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): August 13, 2015

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))

Section 2 - Financial Information

Item 2.02 Results of Operations and Financial Condition.

On August 13, 2015, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended June 30, 2015, as well as information regarding a conference call to discuss these corporate and financial results. The press release is attached hereto as Exhibit 99.1, which is furnished under Item 2.02 of this report and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any of KemPharm's filings under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Section 8 – Other Events

Item 8.01 Other Events

On August 13, 2015, KemPharm issued a press release with respect to data from the first of two intranasal human abuse liability clinical trials of KP201 in accordance with KemPharm's broader KP201/APAP human abuse liability program. KP201/APAP, KemPharm's most advanced product candidate currently being developed for the treatment of acute moderate to moderately severe pain, consists of KP201 formulated in combination with acetaminophen, or APAP. This first intranasal trial, or KP201.A03, was conducted with KP201, a prodrug of hydrocodone and the active ingredient, or API, in KP201/APAP. This single-center, cross-over pharmacokinetic study was designed to measure the amount of hydrocodone released from the API, KP201, when insufflated (i.e., snorted) without APAP, as compared directly to hydrocodone bitartrate, or HB. KP201 demonstrated a statistically significant lowering in peak hydrocodone exposure (C_{max}), and a delay in the time to achieve peak exposure (T_{max}), as well as a significant decrease in total exposure to hydrocodone (AUC_{last} and $AUC_{0\text{-}4h}$) especially in the early time points typically associated with increased drug liking and abuse. Secondary endpoints related to drug liking, pupillometry and ease of snorting also showed significant differences between KP201 and HB with KP201 demonstrating lower drug liking, less pupil dilation and higher difficulty of snorting than HB.

Results from the KP201.A03 trial included:

- 36% decrease in peak hydrocodone exposure (C_{max}) for KP201 compared to HB when taken intranasally;
- Time to peak hydrocodone exposure (T_{max}) delayed by one hour;
- Decreased overall exposure to hydrocodone released from KP201 vs. HB especially in early time points (82% decrease in $AUC_{0\text{-}0.5h}$ and 63% decrease in $AUC_{0\text{-}1.5h}$); and
- Significantly lower drug liking and pupil dilation for KP201 as well as a greater difficulty in snorting KP201 vs. HB.

A second intranasal human abuse liability trial, or KP201.A02, is currently ongoing and is intended to assess the intranasal abuse potential of KP201/APAP. KemPharm anticipates reporting data from the KP201.A02 trial in the third quarter of 2015. The KP201.A03 and KP201.A02 trials are part of a broader human abuse liability program designed by KemPharm to assess key abuse-deterrence criteria as specified by the U.S. Food and Drug Administration, or FDA.

Remaining components of the KP201/APAP human abuse liability program include three nonclinical studies to evaluate the tamper resistance of KP201/APAP (whether the active ingredient can be extracted physically or chemically, abused intravenously or smoked) and KP201.A02. Results from these studies are expected in the third quarter of 2015. KemPharm anticipates submitting a New Drug Application under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for KP201/APAP to the FDA in the fourth quarter of 2015.

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 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 include statements regarding the timing of filing of KemPharm’s anticipated New Drug Application with the FDA and the expected timing of completion of additional clinical trials. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “KemPharm, Inc. Announces Positive Data from Intranasal Human Abuse Liability Study of KP201/APAP; Reports Q2 2015 Results” dated August 13, 2015.

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 hereunto duly authorized.

KEMPHARM, INC.

Date: August 13, 2015

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release titled “KemPharm, Inc. Announces Positive Data from Intranasal Human Abuse Liability Study of KP201/APAP; Reports Q2 2015 Results” dated August 13, 2015.

Exhibit 99.1

KemPharm, Inc. Announces Positive Data from Intranasal Human Abuse Liability Study of KP201/APAP; Reports Q2 2015 Results

Results from First of Two Intranasal Human Abuse Liability Clinical Studies Indicate KP201 Exhibits Significantly Lower Exposure to Hydrocodone When Administered Intranasally

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

Recent Clinical Development Highlights:

- Reports positive pharmacokinetic data from first of two KP201 intranasal human abuse liability clinical trials
- Reported positive data from oral human abuse liability clinical trial of KP201/APAP
- Completed successful KP201/APAP pre-NDA meeting with FDA
- On track to file NDA for KP201/APAP in Q4 2015

Q2 2015 Corporate Highlights:

- Cash balance at 6/30/2015 was $64.2M, an increase of $54.0M from 3/31/2015
- Named Gordon K. “Rusty” Johnson to the new role of Chief Business Officer
- Promoted R. LaDuane Clifton to Chief Financial Officer

Coralville, IA – August 13, 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 June 30, 2015. In addition, KemPharm today announced positive data from the first of two intranasal human abuse liability clinical trials in accordance with the Company's broader KP201/APAP human abuse liability program. KP201/APAP, KemPharm's most advanced product candidate currently being developed for the treatment of acute moderate to moderately severe pain, consists of KP201 formulated in combination with acetaminophen (“APAP”).

