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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 12, 2015**

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**KEMPHARM, INC.**

(Exact name of Registrant as Specified in Its Charter)

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**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)

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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 2.02 Results of Operations and Financial Condition.**

On November 12, 2015, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended September 30, 2015, as well as information regarding a conference call to discuss these corporate and financial results. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information 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 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

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Exhibit No.	Description
99.1	Press Release titled “KemPharm, Inc. Reports Q3 2015 Results” dated November 12, 2015.

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**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 12, 2015

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

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## Exhibit Index

Exhibit No.

Description

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99.1

Press Release titled "KemPharm, Inc. Reports Q3 2015 Results" dated November 12, 2015.



## KemPharm, Inc. Reports Q3 2015 Results

*Conference Call and Live Audio Webcast Scheduled for Today at 4:30 p.m. ET*

### Recent Clinical Development Highlights:

- Completed Human Abuse Liability Program for KP201/APAP, KemPharm's prodrug of hydrocodone (KP201), formulated in combination with acetaminophen (APAP)
- Reported positive results from second intranasal human abuse liability clinical trial of KP201/APAP
- Reported positive data demonstrating tamper-resistant properties of KP201/APAP
- Anticipate filing a new drug application (NDA) for KP201/APAP in Q4 2015

### Recent Product and Financial Highlights:

- Initiated the development of an APAP-free formulation of KP201 as well as the development of an immediate release (IR) formulation of KemPharm's oxycodone prodrug, KP606
- Announced enhancements to United States Patent and Trademark Office U.S. Patent No. 9,079,928 for KP415 and an additional composition of matter patent for KP201.
- Net loss of \$0.68 per share for Q3 2015, cash and cash equivalents balance was \$59.0M at 9/30/2015, a decrease of \$5.2M from 6/30/2015

**Coralville, IA – November 12, 2015** – 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 quarter ended September 30, 2015.

Travis C. Mickle, Ph.D., President and CEO of KemPharm, stated, "We have advanced on several fronts since our last quarterly update, the most significant being the completion of the human abuse liability program for KP201/APAP. We believe the results demonstrate that the prodrug design of KP201/APAP offers the ability to limit opioid exposure when misused, either intranasally (with and without APAP), intravenously, smoked, or orally at high doses, when compared to non-prodrug formulations. We look forward to presenting the full KP201/APAP human abuse liability data package as part of the NDA, which we expect to submit to the FDA as early as by the end of 2015."

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Dr. Mickle continued, "While the clinical and regulatory progress of KP201/APAP has been and continues to be a primary driver for KemPharm, we believe our product candidate pipeline offers numerous value-enhancing opportunities for the company. Recently, we strengthened our prodrug pain franchise with the addition of an APAP-free formulation of KP201 and an IR formulation of our oxycodone prodrug, KP606, to our pipeline of product candidates. We believe that, beginning in 2017, these additions may position us to file at least one new NDA each year through 2019. This highlights the potential of our LAT prodrug technology to rapidly advance multiple product candidates from early to late stage clinical development."

Dr. Mickle concluded, "Filing the NDA for KP201/APAP before year-end is our top priority, and we expect to meet this milestone. Based on guidance obtained at our May 2015 pre-NDA meeting with the FDA, we believe the results from the human abuse liability program may support FDA Category 1 and Category 2 abuse-deterrent language in the KP201/APAP product label. If approved by the FDA, KP201/APAP has the potential to be the first abuse-deterrent opioid to have such language in its product label, as well as potentially being the first immediate release, abuse deterrent hydrocodone/APAP option for acute pain."

**KP201/APAP Human Abuse Liability Program Design and Data Review:**

The KP201/APAP human abuse liability program was designed by KemPharm to assess key abuse-deterrence criteria as specified by the FDA. The program included three clinical trials, KP201.A01, KP201.A02 and KP201.A03, as well as three distinct trials designed to evaluate the tamper-resistant properties of KP201/APAP.

Results from the KP201.A01 oral human abuse liability trial, which was designed to measure hydrocodone exposure, drug likability and the safety of KP201/APAP, as compared to Norco®, when taken orally at 4, 8 and 12 tablet dosages, indicated that KP201/APAP resulted in lower exposure to hydrocodone at the two highest dose levels for the trial, as well as lower incidence of hypoxia across the same dosage levels, in each case compared to Norco®, suggesting the potential for improved safety.

