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 10, 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 2.02 Results of Operations and Financial Condition.

On August 10, 2016, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended June 30, 2016, 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

Exhibit No.	Description
99.1	Press Release titled "KemPharm, Inc. Reports Second Quarter 2016 Results" dated August 10, 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: August 10, 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 Second Quarter 2016 Results” dated August 10, 2016.

Exhibit 99.1

KemPharm, Inc. Reports Second Quarter 2016 Results

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

Recent Clinical Development & Regulatory Highlights:

- Completed FDA End of Review meeting for Apadaz™ following receipt of Complete Response Letter
- Reported results from KP511 Phase 1 Proof-of-Concept Trial; Announces plans to initiate human abuse liability program for KP511 before year-end
- Completed key FDA regulatory milestones for KP415 and KP201/IR

Recent Corporate and Financial Highlights:

- Hosted annual meeting of stockholders on May 24
- Total cash and cash equivalents, restricted cash, marketable securities and long-term investments of $102.6 million at June 30, 2016
- Net income of $9.8 million, or $0.59 per basic share, and ($0.58) net loss per diluted share for the quarter ended June 30, 2016
- Operating loss of $9.3 million for the quarter ended June 30, 2016

Coralville, IA – August 10, 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 second quarter ended June 30, 2016, including an update on key regulatory and clinical events involving KemPharm's product candidate Apadaz™ and KemPharm's pipeline of other proprietary prodrugs.

On June 13, 2016, KemPharm announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for Apadaz (benzhydrocodone and acetaminophen), the Company’s investigational abuse-deterrent product candidate for the short term management of acute pain. KemPharm subsequently requested an End of Review meeting with the FDA, which occurred on August 3, 2016.

At the End-of-Review (EOR) meeting, the Company and the FDA discussed the issues identified by the FDA in the Apadaz NDA and what KemPharm believes is the potential to achieve a path forward for an Apadaz product label that could include abuse deterrence claims. The meeting also involved discussions pertaining to abuse deterrence in relation to the broader immediate-release (IR) prescription opioid market, hydrocodone-acetaminophen combination products, and published industry guidance from the FDA concerning the evaluation and labeling of abuse deterrent opioids.

The Company and the FDA also discussed the proposed short-duration “blister” packaging for Apadaz at the EOR meeting, which was put forth as part of KemPharm's Major Amendment Request to the Apadaz NDA prior to the June 9, 2016 PDUFA date. The Company confirmed the information expected for the FDA to complete its review of the amendment. The short duration blister packaging was proposed in alignment with the recently published Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain, which advises that clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.

“KemPharm’s mission today is unchanged – to leverage our unique and highly differentiated Ligand Activated Therapy (LAT) discovery platform to develop proprietary prodrugs that have improved properties over currently approved drugs and address significant medical needs in large, established markets,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “While the ongoing effort with the FDA concerning Apadaz has presented a near-term challenge for the company to work through, we view it as a single event against multiple potential new product opportunities that hold considerable promise for KemPharm. Our broad pipeline allows us to move forward with the development of our two most advanced extended-release product candidates – KP511/ER for the treatment of severe pain and KP415 for the treatment of attention deficit hyperactivity disorder – as well as with KP201/IR, our acetaminophen-free immediate release hydrocodone prodrug.”

Dr. Mickle concluded, “Looking ahead, we anticipate initiating the human abuse liability clinical program for KP511/ER and filing Investigational New Drug (IND) applications for KP415 and KP201/IR by year-end. These programs represent the most immediate value-building opportunities for KemPharm, and we are orienting our financial and R&D resources to support their potential for success. Overall, we believe KemPharm remains well capitalized to advance its full pipeline of product candidates, while we determine the optimal path forward for Apadaz.”

Ligand Activated Therapy (LAT) Prodrug Pipeline Update:
During the second quarter and early third quarter 2016, KemPharm achieved key clinical and regulatory milestones for KP511/ER, KP415 and KP201/IR. Each of these prodrugs is based on KemPharm’s proprietary LAT discovery platform and is designed to improve one or more of the attributes of the approved comparator drug, such as susceptibility to abuse, bioavailability and safety.

On June 28, 2016, KemPharm reported positive results from its Phase 1 proof-of-concept trial of KP511, the Company’s prodrug of hydromorphone. In the trial (KP511.101), KemPharm observed comparable hydromorphone exposure between 4 mg Dilaudid™ Oral Liquid and an equimolar 8 mg dose of KP511. KemPharm is developing KP511 as an abuse-deterrent, extended release (ER) formulation (KP511/ER) for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatments are inadequate. Based on these Phase 1 results, KemPharm plans to initiate a human abuse liability clinical program for KP511/ER to assess the product candidate’s tamper and extraction resistance, its intranasal and intravenous abuse potential, as well as its potential to limit oral abuse and/or overdose. Additionally, KemPharm intends to investigate KP511’s potential to improve or reduce opioid-induced constipation (OIC), a common side effect of opioid therapy. KemPharm anticipates initiating the KP511/ER human abuse liability program prior to the end of 2016.

On July 14, 2016, KemPharm announced the completion of a Pre-Investigational New Drug (Pre-IND) review of KP415, the Company's prodrug of d-threo-methylphenidate for the treatment of attention deficit hyperactivity disorder (ADHD). Based on input received from the FDA, KemPharm expects to file an IND for KP415 before the end of 2016.