This first intranasal trial (KP201.A03) was conducted with KP201, a prodrug of hydrocodone and the active ingredient (“API”) in KP201/APAP. This single-center, cross-over pharmacokinetic study was designed to measure the amount of hydrocodone released from the API, KP201, when insufflated (i.e. snorted) without acetaminophen (“APAP”), as compared directly to hydrocodone bitartrate (HB). KP201 demonstrated a statistically significant lowering in peak hydrocodone exposure (C_{max}), and a delay in the time to achieve peak exposure (T_{max}), as well as a significant decrease in total exposure to hydrocodone (AUC_{last} and $AUC_{0\text{-}4h}$) especially in the early time points typically associated with increased drug liking and abuse. Secondary

endpoints related to drug liking, pupillometry and ease of snorting also showed significant differences between KP201 and HB with KP201 demonstrating lower drug liking, less pupil dilation and higher difficulty of snorting than HB.

Results from the KP201.A03 trial included:

- 36% decrease in peak hydrocodone exposure (C_{max}) for KP201 compared to hydrocodone bitartrate ("HB") when taken intranasally;
- Time to peak hydrocodone exposure (T_{max}) delayed by one hour;
- Decreased overall exposure to hydrocodone released from KP201 vs. HB especially in early time points (82% decrease in $AUC_{0\text{-}0.5h}$ and 63% decrease in $AUC_{0\text{-}1.5h}$); and
- Significantly lower drug liking and pupil dilation for KP201 as well as a greater difficulty in snorting KP201 vs. HB.

A second intranasal human abuse liability trial (KP201.A02) is currently ongoing and is intended to assess the intranasal abuse potential of the final commercial formulation of KP201/APAP. KemPharm anticipates reporting data from the KP201.A02 trial in the third quarter of 2015. The KP201.A03 and KP201.A02 trials are part of a broader human abuse liability program designed by KemPharm to assess key abuse-deterrence criteria as specified by the U.S. Food and Drug Administration ("FDA").

Travis C. Mickle, Ph.D., President and CEO of KemPharm, stated, "This is a very exciting time for KemPharm as we continue to make significant progress in the clinical and regulatory development of KP201/APAP. Today's results from the KP201.A03 intranasal human abuse liability clinical study indicate that KP201 drastically limits hydrocodone exposure when taken through a route typically associated with abuse, adding to the growing library of favorable data demonstrating the abuse- and tamper-resistant properties of KP201/APAP. We believe this study is the first direct head-to-head comparison of an API for immediate release prescription opioid products to demonstrate such a meaningful difference in opioid exposure, highlighting the inherent benefits of our prodrug technology. Based on guidance obtained at our May 2015 pre-NDA meeting with the FDA, we believe these differences would qualify for Category 2 abuse-deterrent labeling based on the established FDA guidance."

Dr. Mickle continued, "The unique attributes of KP201/APAP were also observed in the results of the recently announced KP201.A01 oral human abuse liability trial. Importantly, data from that study indicated that our prodrug technology may offer an improvement in the safety of the drug when taken in high amounts orally, further supporting the potential for Category 2 abuse-deterrent labeling for KP201/APAP."

Dr. Mickle concluded, "Looking ahead, we anticipate reporting data from the remaining studies in our comprehensive KP201/APAP human abuse liability program – the KP201.A02 intranasal human abuse liability trial and three tamper resistance studies – during the third quarter of 2015. Based on reaching these milestones, and the results of our May 2015 pre-NDA meeting with the

FDA, we now anticipate filing the NDA for KP201/APAP with the FDA in the fourth quarter of 2015."

KP201/APAP Clinical and Regulatory Progress

The KP201.A03 trial is part of a broader human abuse liability program designed by KemPharm to assess key abuse-deterrence criteria as specified by the FDA. On June 11, 2015, KemPharm reported positive results from its 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, each of which are much greater than the recommended amount (1 to 2 tablets). Highlights of the trial results included lower exposure to hydrocodone at the highest dose levels for the trial, as well as lower incidence of hypoxia across the same dosage levels, in each case compared to the hydrocodone reference drug, suggesting the potential for improved safety. As expected, liking data was similar at each equivalent dose level.

Remaining components of the human abuse liability program include three nonclinical studies to evaluate the tamper resistance of KP201/APAP (whether the active ingredient can be extracted physically or chemically, abused intravenously or smoked) and a second intranasal human abuse liability clinical trial (KP201.A02) designed to assess the relative pharmacokinetics and drug likability of KP201/APAP compared to Norco®. Results from these studies are expected in the third quarter of 2015.