Results from the KP201.A02 intranasal human abuse liability trial, which was designed to determine the relative bioavailability, abuse potential, and safety of equivalent doses of crushed and intact KP201/APAP as compared to Norco®, indicated that KP201/APAP, when insufflated, reduces peak hydrocodone exposure (C<sub>max</sub>), delays the time to achieve peak exposure (T<sub>max</sub>), and significantly decreases in exposure to hydrocodone (AUC<sub>0-2h</sub>) at early time points typically associated with an increased safety risk.

Data from the KP201.A03 intranasal human abuse liability trial, which was designed to compare the amount of hydrocodone released from KP201 and from hydrocodone bitartrate (HB) (both without APAP) after insufflation, demonstrated a statistically significant reduction in C<sub>max</sub>, a delay in T<sub>max</sub>, and a significant decrease in total exposure to hydrocodone especially at early time points typically associated with increased drug liking, abuse and safety. Secondary endpoints related to drug liking, pupillometry and ease of snorting also showed significant

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differences between KP201 and HB, with KP201 demonstrating lower drug liking, less pupil dilation and higher difficulty of snorting than HB.

Lastly, results from three distinct trials designed to evaluate the tamper-resistant properties of KP201/APAP indicated that KP201 remains mostly intact in its inactive prodrug form when being subjected to various chemical manipulation techniques used commonly by opioid abusers. The trials demonstrated that efforts to extract and hydrolyze KP201/APAP were less efficient compared to HB/APAP tablets. Under the more than 1,000 conditions tested, KP201/APAP released less hydrocodone compared to the hydrocodone released from the HB/APAP tablets in every case, usually only yielding the inactive prodrug, KP201. Additionally, KP201/APAP is difficult to prepare for injection and it does not appear to be possible to smoke either KP201 or KP201/APAP.

KemPharm plans to present the FDA with the full KP201/APAP human abuse liability data package as part of its NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for KP201/APAP as early as the end of 2015. Post-NDA filing, KemPharm plans to conduct additional trials with KP201 to further explore the overdose protective properties of KP201 at high oral doses as exhibited in the KP201.A01 oral human abuse liability trial.

### **Q3 2015 Financial Results:**

KemPharm's net loss for the three months ended September 30, 2015, was \$9.7 million, or \$0.68 per basic and diluted share, compared to a net loss of \$7.1 million, or \$3.00 per basic and diluted share, for the same period in 2014. The increase in net loss period-to-period is primarily due to a \$1.0 million increase in research and development costs primarily related to KP201/APAP, a \$1.1 million increase in general and administrative costs associated with increased personnel-related costs due to increased headcount and stock-based compensation and an increase in non-cash interest expense of \$0.5 million for the three months ended September 30, 2015.

As of September 30, 2015, KemPharm had cash and cash equivalents of \$59.0 million, which was an increase of \$48.7M compared to cash and cash equivalents of \$10.3M as of December 31, 2014, as a result of KemPharm's initial public offering in April 2015, and a decrease of \$5.2 million compared to cash and cash equivalents of \$64.2M as of June 30, 2015, primarily due to KemPharm's continuing product development activities.

### **Conference Call Information:**

KemPharm will host a conference call and live audio webcast today at 4:30 p.m., E.T. to discuss its corporate and financial results.

Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.); Conference ID: 73115081
  - (678) 509-7538 (international); Conference ID: 73115081
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An audio webcast will be accessible via the Investor Relations section of the KemPharm website <http://investors.kempharm.com/>. A replay of the call will be available for 90 days beginning at approximately 5:30 p.m., ET today.

