
**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): March 9, 2017

KEMPHARM, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36913
(Commission File Number)

20-5894398
(IRS Employer
Identification No.)

2500 Crosspark Road, Suite E126
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)

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 March 9, 2017, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter and year ended December 31, 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 Fourth Quarter and Year End 2016 Results" dated March 9, 2017.
99.2	Presentation titled "Fourth Quarter & Year-End 2016 Results" dated March 9, 2017.

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.

KEMPARM, INC.

Date: March 9, 2017

By: /s/ R. LaDuane Clifton

R. LaDuane Clifton, CPA

Chief Financial Officer, Secretary and Treasurer

Exhibit Index

Exhibit No.

Description

99.1	Press Release titled "KemPharm, Inc. Reports Fourth Quarter and Year End 2016 Results" dated March 9, 2017.
99.2	Presentation titled "Fourth Quarter & Year-End 2016 Results" dated March 9, 2017.



KemPharm, Inc. Reports Fourth Quarter and Year End 2016 Results

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

Recent Clinical Development & Regulatory Highlights:

- Reported Positive Data from Phase 1 Proof-of-Concept Clinical Trial of KP415
- Received Clearance from FDA to Initiate Clinical Program for KP201/IR
- Granted "Fast Track" Designation from FDA for KP201/IR
- Reported Positive Data from Proof-of-Concept Phase 1 Intranasal Pharmacokinetic Study of KP511

Recent Corporate and Financial Highlights:

- Net loss of \$0.68 per basic and diluted share for the quarter ended December 31, 2016; net loss of \$1.13 per basic and diluted share for the year ended December 31, 2016
- Total cash and security-related amounts were \$82.1 million at December 31, 2016, which includes cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments balance

Coralville, IA – March 9, 2017 – 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 fourth quarter ended December 31, 2016, including an update on key clinical events involving its prodrug development pipeline.

"The fourth quarter of 2016 and early 2017 were highlighted by substantive progress across our clinical-stage programs, demonstrating the strength and potential of our Ligand Activated Therapy prodrug discovery platform and our product candidate pipeline," said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "During the fourth quarter we received clearance to initiate clinical testing of and reported positive proof-of-concept clinical data for KP415, our extended-release prodrug of methylphenidate for the treatment of attention deficit hyperactivity disorder (ADHD), as well as received both IND clearance and Fast Track status for KP201, our single-entity benzhydrocodone HCl immediate release abuse-deterrent prodrug for the treatment of acute pain. Additionally, in January 2017, we observed statistically significant pharmacokinetic (PK) and pharmacodynamic (PD) differences of abuse potential in our Phase 1 proof-of-concept intranasal study of KP511, our investigational prodrug of hydromorphone for the treatment of pain."

"Looking ahead to the coming year, we anticipate several clinical and developmental milestones that could serve to greatly enhance the value of the LAT prodrug platform and our product candidate portfolio," Dr. Mickle continued. "As a prodrug discovery company, KemPharm's mission is to develop prodrugs that are an improvement on currently approved drugs and address unmet medical needs in large, established markets. We believe our current product candidate portfolio, led by KP415, which has demonstrated the potential to address critical patient needs in the multi-billion dollar ADHD market, exemplifies this strategy. Our scientific discovery is intended to showcase opportunities that could be extended to other drug products in large markets where improving one or more attributes, such as bioavailability, safety or efficacy, could potentially enable the capture of significant market share."

Q4 and Year-End 2016 Financial Results:

KemPharm's reported net loss of \$10.0 million, or \$0.68 per basic and diluted share, for Q4 2016, compared to net loss of \$9.2 million, or \$0.64 per basic and diluted share, for the same period in 2015. Net loss for the Q4 2016 was driven primarily by a loss from operations of \$10.9 million and interest expense, net, of \$1.8 million, partially offset by a favorable fair value adjustment of \$2.7 million. Loss from operations for Q4 2016 was \$10.9 million, compared to \$7.3 million for the same period in 2015. The increase in loss from operations for Q4 2016 compared to Q4 2015 was primarily due to an increase in third-party research and development costs of \$2.8 million due to increased activity on the development programs for KP415, KP201/IR and KP511, and an increase of \$0.6 million in personnel-related costs for research, development, general and administrative activities driven primarily by an increase in headcount compared to the same period in 2015.

