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 15, 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 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On September 15, 2016, KemPharm, Inc., or the Company, announced that the employment of Tracy Woody, the Company's chief commercial officer, ended effective as of September 15, 2016.

In accordance with the terms of Ms. Woody's employment agreement dated March 30, 2015 (previously filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q as filed with the Securities and Exchange Commission on May 29, 2015), as amended on September 4, 2015 (previously filed as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q as filed with the Securities and Exchange Commission on November 13, 2015), upon the execution of a release of claims, Ms. Woody is eligible to receive the following severance benefits: (a) an amount equal to 12 months of her annual base salary, less applicable deductions, payable in accordance with the Company's normal payroll schedule, (b) a pro rata bonus award payable on the first regularly scheduled pay day following the 60th day after her termination, (c) 12 months of continued health coverage and (d) full vesting of her outstanding equity awards.

Item 7.01 Regulation FD Disclosure.

On September 15, 2016, the Company issued a press release announcing several corporate and clinical updates as a follow up to the Company's second quarter 2016 business and financial update.

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.

In the press release described above, on September 15, 2016, the Company announced that it has designated KP415, the Company's extended release, or ER, d-threo-methylphenidate product for the treatment of attention deficit hyperactivity disorder, and KP201/IR, the Company's single-entity, benzhydrocodone hydrochloride immediate-release, or IR, abuse-deterrent product candidate designed for the treatment of acute pain, as its two lead product candidates. As a result, the Company now anticipates the filing of New Drug Applications, or NDAs, for KP415 and KP201/IR in 2018.

The Company expects to file the Investigational New Drug, or IND, application for KP415 prior to the close of the third quarter of this year. Based on this timeline, the Company's plan is to initiate and complete proof-of-concept studies before the end of 2016 with human clinical trials potentially during the first half of 2017.

The Company will also continue to advance the development of an abuse-deterrent, ER formulation of KP511, the Company's prodrug of hydromorphone, or KP511/ER. However, the need to add external ER technology, as well as the investigation of the potential for both overdose protection and limitation of opioid induced constipation, has required the Company to extend the original timeline for this product candidate. The Company now anticipates filing a NDA for KP511/ER in 2019.

The Company also announced on September 15, 2016 that it has notified the United States Food and Drug Administration, or the FDA, that it will elect to continue the regulatory review process for Apadaz with the submission of a Formal Dispute Resolution Request, or FDRR. The Company anticipates up to twelve months may be required to complete all parts of the FDRR process.

The intent of a FDRR submission is to provide a pathway by which applicants seek to resolve scientific and/or medical policy disputes that cannot be resolved at the Division of Anesthesia, Analgesia and Addiction Products, or the Division, level within the FDA. If an issue is not resolved at the Division level, the applicant may request that the matter be reviewed at the next higher management level. The Company has elected to pursue a FDRR in order to address and hopefully resolve certain disagreements with the Division's interpretation of the "Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling" and the data provided within the Apadaz NDA related to the potential abuse-deterrence properties of the product candidate. The issues for the FDRR are solely related to these abuse-deterrence properties of Apadaz and what constitutes abuse-deterrence in the context of a label claim.

Given the anticipated timeline for the FDRR and, if successful, the time needed to submit any required elements to modify the existing Apadaz NDA, the Company has decided to defer its commercial operations and realign its financial resources and operational priorities towards its product development pipeline. With this strategic adjustment, the Company has eliminated the positions of several managers and executives from the Company's commercial team, including that of Ms. Woody as described in more detail in Section 5.02 of this Current Report on Form 8-K.

The Company also provided an update on its anticipated cash position as of September 15, 2016. Based on the Company's updated corporate, operational and clinical plans, the Company anticipates that its current cash on hand may fund the Company through 2018.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K 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 features and characteristics of KP201/IR, KP415 and KP511/ER and the timelines surrounding potential clinical trials for KP415, the expected timing of filing of an IND for KP415, potential submissions of NDAs for KP201/IR, KP415 and KP511/ER, the outcome of the FDRR process for Apadaz and the Company's ability to fund its operations through 2018. 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 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 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 quarter ended June 30, 2016, 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, Inc. Provides Corporate and Clinical Update” dated September 15, 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: September 15, 2016

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release titled “KemPharm, Inc. Provides Corporate and Clinical Update" dated September 15, 2016.