**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.

**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 21 E 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 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; and the impact of competitive products and technological changes. 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 Registration Statement on Form S-1 (Registration No. 333-202660) declared effective April 15, 2015, 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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**For KemPharm, Inc.:**

Gordon K. "Rusty" Johnson  
321-939-3416  
[info@kempharm.com](mailto:info@kempharm.com)

**Media / Investor Contacts:**

Jason Rando / Joshua Drumm, Ph.D.  
[Tiberend Strategic Advisors, Inc.](http://TiberendStrategicAdvisors.com)  
212-375-2665 / 2664  
[jrando@tiberend.com](mailto:jrando@tiberend.com)  
[jdrumm@tiberend.com](mailto:jdrumm@tiberend.com)

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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,	
	2015	2014	2015	2014
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	4,328	3,253	9,215	6,006
General and administrative	2,152	1,086	6,317	2,949
Total operating expenses	<u>6,480</u>	<u>4,339</u>	<u>15,532</u>	<u>8,955</u>
Loss from operations	<u>(6,480)</u>	<u>(4,339)</u>	<u>(15,532)</u>	<u>(8,955)</u>
Other income (expenses):				
Gain on extinguishment of debt	—	—	—	1,900
Amortization of debt discount	(479)	(477)	(1,434)	(636)
Interest expense	(687)	(173)	(1,973)	(974)
Fair value adjustment	(2,089)	(2,189)	(26,512)	(4,002)
Interest and other income	11	3	17	3
Total other expenses	<u>(3,244)</u>	<u>(2,836)</u>	<u>(29,902)</u>	<u>(3,709)</u>
Loss before income taxes	(9,724)	(7,175)	(45,434)	(12,664)
Income tax (expense) benefit	(20)	38	(27)	49
Net loss	<u>\$ (9,744)</u>	<u>\$ (7,137)</u>	<u>\$ (45,461)</u>	<u>\$ (12,615)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.68)</u>	<u>\$ (3.00)</u>	<u>\$ (4.71)</u>	<u>\$ (5.30)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>14,232,133</u>	<u>2,381,041</u>	<u>9,643,231</u>	<u>2,381,041</u>

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

	As of September 30, 2015 (unaudited)	As of December 31, 2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 59,009	\$ 10,255
Prepaid expenses and other current assets	607	23
Total current assets	59,616	10,278
Debt issuance costs, net	1,215	1,468
Property and equipment, net	386	352
Other long-term assets	199	1,616
Total assets	<u>\$ 61,416</u>	<u>\$ 13,714</u>
<b>Liabilities, redeemable convertible preferred stock, and stockholders' deficit</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,031	\$ 3,711
Current portion of convertible notes	1,097	77
Current portion of term notes	1,632	115
Current portion of capital lease obligation	32	32
Total current liabilities	6,792	3,935
Convertible notes, net	7,708	7,235
Term notes, net	11,562	10,853
Derivative and warrant liability	41,097	15,966
Capital lease obligation, net	3	26
Total liabilities	<u>67,162</u>	<u>38,015</u>
Commitments and contingencies (Note D)		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of September 30, 2015 (unaudited); 9,705,000 authorized, 9,704,215 shares issued and outstanding as of December 31, 2014	—	3,343
Series B redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of September 30, 2015 (unaudited); 6,220,000 shares authorized, issued and outstanding as of December 31, 2014	—	3,313
Series C redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of September 30, 2015 (unaudited); 18,558,000 shares authorized, 18,557,408 shares issued and outstanding as of December 31, 2014	—	11,892
Series D redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of September 30, 2015 (unaudited); 75,000,000 shares authorized, 7,255,425 shares issued and outstanding as of December 31, 2014	—	5,659
Series D-1 redeemable convertible preferred stock, \$0.0001 par value, no shares authorized, issued or outstanding as of September 30, 2015 (unaudited) or December 31, 2014, respectively	—	—
Total redeemable convertible preferred stock	<u>—</u>	<u>24,207</u>
Stockholders' deficit:		
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 14,241,562 shares issued and outstanding as of September 30, 2015 (unaudited); \$0.0001 par value, 140,000,000 shares authorized, 2,381,041 shares issued and outstanding as of December 31, 2014	3	2
Additional paid-in capital	89,873	1,650
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2015 (unaudited) or December 31, 2014, respectively	—	—
Accumulated deficit	(95,622)	(50,160)
Total stockholders' deficit	<u>(5,746)</u>	<u>(48,508)</u>
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	<u>\$ 61,416</u>	<u>\$ 13,714</u>