In preclinical studies of KP415, KemPharm observed features that it believes 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. KemPharm believes this potential controlled release attribute of KP415's molecular structure may allow for convenient, once-daily dosing. KP415 utilizes KemPharm's LAT platform technology to potentially enable abuse-deterrent properties at the molecular level which addresses the need for methylphenidate products with abuse deterrent features on the market.

In addition, on July 14, 2016, KemPharm announced the completion of an End-of-Phase 1 (EOP1) review for KP201/IR, KemPharm's single-entity, benzhydrocodone HCl immediate-release product candidate designed for the treatment of acute pain. KemPharm believes that KP201/IR may also have abuse deterrent properties. KemPharm requested an EOP1 review for KP201/IR ahead of an anticipated IND submission based on the amount of data, both nonclinical and clinical, generated from the development of Apadaz. As previously reported, data from KemPharm's intranasal human abuse liability trial (KP201.A03), which compared hydrocodone exposure following insufflation of benzhydrocodone HCl (KP201) vs. hydrocodone bitartrate (HB), demonstrated a statistically significant reduction in Cmax, a delay in Tmax, 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, including drug liking Emax, 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. KemPharm remains encouraged by these findings and anticipates filing an IND for KP201/IR before the end of 2016.

Q2 2016 Financial Results:
KemPharm's reported net income of $9.8 million, or $0.59 of income per basic share, and ($0.58) of net loss per diluted share for the quarter ended June 30, 2016, compared to a net loss of ($29.7) million, or ($2.45) loss per basic and diluted share, for the same period in 2015. Net income for the quarter ended June 30, 2016, was driven primarily by a $20.8 million decrease in the fair value of KemPharm's derivative and warrant liability as of June 30, 2016. Loss from operations for the quarter ended June 30, 2016, was $9.3 million, compared to $6.0 million for the same period in 2015. The increase in loss from operations period-to-period was primarily due to a $2.2 million increase in research and development expenses primarily related to activity for KP511 and KP415, and an increase in general and administrative costs of $1.1 million, primarily due to an increase in headcount and commercial activities.

As of June 30, 2016, the total of cash and cash equivalents, restricted cash, marketable securities and long-term investments was $102.6 million, and was a decrease of $8.4 million compared to March 31, 2016.

Conference Call Information:
The Company will host a conference call and live audio webcast on Wednesday, August 10, 2016, at 8:30 a.m. ET, to discuss its corporate and financial results for the second quarter 2016. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 56389138

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 90 days beginning at approximately 9:30 a.m., ET on August 10, 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.

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 outcome of the regulatory approval for Apadaz, the expected features and characteristics of KP201/IR, KP511/ER and KP415, the expected timing of filing of INDs for KP201/IR and KP415, and potential submissions of NDAs for KP201/IR, KP511/ER and KP415. 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 June 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 June 30,		Six months ended June 30,	
	2016	**2015**	**2016**	**2015**
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,988	2,768	8,222	4,887
General and administrative	4,287	3,188	8,023	4,165
Total operating expenses	9,275	5,956	16,245	9,052
Loss from operations	(9,275)	(5,956)	(16,245)	(9,052)
Other income (expense):				
Loss on extinguishment of debt	—	—	(4,740)	—
Interest expense related to amortization of debt issuance costs and discount	(393)	(477)	(835)	(954)
Interest expense on principal	(1,475)	(654)	(2,625)	(1,286)
Fair value adjustment	20,763	(22,661)	31,041	(24,423)
Interest and other income	144	5	246	6
Total other income (expense)	19,039	(23,787)	23,087	(26,657)
Income (loss) before income taxes	9,764	(29,743)	6,842	(35,709)
Income tax benefit (expense)	4	—	(8)	(7)
Net income (loss)	$ 9,768	$ (29,743)	$ 6,834	$ (35,716)
Net income (loss) per share:				
Basic	$ 0.59	$ (2.45)	$ 0.41	$ (4.91)
Diluted	$ (0.58)	$ (2.45)	$ (1.36)	$ (4.91)
Weighted average common shares outstanding:				
Basic	14,597,449	12,157,514	14,546,576	7,272,326
Diluted	15,435,322	12,157,514	15,583,390	7,272,326

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

	As of June 30, 2016 (unaudited)	As of December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 27,510	$ 32,318
Restricted cash	1,100	—
Marketable securities	55,134	19,002
Prepaid expenses and other current assets	824	2,758
Total current assets	84,568	54,078
Property and equipment, net	1,105	403
Long-term investments	18,850	—
Other long-term assets	111	109
Total assets	$ 104,634	$ 54,590
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,356	$ 4,906
Current portion of convertible notes	1,932	1,369
Current portion of term notes	—	2,041
Current portion of capital lease obligation	103	26
Total current liabilities	7,391	8,342
Convertible notes, net	90,389	7,412
Term notes, net	—	11,118
Derivative and warrant liability	6,043	37,839
Other long-term liabilities	478	—
Total liabilities	104,301	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 June 30, 2016 (unaudited); 14,490,954 shares issued and outstanding as of December 31, 2015	1	1
Additional paid-in capital	98,322	94,702
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2016 (unaudited) or December 31, 2015	—	—
Accumulated deficit	(97,990)	(104,824)
Total stockholders' equity (deficit)	333	(10,121)
Total liabilities and stockholders' equity (deficit)	$ 104,634	$ 54,590