Exhibit 99.1

KemPharm, Inc. Provides Corporate and Clinical Update

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

- KemPharm adjusts product development timelines following full pipeline analysis and positions KP415 and KP201/IR as lead product candidates to capitalize on favorable developmental, regulatory and market conditions
- Announces intent to begin the Formal Dispute Resolution regulatory process with the FDA for Apadaz™
- Defers commercial program for Apadaz

Coralville, IA – Sept. 15, 2016 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced several key corporate and clinical updates as a follow up to the Company's second quarter 2016 business and financial update.

Ligand Activated Therapy (LAT) Prodrug Pipeline Update:
After a thorough evaluation of its entire drug development pipeline, KemPharm has designated KP415, the Company's extended release (ER) d-threo-methylphenidate (d-MPH) product for the treatment of attention deficit hyperactivity disorder (ADHD), and KP201/IR, the Company's single-entity, benzhydrocodone hydrochloride (HCl) immediate-release (IR), abuse-deterrent product candidate designed for the treatment of acute pain, as its two lead product candidates. This decision was based on KemPharm's comprehensive review of the expected development timelines, regulatory pathways and market economics for each product candidate. As a result, KemPharm now anticipates the filing of New Drug Applications (NDAs) for KP415 and KP201/IR in 2018, and for the ER formulation of KP511, KemPharm's prodrug of hydromorphone, in 2019.

"We believe KP415 and KP201/IR represent substantial value opportunities for KemPharm as each offers the potential to address important patient, prescriber and market needs," stated Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "Based on the strength of our existing data, as well as what we believe are favorable developmental, regulatory and market conditions, we are advancing KP415 and KP201/IR as our lead pipeline candidates and expect to meet several clinical and regulatory milestones for each product candidate prior to year-end and over the course of the next 18 to 24 months."

In preclinical studies of KP415, KemPharm observed features that could provide significant benefits when compared with other FDA-approved and widely prescribed methylphenidate products. Pharmacokinetic data from preclinical studies suggest that the time to maximum plasma concentration of methylphenidate after oral administration of KP415 is approximately three times longer compared to currently marketed IR methylphenidate. As a prodrug that requires metabolism, KemPharm believes KP415 may be able to deliver d-MPH more consistently than the current formulation based approaches. This improved delivery may provide more consistent therapy.

Dr. Mickle commented, “KemPharm expects to file the Investigational New Drug (IND) application for KP415 prior to the close of the third quarter of this year. Based on this timeline, our plan is to initiate and complete proof-of-concept studies before the end of 2016 with human clinical trials potentially beginning during the first half of 2017. This would put KemPharm on target to potentially file an NDA for KP415 in 2018 with the potential to introduce a differentiated product to the ADHD market that could enable a more predictable therapy compared with currently available, IR d-MPH products.”

As previously reported, KemPharm completed its End-of-Phase 1 (EOP1) meeting with the FDA for KP201/IR on June 23, 2016. KemPharm had requested an EOP1 meeting for KP201/IR ahead of the anticipated IND application based on the amount of data, both nonclinical and clinical, that was generated from the development of Apadaz™. KemPharm believes that data from its KP201.A03 study, which compared hydrocodone exposure following insufflation of benzhydrocodone HCl (KP201) vs. hydrocodone bitartrate (HB), aligns with the FDA Division of Anesthesia, Analgesia and Addiction Products (Division) criteria for achieving abuse-deterrent product labeling, and may potentially provide KP201/IR with a favorable regulatory pathway.

Dr. Mickle remarked, “We expect to file the IND for KP201/IR during the fourth quarter of 2016 with the potential to initiate human clinical trials in the first quarter of 2017. As previously announced, we guided towards a NDA filing for KP201/IR by year-end 2017 and we are now targeting 2018 to file the KP201/IR NDA due to the acceleration of the KP415 program as well as to allow for current issues within the IR abuse-deterrent opioid space to clarify. We believe this timeline would still enable KP201/IR to potentially reach the market as the first abuse-deterrent IR hydrocodone product as well as the first hydrocodone-related product without acetaminophen.”