As announced previously, KemPharm's management held a pre-NDA meeting with the FDA for KP201/APAP on May 20, 2015. Based on this pre-NDA meeting with FDA and the favorable data generated from the KP201.A01 and KP201.A03 trials, KemPharm anticipates submitting an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for KP201/APAP to the FDA in the fourth quarter of 2015.

Corporate Highlights and Q2 2015 Financial Results

During the second quarter, KemPharm announced the appointment of Gordon K. "Rusty" Johnson to the new role of Chief Business Officer and the promotion of R. LaDuane Clifton to Chief Financial Officer. These changes are intended to enhance KemPharm's focus on strategic opportunities for KP201/APAP and its pipeline of other prodrug product candidates in development.

Dr. Mickle said, "Creating the role of Chief Business Officer is an exciting milestone for KemPharm, enhancing our focus on strategic opportunities and reflecting our growth into a mature, development-stage, specialty pharmaceutical company. Based on the current status of our product candidate pipeline, we see this management re-alignment as a key element of our business development strategy."

As of June 30, 2015, KemPharm had cash and cash equivalents of $64.2 million, an increase of $54.0 million from March 31, 2015. This increase was due primarily to proceeds from KemPharm's IPO of $59.9 million, net of underwriting discounts and commissions.

KemPharm's net loss for the three months ended June 30, 2015, was $29.8 million, or $2.45 per basic and diluted share, compared to a net loss of $3.6 million, or $1.50 per basic and diluted share, for the same period in 2014. The increase in net loss period-to-period is primarily due to the non-cash fair value adjustment for the Company's derivative and warrant liability of $22.7 million for the three months ended June 30, 2015, as well as an increase in research and development costs for KP201/APAP and an increase in general and administrative costs associated with increased personnel-related costs due to increased headcount, stock-based compensation and costs associated with KemPharm's IPO-related 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. The conference call can be accessed by dialing (866) 395-2480 toll-free in the U.S., or (678) 509-7538 for participants outside the U.S. The live audio webcast can be accessed via the Investor Relations section of the KemPharm website: http://investors.kempharm.com/. A replay of the call will be available on KemPharm's website for 90 days.

About KemPharm
KemPharm is a clinical-stage specialty pharmaceutical company focused on the discovery and development of NME 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 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; and, the impact of competitive products and technological changes. 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 KemPharm's business are described in additional detail in the Company's Registration Statement on Form S-1 (Registration No. 333-202660) declared effective April 15, 2015, and the Company'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 June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	2,768	1,715	4,887	2,752
General and administrative	3,188	1,330	4,165	1,864
Total operating expenses	5,956	3,045	9,052	4,616
Loss from operations	(5,956)	(3,045)	(9,052)	(4,616)
Other income (expenses):				
Gain on extinguishment of debt	—	1,900	—	1,900
Amortization of debt discount	(477)	(159)	(954)	(159)
Interest expense	(649)	(704)	(1,280)	(800)
Fair value adjustment	(22,661)	(1,570)	(24,423)	(1,812)
Total other expenses	(23,787)	(533)	(26,657)	(871)
Loss before income taxes	(29,743)	(3,578)	(35,709)	(5,487)
Income tax (expense) benefit	(8)	6	(15)	11
Net loss	$ (29,751)	$ (3,572)	$ (35,724)	$ (5,476)
Net loss per share:				
Basic and diluted	$ (2.45)	$ (1.50)	$ (4.91)	$ (2.30)
Weighted average common shares outstanding:				
Basic and diluted	12,157,757	2,381,041	7,272,447	2,381,041

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

	As of June 30, 2015 (unaudited)	As of December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 64,223	$ 10,255
Prepaid expenses and other current assets	599	23
Total current assets	64,822	10,278
Debt issuance costs, net	1,301	1,468
Property and equipment, net	352	352
Other long-term assets	56	1,616
Total assets	$ 66,531	$ 13,714
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,878	$ 3,903
Current portion of capital lease obligation	32	32
Total current liabilities	4,910	3,935
Convertible notes, net of discount	7,550	7,235
Term notes, net of discount	11,326	10,853
Derivative and warrant liability	39,279	15,966
Capital lease obligation, net of current portion	11	26
Total liabilities	63,076	38,015
Commitments and contingencies		
Redeemable convertible preferred stock:	—	24,207
Stockholders' deficit:		
Common stock, $0.0001 par value, 250,000,000 shares authorized, 14,229,552 shares issued and outstanding as of June 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	89,336	1,650
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2015 (unaudited) or December, 31, 2014, respectively	—	—
Accumulated deficit	(85,884)	(50,160)
Total stockholders' deficit	3,455	(48,508)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 66,531	$ 13,714