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): November 9, 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.)**
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))

Item 2.02 Results of Operations and Financial Condition.

On November 9, 2016, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended September 30, 2016, as well as information regarding a conference call and live webcast presentation to discuss these corporate and financial results. A copy of the press release and presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K. The information contained in the press release and presentation furnished as Exhibits 99.1 and 99.2, respectively, 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 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "KemPharm, Inc. Reports Third Quarter 2016 Results" dated November 9, 2016.
99.2	Presentation titled "Third Quarter 2016 Results" dated November 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: November 9, 2016

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release titled “KemPharm, Inc. Reports Third Quarter 2016 Results” dated November 9, 2016.
99.2	Presentation titled "Third Quarter 2016 Results" dated November 9, 2016.

EXHIBIT 99.1

KemPharm, Inc. Reports Third Quarter 2016 Results

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today at 5:00 p.m., ET

Recent Clinical Development & Regulatory Highlights:

- Prioritized KP415 and KP201/IR as co-lead product candidates
- Received clearance from the U.S. Food and Drug Administration (FDA) to initiate clinical program for KP415
- Filed Investigational New Drug (IND) application with FDA for KP201/IR
- Initiated Formal Dispute Resolution Request (FDRR) Process with the FDA for Apadaz™

Recent Corporate and Financial Highlights:

- Announced licensing agreement with Acura Pharmaceuticals, Inc. for its Aversion® Technology
- Net loss of $0.92 per basic and diluted share for the quarter ended September 30, 2016
- Total cash was $92.0 million at September 30, 2016, which includes cash, cash equivalents, restricted cash, marketable securities and long-term investments balance

Coralville, IA – November 9, 2016 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today reported its corporate and financial results for the third quarter ended September 30, 2016, including an update on key clinical and regulatory events involving its product development pipeline.

“The third quarter 2016 began a transformative period for KemPharm as we completed a strategic review of our development pipeline and prioritized KP415 and KP201/IR as our co-lead product candidates. We believe we achieved key milestones that should enable us to capitalize on the value opportunities that each of these product candidates offers to potentially address important patient, prescriber and market needs,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “We expect to report proof-of-concept data for KP415 by year-end and we anticipate initiating human clinical trials of KP201/IR in 2017. KemPharm remains on target to potentially submit New Drug Applications (NDA) for each lead candidate product in 2018.”

“In addition to our clinical progress this quarter, we entered into a licensing agreement with Acura to utilize its proprietary Aversion® Technology with our current and in-development immediate release (IR) opioid prodrugs, starting with KP201/IR,” Dr. Mickle continued. “We believe our Ligand Activated Therapy (LAT) prodrug technology with an aversive formulation approach offers the potential to develop IR opioid therapeutics that may satisfy current FDA standards for abuse-deterrence and could potentially raise the bar on abuse-deterrence within the opioid space.”

Q3 2016 Financial Results:

KemPharm's reported net loss of $13.4 million, or $0.92 per basic and diluted share, for the quarter ended September 30, 2016, compared to net loss of $9.7 million, or $0.68 per basic and diluted share, for the same period in 2015. Net loss for third quarter of 2016 was driven primarily by a loss from operations of $10.4 million, interest expense, net, of $1.7 million and a fair value adjustment expense of $1.3 million for the quarter ended September 30, 2016. Loss from operations for the quarter was $10.4 million, compared to $6.5 million for the same period in 2015. The increase in loss from operations compared to the third quarter of 2015 was primarily due to $3.0 million of severance expense recorded in the third quarter of 2016 related to the deferral of commercial operations and realignment of financial resources and operational priorities during the period, and an increase in general and administrative costs of $0.9 million due primarily to an increase in headcount compared to the same period in 2015.

As of September 30, 2016, total cash, cash equivalents, restricted cash, marketable securities and long-term investments was $92.0 million, which reflected a decrease of $10.6 million compared to June 30, 2016.

Conference Call Information:

The company will host a conference call and live audio webcast with slide presentation on Wednesday, November 9, 2016, at 5:00 p.m. ET, to discuss its corporate and financial results for the third quarter of 2016. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 11692265

The live webcast with accompanying slides will be accessible via the Investor Relations section of the KemPharm website http://investors.kempharm.com/. An archive of the webcast and presentation will remain available for 90 days beginning at approximately 6:00 p.m., ET on November 9, 2016.

Third Quarter and Recent Activities:

Clinical & Regulatory

- **Prioritized KP415 and KP201/IR as Co-Lead Product Candidates**
  As announced in the corporate and clinical update on September 15, 2016, after a thorough evaluation of its entire drug development pipeline, KemPharm has designated KP415, it's extended release (ER) prodrug of d-threo-methylphenidate (d-MPH) product candidate for the treatment of attention deficit hyperactivity disorder (ADHD), and KP201/IR, it's single-entity, benzhydrocodone hydrochloride (HCl) IR, abuse-deterrent product candidate for the treatment of acute pain, as its co-lead product candidates. KemPharm is targeting submission of an NDA for the ER formulation of KP511, its prodrug of hydromorphone, in 2019.