For the year ended December 31, 2016, KemPharm reported net loss of \$16.5 million, or \$1.13 per basic and diluted share, compared to net loss of \$54.7 million, or \$7.42 per basic and diluted share for the same period in 2015. The reduced net loss for FY 2016 was driven by an increase in the non-cash income recognized from fair value adjustments of \$59.7 million, offset by an increase in loss from operations of \$14.7M due to increased activity on the development programs for KP415, KP201/IR and KP511, increased personnel-costs related to an increase in headcount compared and severance expense, as well as recognition of non-cash loss on extinguishment of debt of \$4.7M and an increase in interest expense of \$2.8M compared to FY 2015.

As of December 31, 2016, total cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments was \$82.1 million, which reflected a decrease of \$9.9 million compared to September 30, 2016. Based on the Company's current forecast, existing resources are expected to fund operating expenses and capital expenditure requirements through Q2 2019.

Conference Call Information:

The Company will host a conference call and live audio webcast with slide presentation on Thursday, March 9, 2017, at 4:30 p.m. ET, to discuss its corporate and financial results for the fourth quarter and year-end 2016. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 80582549

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 5:30 p.m., ET on March 9, 2017.

Fourth Quarter and Recent Activities:

- **Reported Positive Data from Phase 1 Proof-of-Concept Clinical Trial of KP415**

On December 14, 2016, KemPharm announced the results of its Phase 1 proof-of-concept clinical trial of KP415, the Company's extended-release prodrug of d-threo-methylphenidate (d-MPH) for the treatment of ADHD. Data from the study indicated that KP415 demonstrated PK properties that produced earlier d-MPH exposure followed by a slower extended release of d-MPH relative to the comparator, Concerta[®]. KemPharm expects to initiate pivotal efficacy trials during 2017 and submit an NDA in 2018.

- **Received Clearance from FDA to Initiate Clinical Program for KP201/IR**

On November 29, 2016, KemPharm announced that its Investigational New Drug (IND) application for KP201/IR was accepted by the U.S. Food and Drug Administration (FDA). KP201/IR is KemPharm's single-entity benzhydrocodone HCl immediate release abuse-deterrent prodrug for the treatment of acute pain. KemPharm expects to initiate human clinical trials of KP201/IR in the first half of 2017 and remains on target for a potential submission in 2018 of the KP201/IR NDA.

- **Granted "Fast Track" Designation from FDA for KP201/IR**

On December 20, 2016, KemPharm announced that its IND application for KP201/IR was granted "Fast Track" designation by the FDA. Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.

- **Reported Positive Data from Phase 1 Intranasal Pharmacokinetic Study of KP511**

On January 9, 2017, KemPharm announced the results of its exploratory Phase 1, double-blind, single-dose, 2-treatment, 2-period, randomized, crossover study (KP511.A01) intended to assess the PK, safety and intranasal abuse potential of KP511 Active Pharmaceutical Ingredient (API) compared to equivalent doses of hydromorphone hydrochloride (HM API). KP511 is KemPharm's investigational prodrug of hydromorphone for the treatment of pain. The results of the study indicated that KP511 demonstrated statistically significant reduction in peak and overall hydromorphone exposure with KP511 API versus HM API. The improved PK of KP511 resulted in meaningful, statistically lower scores in the exploratory PD measures of "Drug Liking," "Feeling High," "Overall Drug Liking" and "Take Drug Again" when compared to HM API.

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 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 central nervous system disorders. KemPharm's co-lead clinical development candidates are KP415, an extended-release prodrug of methylphenidate for the treatment of ADHD, and KP201/IR, an acetaminophen-free formulation of the company's immediate release abuse deterrent hydrocodone product, KP201. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com.

