an amended New Drug Application, or NDA, for Apadaz™. The FDA has notified the Company with the determination that the NDA application for Apadaz™ is complete and has assigned February 23, 2018 as the expected date by which an approval decision will be determined. Apadaz™ is the Company’s investigational product candidate that is intended to provide short-term management of acute pain.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K and the materials furnished herewith 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 potential outcome of the FDA’s review of the amended NDA for Apadaz™, the potential labeling for Apadaz™, the potential commercial pathway for Apadaz™ and the expected features and characteristics of KemPharm’s product candidates, including 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 Quarterly Report on Form 10-Q for the period ended June 30, 2017, 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 Announces FDRR Process Completion and Resubmission of the Apadaz™ NDA” dated September 12, 2017.

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 12, 2017

By: /s/ Timothy J. Sangiovanni
Timothy J. Sangiovanni, CPA
Vice President, Corporate Controller

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release titled “KemPharm Announces FDRR Process Completion and Resubmission of the Apadaz™ NDA” dated September 12, 2017.

EXHIBIT 99.1

KemPharm Announces FDRR Process Completion and Resubmission of the Apadaz™ NDA

FDA Has Assigned a PDUFA Action Date of February 23, 2018

Conference Call and Live Audio Webcast Today at 8:30 a.m. ET

Coralville, IA – September 12, 2017 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced completion of the Formal Dispute Resolution Request (FDRR) process with the U.S. Food and Drug Administration (FDA) for Apadaz™ (benzhydrocodone and acetaminophen). Following detailed discussions with the FDA, KemPharm has responded to the Complete Response Letter (CRL) received on June 13, 2016 by submitting an amended New Drug Application (NDA) for Apadaz™. The FDA has notified the Company with the determination that the NDA application for Apadaz™ is complete and has assigned February 23, 2018 as the expected date by which an approval decision will be determined. Apadaz™ is KemPharm's investigational product candidate that is intended to provide short-term management of acute pain.

"We are very pleased to have completed the FDRR process and are appreciative of the FDA's response," stated Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "The discussions with the FDA provided clarity in the areas of disagreement concerning the appropriate information for the Apadaz™ product label, especially their determination that intranasal abuse of immediate release hydrocodone/acetaminophen is a relevant concern. If approved, we believe that there may be a potential commercial pathway for which truthful and non-misleading information about our clinical data can be included in the labeling, subject to review of our amended NDA for Apadaz™ by the FDA."

"When we initiated the FDRR process, it was done with the expectation that it would provide an open forum to discuss questions of science and policy involving appropriate labeling language for Apadaz™," added Dan Cohen, Executive Vice President, Government and Public Relations. "While the FDA formally denied our appeal in the FDRR due to the nature of the label dispute in the CRL, they provided us with valuable insights into the criteria that the FDA will use to evaluate the label information we submitted in our amended NDA for Apadaz™. We thank the Review Division, Office of Drug Evaluation II, Office of New Drugs, and the Center for Drug Evaluation and Research (CDER) for their time and professionalism throughout the FDRR review."

KemPharm initiated the FDRR process with the FDA on November 3, 2016, to appeal the CRL for Apadaz™. The appeal was submitted in accordance with the FDRR process following an end-of-review meeting in August 2016 in which the FDA provided the Company with a more complete understanding of its assessment of the NDA. The FDRR process is designed to provide a mechanism for those seeking regulatory approval of a drug product pursuant to an NDA to obtain formal review of any FDA decision. KemPharm believes its amended NDA for Apadaz™ addresses the points raised in the CRL and the amended NDA was resubmitted in accordance with applicable federal regulations for the approval of a new medicinal product (21 CFR 314.110).

Conference Call Information:

The company will host a conference call and live audio webcast today, September 12, 2017, at 8:30 a.m. ET. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 84323733

The live webcast will be accessible via the Investor Relations section of the KemPharm website http://investors.kempharm.com/. An archive of the webcast will remain available following the call.

About the FDA's Formal Dispute Resolution Process
KemPharm's appeal was submitted in accordance with the FDRR process that exists within FDA's CDER. FDA regulations provide a mechanism for those seeking regulatory approval of a drug product pursuant to an NDA to obtain formal review of any FDA decision. The process exists to encourage open, prompt discussion of scientific (including medical) disputes and procedural (including administrative) disputes that arise during the drug development, NDA review, and post-marketing oversight processes. While the FDA rarely grants an appeal during the FDRR process, companies are often able to gain further clarity into the FDA's regulatory requirements for product approval. With this clarity, companies may further assess if the FDA requirements for obtaining regulatory approval will still allow a product candidate to be commercially viable.

About the FDA's Prescription Drug User Fee Act
PDUFA was a law passed by the US Congress initially in 1992, and reauthorized recently in 2017, which allows the FDA to collect fees from drug manufacturers to fund the new drug approval process. PDUFA dates are deadlines for the FDA to approve new drugs. The FDA is normally given 10 months to review new drugs. If a drug is selected for priority review, the FDA is allotted 6 months to review the drug. These time frames begin on the date that an NDA is accepted by the FDA as complete.

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™ (Ligand Activated Therapy) 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 (ADHD) and other central nervous system disorders. KemPharm's lead clinical development candidates are KP415 and KP484, both based on a prodrug of methylphenidate, but with differing extended-release profiles for the treatment of ADHD, and KP201/IR, an acetaminophen-free formulation of the company's immediate release abuse deterrent hydrocodone product candidate, KP201. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com.

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Investor Contacts:
Jason Rando / Joshua Drumm, Ph.D.
Tiberend Strategic Advisors, Inc.
212-375-2665 / 2664
jrando@tiberend.com
jdrumm@tiberend.com

Media Contact:
Daniel L. Cohen
Executive VP, Government and Public Relations
KemPharm, Inc.
202-329-1825
dcohen@kempharm.com