- **Received Clearance from FDA to Initiate Clinical Program for KP415**
  On October 11, 2016, KemPharm announced that its IND application for KP415 was accepted by the FDA. As a result, KemPharm expects to complete a proof of concept human trial prior to the end of 2016, with the goal of initiating pivotal efficacy trials during 2017, and submitting an NDA in 2018.

- **Filed IND with FDA for KP201/IR.**
  On October 25, 2016, KemPharm announced that it filed an IND application with the FDA to begin human clinical trials of KP201/IR. KemPharm intends to initiate human clinical trials of KP201/IR in 2017, with the goal of submitting an NDA in 2018.

- **Initiated Formal Dispute Resolution Request (FDRR) Process with FDA for Apadaz™**
  As announced on November 3, 2016, KemPharm appealed the FDA's Complete Response Letter for Apadaz™ (benzhydrocodone and acetaminophen) through the initiation of the FDRR process.

Corporate & Operational

- **Announced Licensing Agreement with Acura Pharmaceuticals for Aversion® Technology**
  On October 18, 2016, KemPharm announced that it entered into a license agreement with Acura Pharmaceuticals to utilize Aversion® Technology with KemPharm's current and in-development IR opioid product candidates.

- **Deferred Commercial Operations and Realigned Financial Resources and Operational Priorities Towards Product Development Pipeline**
  As announced in the corporate and clinical update on September 15, 2016, KemPharm decided to defer its commercial operations and realign its financial resources and operational priorities towards its product development pipeline.

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 prodrug 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 features and characteristics of KP415, KP201/IR and KP511/ER the expected timing of potential submissions of NDAs for KP415, KP201/IR and KP511/ER, the expected timing of the initiation and completion of clinical trials and the timeline and potential outcome of the FDRR process 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, and 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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KEMPHARM, INC.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,287	4,328	12,509	9,215
General and administrative	3,104	2,152	11,127	6,317
Severance expense	3,010	—	3,010	—
Total operating expenses	10,401	6,480	26,646	15,532
Loss from operations	(10,401)	(6,480)	(26,646)	(15,532)
Other (expense) income:				
Loss on extinguishment of debt	—	—	(4,740)	—
Interest expense related to amortization of debt issuance costs and discount	(390)	(479)	(1,225)	(1,434)
Interest expense on debt principal	(1,441)	(687)	(4,066)	(1,973)
Fair value adjustment	(1,299)	(2,089)	29,742	(26,512)
Interest and other income	98	11	344	17
Total other (expense) income	(3,032)	(3,244)	20,055	(29,902)
Loss before income taxes	(13,433)	(9,724)	(6,591)	(45,434)
Income tax benefit (expense)	19	(20)	11	(27)
Net loss	$ (13,414)	$ (9,744)	$ (6,580)	$ (45,461)
Net loss per share:				
Basic and diluted	$ (0.92)	$ (0.68)	$ (0.45)	$ (4.71)
Weighted average common shares outstanding:				
Basic and diluted	14,646,982	14,232,133	14,580,289	9,643,231

KEMPHARM, INC.
CONDENSED BALANCE SHEETS
(In Thousands, Except Share and Par Value Amounts)

	As of September 30, 2016 (unaudited)	As of December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 20,846	$ 32,318
Restricted cash	1,100	—
Marketable securities	42,679	19,002
Prepaid expenses and other current assets	636	2,758
Total current assets	65,261	54,078
Property and equipment, net	1,456	403
Long-term investments	27,355	—
Other long-term assets	472	109
Total assets	$ 94,544	$ 54,590
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,599	$ 4,906
Current portion of convertible notes	—	1,369
Current portion of term notes	—	2,041
Current portion of capital lease obligation	105	26
Total current liabilities	5,704	8,342
Convertible notes, net	90,779	7,412
Term notes, net	—	11,118
Derivative and warrant liability	7,342	37,839
Other long-term liabilities	521	—
Total liabilities	104,346	64,711
Commitments and contingencies (Note D)		
Stockholders' deficit:		
Common stock, $0.0001 par value, 250,000,000 shares authorized, 14,646,982 shares issued and outstanding as of September 30, 2016 (unaudited); 14,490,954 shares issued and outstanding as of December 31, 2015	1	1
Additional paid-in capital	101,601	94,702
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2016 (unaudited) or December 31, 2015	—	—
Accumulated deficit	(111,404)	(104,824)
Total stockholders' deficit	(9,802)	(10,121)
Total liabilities and stockholders' deficit	$ 94,544	$ 54,590

Exhibit 99.2

KemPharm

Third Quarter 2016 Results

November 9, 2016

Forward Looking Statement

This presentation contains forward-looking statements, including statements about our plans to develop and commercialize our product candidates, our planned clinical trials for our prodrug product candidates, the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including expectations about our ability to use the 505(b)(2) pathway and expedited FDA review, the clinical utility of our product candidates and our intellectual property position. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this presentation represent our views as of the date of this presentation. These and other risks concerning our business are described in additional detail in our Quarterly Report on Form 10-Q filed with the SEC on August 11, 2016 and our other Periodic and Current Reports filed with the SEC. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. Further, the information contained in this presentation speaks only as the date hereof. While we may elect to update the information in this presentation in the future, we disclaim any obligation to do so except to the extent required by applicable law.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Third Quarter 2016 – Conference Call Participants