KemPharm will maintain the current investment plan to advance the development of an abuse-deterrent, ER formulation of KP511 (KP511/ER). However, the need to add an external ER technology, as well as the investigation of the potential for both overdose protection and limitation of opioid induced constipation, has required KemPharm to extend the original timeline for this product candidate. KemPharm now anticipates filing a NDA for KP511/ER in 2019.

Dr. Mickle stated, “KP511/ER remains an important asset for KemPharm, and we plan to continue its development as we believe a differentiated product with potential abuse-deterrent and patient benefits could capture a significant portion of the estimated $350 million hydromorphone market. However, we have made a strategic decision to dedicate greater R&D and financial resources to the development of KP415 and KP201/IR given what we believe to be the developmental efficiencies and market potential of each product candidate.”

Apadaz Regulatory & Commercial Update:
As previously announced, on August 3, 2016, KemPharm completed its End of Review (EoR) meeting with the FDA for Apadaz (benzhydrocodone and acetaminophen) after receiving a Complete Response Letter (CRL) to the NDA. KemPharm has recently received and reviewed the minutes from the EoR meeting and has notified the FDA that the Company will elect to continue the regulatory review process with the submission of a Formal Dispute Resolution Request (FDRR). KemPharm anticipates up to twelve months may be required to complete all parts of the FDRR process.

The intent of a FDRR submission is to provide a pathway by which applicants seek to resolve scientific and/or medical policy disputes that cannot be resolved at the Division level within the FDA. If an issue is not resolved at the Division level, the applicant may request that the matter be reviewed at the next higher management level. KemPharm has elected to pursue a FDRR in order to address and hopefully resolve certain disagreements with the Divison's interpretation of the "Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling" and the data provided within the Apadaz NDA related to the abuse-deterrence properties of the product candidate. The issues for the FDRR are solely related to the abuse-deterrence properties of Apadaz and what constitutes abuse-deterrence in the context of a label claim.

As reported during the second quarter corporate and financial update, the Apadaz EoR meeting provided clarity into the issues identified by the FDA in the Apadaz NDA and involved discussions of fundamental questions pertaining to abuse deterrence in relation to the broader IR prescription opioid market and hydrocodone-acetaminophen combination products, as well as published industry guidance from the FDA concerning the evaluation and labeling of abuse deterrent opioids. The EoR meeting minutes have confirmed that the Division is focused primarily on Category 3 data in determining whether an IR opioid product is eligible for any abuse-deterrent label claims.

"Though we believe the data submitted in the Apadaz NDA supported important elements of the Category 3 criteria, the data did not meet the endpoints of greatest relevance to the Division," stated Dan Cohen, Executive Vice President of Government and Public Relations. "Consequently, KemPharm and the Division could not agree as to an appropriate label, resulting in the issuance of the CRL, and now the next step is our submission of an appeal through the FDRR process. By this petitioning for review at the next levels within the FDA, we hope to find a path forward for an Apadaz product label that could include abuse deterrence claims."

Given the anticipated timeline for the FDRR and, if successful, the time needed to submit any required elements to modify the existing Apadaz NDA, KemPharm has decided to defer its commercial operations and realign its financial resources and operational priorities towards its product development pipeline. With this strategic adjustment, KemPharm has eliminated the positions of several managers and executives from the Company's commercial team, including that of Tracy M. Woody, Chief Commercial Officer.

Dr. Mickle continued, "Due to the ongoing process with Apadaz, we made the difficult decision to defer our commercial operations and as a result have eliminated several commercial-oriented positions, including that of Tracy Woody and other members of the commercial team. I would like to express my sincerest gratitude to Tracy and her team for their exceptional work and wish them the very best in their future endeavors."

Cash Position & Financial Update:
As of June 30, 2016, total cash, cash equivalents, restricted cash, marketable securities and long-term investments, was $102.6 million. KemPharm continues to assess opportunities to strengthen its balance sheet as it deems advantageous. Based on KemPharm's updated corporate, operational and clinical plans, KemPharm anticipates that current cash on hand may fund the Company through 2018.

Conference Call Information:
The Company will host a conference call and live audio webcast on Thursday, September 15, 2016, 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: 82561137

An audio 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 for 30 days beginning at approximately 9:30 a.m. ET, on September 15, 2016.

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 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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