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 the expected timing of potential submissions of NDAs for KP415, KP201/IR and KP511, the expected timing of the initiation and completion of any clinical trials for the Company's product candidates. 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.
STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three months ended December 31,		Twelve months ended December 31,	
	2016	2015	2016	2015
	(unaudited)	(unaudited)		
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	7,973	4,716	20,472	13,931
General and administrative	2,878	2,566	14,000	8,883
Severance expense	—	—	3,010	—
Total operating expenses	<u>10,851</u>	<u>7,282</u>	<u>37,482</u>	<u>22,814</u>
Loss from operations	<u>(10,851)</u>	<u>(7,282)</u>	<u>(37,482)</u>	<u>(22,814)</u>
Other income (expense):				
Loss on extinguishment of debt	—	—	(4,740)	—
Interest expense related to amortization of debt issuance costs and discount	(391)	(475)	(1,616)	(1,909)
Interest expense on principal	(1,445)	(698)	(5,511)	(2,671)
Fair value adjustment	2,723	(764)	32,465	(27,276)
Interest and other income	9	15	353	32
Total other income (expense)	<u>896</u>	<u>(1,922)</u>	<u>20,951</u>	<u>(31,824)</u>
Loss before income taxes	<u>(9,955)</u>	<u>(9,204)</u>	<u>(16,531)</u>	<u>(54,638)</u>
Income tax benefit (expense)	4	1	15	(26)
Net loss	<u>\$ (9,951)</u>	<u>\$ (9,203)</u>	<u>\$ (16,516)</u>	<u>\$ (54,664)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.68)</u>	<u>\$ (0.64)</u>	<u>\$ (1.13)</u>	<u>\$ (7.42)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>14,646,982</u>	<u>14,443,421</u>	<u>14,597,053</u>	<u>7,368,681</u>

KEMPHARM, INC.
BALANCE SHEETS

(in thousands, except share and par value amounts)

	As of December 31, 2016	As of December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,762	\$ 32,318
Restricted cash	1,100	—
Marketable securities	51,003	19,002
Trade date receivables	5,003	—
Prepaid expenses and other current assets	489	2,758
Total current assets	74,357	54,078
Property and equipment, net	1,970	403
Long-term investments	8,200	—
Other long-term assets	360	109
Total assets	\$ 84,887	\$ 54,590
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,444	\$ 4,906
Current portion of convertible notes	—	1,369
Current portion of term notes	—	2,041
Current portion of capital lease obligation	157	26
Other current liabilities	41	—
Total current liabilities	6,642	8,342
Convertible notes, net	91,170	7,412
Term notes, net	—	11,118
Derivative and warrant liability	4,618	37,839
Other long-term liabilities	1,153	—
Total liabilities	103,583	64,711
Stockholders' deficit:		
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 14,646,982 shares issued and outstanding as of December 31, 2016; 14,490,954 shares issued and outstanding as of December 31, 2015	1	1
Additional paid-in capital	102,643	94,702
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2016 or December 31, 2015	—	—
Accumulated deficit	(121,340)	(104,824)
Total stockholders' deficit	(18,696)	(10,121)
Total liabilities and stockholders' deficit	\$ 84,887	\$ 54,590



KemPharm

Fourth Quarter & Year-End 2016 Results

March 9, 2017

Cautionary Note Regarding Presentation Information

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 November 10, 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.



Fourth Quarter & Year-End 2016 – Conference Call Participants

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **R. LaDuane Clifton** – Chief Financial Officer



KemPharm Overview

- Specialty pharmaceutical company discovering and developing novel **prodrugs**
- Leveraging our **LAT Platform Technology** to improve the attributes of approved drugs in large markets
- Building a pipeline of **product candidates** for the treatment of ADHD, pain and CNS disorders
- Potentially utilizing FDA's **505(b)(2) pathway** to reduce risk and expense
- Generating long-lived **composition-of-matter** patent protection



Ligand Activated Therapy (LAT) Platform Technology



- 1) Select FDA-approved and widely prescribed drug for improvement
 - 2) Chemically modify using a ligand to create a prodrug
 - Ligands – GRAS or demonstrated to be safe
 - Prodrugs generate composition-based patents
 - 3) Following ingestion, normal human metabolic processes cleave the ligand and release the active drug
- Proprietary to KemPharm and **applicable across therapeutic areas**
 - Amenable to **both immediate and extended release formulations**