Presenters

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **Dan Cohen** – EVP, Government & Public Relations
- **R. LaDuane Clifton** – Chief Financial Officer

KemPharm Overview

- Specialty pharmaceutical company discovering and developing novel **prodrugs**

- Building a pipeline of **product candidates** for ADHD, pain and CNS disorders

- Leveraging our **LAT Platform Technology** to improve the attributes of approved drugs in large markets

Third Quarter 2016 & Recent Updates

Clinical & Regulatory

- Prioritized KP415 and KP201/IR as Co-Lead Product Candidates
- Received Clearance from FDA to Initiate Clinical Program for KP415
- Filed IND with FDA for KP201/IR
- Initiated Formal Dispute Resolution Request (FDRR) Process with FDA for Apadaz™

Corporate & Financial

- Net loss of $0.92 per basic and diluted share for the quarter ended 9/30/2016
- Total cash was $92.0 million at 9/30/2016, inclusive of cash, cash equivalents, restricted cash, marketable securities and long-term investments balance
- Announced Licensing Agreement with Acura Pharmaceuticals for Aversion® Abuse-Deterrent Technology

KP415

Product Overview

- Extended release prodrug of methylphenidate
- Preclinical data: T_{max} approximately three times longer than IR methylphenidate
- May offer more consistent drug delivery
- Methylphenidate accounted for approximately 19.7 million TRx's and $4.2 billion in sales in 2015*
- Branded products are being pressured by patent expirations

(*) Management estimate

Development Timeline

- ✓ KP415 IND filed on Sept. 6, 2016; Accepted by FDA on October 6, 2016
- Results from Phase 1 PoC trial expected by year-end 2016
- Pivotal efficacy trial of KP415 expected to begin in 2017
- KP415 NDA filling expected in 2018

KP201/IR (APAP-free)

Product Overview

- IR formulation of benzhydrocodone in an aversive formulation
- Potentially the first IR hydrocodone-related product without APAP in the U.S.
- KP201 Intranasal PK Trial (A03) already completed (n=51):
  - Significantly lower drug liking
  - 36% decrease in KP201 Cmax
  - KP201 Tmax delayed by one hour

Development Timeline

- ✓ Completed KP201/IR EOP1 meeting with the FDA on June 23, 2016
- ✓ KP201/IR IND filing announced on Oct. 25, 2016
- Human clinical trials of KP201/IR expected to begin in 2017
- KP201/IR NDA expected to be filed in 2018
- Priority Review status expected

KP511/ER

Product Overview

- ER formulation of KP511, a prodrug of hydromorphone
- Demonstrated comparable hydromorphone exposure vs. equimolar dose of Dilaudid™ in oral human proof-of-concept trial
- Limited oral bioavailability at high doses (potential overdose protection)

Development Timeline

- ✓ Positive results reported from Phase 1 proof-of-concept trial in June 2016
- Data from intranasal HAL studies of KP511 API expected in 1Q 2017
- KP511/ER NDA expected to be filed in 2019
- Priority Review status expected

Formal Dispute Resolution Request (FDRR) Update

- KemPharm filed an appeal of the CRL for Apadaz™ through the initiation of the FDRR process (announced on Nov. 3, 2016)
- FDRR process is designed to provide pathway by which applicants seek to resolve scientific and/or medical policy disputes that cannot be resolved at the Division level within the FDA
- During the FDRR process, the FDA typically requests that companies not comment. The next announcement will be the final determination of the FDRR.

Q3 2016 Financial Update

- Total cash of $92.0M as of 9/30/2016, a decrease of $10.6M vs. 6/30/2016
  (includes cash, cash equivalents, restricted cash, marketable securities and long-term investments)

- Q3 2016 net loss of ($13.4M), or ($0.92) per basic and diluted share, and vs. Q3 2015 net loss of ($9.7M), or ($0.68) per basic and diluted share
  - Net loss for Q3 2016 driven by loss from operations of $10.4M, interest expense, net, of $1.7M and $1.3M fair value adjustment for the quarter ended 9/30/2016

- Operating loss for Q3 2016 was $10.4M vs. $6.5M for Q3 2015
  - Includes $3.0M of severance expense related to the deferral of commercial operations and realignment of financial resources and operational priorities

- Shelf registration declared effective 10/17/2016; ATM sales agreement executed 10/03/2016

- 14,646,982 common shares outstanding at 9/30/2016

KemPharm Expected Milestones

	Product	Event
2016	KP415	Human POC Data
2017	KP415	Initiate Pivotal Efficacy Trial
	KP201/IR	Human Clinical Trial Initiation & Intranasal HAL Study Data
	KP511 (API)	Intranasal PK and HAL Study Data
2018	KP415	Pivotal Efficacy Trial Results
	KP415	NDA Submission
	KP201/IR	NDA Submission with Priority Review
2019	KP511/ER	NDA Submission with Priority Review

KemPharm

Third Quarter 2016 Results

Q&A