Q4/YE 2016 & Recent Updates

Clinical & Regulatory

- Reported Positive Data from Phase 1 Proof-of-Concept Clinical Trial of KP415
- Received Clearance from FDA to Initiate Clinical Program for KP201/IR
- Granted “Fast Track” Designation from FDA for KP201/IR
- Reported Positive Data from Phase 1 Proof-of-Concept Intranasal Pharmacokinetic Trial of KP511

Financial

- Net loss of \$0.68 per basic and diluted share for the quarter ended 12/31/2016
- Total cash was \$82.1 million at 12/31/2016, inclusive of cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments balance
- Existing resources expected to fund activities at least through end of Q2 2019



KP415

Product Overview

- Extended release prodrug of methylphenidate
- Phase 1 PoC Data: Earlier d-MPH exposure followed by a slower extended release of d-MPH relative to Concerta
- Data from preclinical studies suggests KP415 could allow for once-daily dosing with a potentially improved onset of action
- Branded products are being pressured by patent expirations

Development Timeline

- ✓ KP415 IND accepted by FDA on October 6, 2016
- ✓ Results from Phase 1 PoC trial announced on Dec. 14, 2016
- Additional PK studies expected to begin in 1H 2017; final data expected 2H 2017
- Pivotal efficacy trial expected to begin in 2H 2017; final data expected Q1 2018
- KP415 NDA filling expected in 2018

~\$13 billion ADHD market with prescriptions growing at >5% year-over-year

Source: Symphony Health Solutions, PHAST Prescription Monthly, 2012-2016



KP201/IR (APAP-free)

Product Overview

- IR formulation of benzhydrocodone combined with an aversive formulation
- Potentially the first IR hydrocodone-related product without APAP in the U.S.
- Fast Track designation
- 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

- ✓ KP201/IR IND accepted by FDA on Nov. 29, 2016
- Human clinical trials of KP201/IR expected to begin in 2017; IN HAL study data projected late 2017
- KP201/IR NDA anticipated to be filed in 2018
- Priority Review expected



KP511/ER and KP511/IR

Product Overview

- Prodrug of hydromorphone
- Being developed as ER and IR formulations
- Demonstrated comparable hydromorphone exposure vs. equimolar dose of Dilaudid™ in oral human proof-of-concept trial
- Phase 1 Intranasal Data: Demonstrated statistically significant PK and PD differences of abuse potential
- Limited oral bioavailability at high doses observed in preclinical studies (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 announced Jan. 9, 2017
- Investigation anticipated into KP511's potential to limit oral abuse and/or overdose and improve or reduce opioid-induced constipation (OIC)
- KP511/ER and KP511/IR NDAs estimated to be filed in 2019
- Priority Review expected



Q4 / YE 2016 Financial Update

- Q4 2016 net loss of \$10.0M, or \$0.68 per basic and diluted share, vs. Q4 2015 net loss of \$9.2M, or \$0.64 per basic and diluted share

Increased net loss for Q4 2016 driven primarily by the \$3.5M payment to license the Aversion™ technology, increased activity on the development programs for KP415, KP201/IR and KP511, and increased headcount compared to Q4 2015

- FY 2016 net loss of \$16.5M, or \$1.13 per basic and diluted share, vs. FY 2015 net loss of \$54.7M, or \$7.42 per basic and diluted share

Reduced net loss for FY 2016 driven primarily by non-cash fair value adjustments, offset by increased activity on the KP415, KP201/IR and KP511 programs, activities to support the Apadaz NDA, and increased headcount compared to 2015

- Total cash of \$82.1M as of 12/31/2016, a decrease of \$9.9M vs. 9/30/2016 (includes cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments)

Existing resources expected to meet operating and capital expenditure requirements through Q2 2019



KemPharm Expected Milestones

	Product	Event
2017	KP415	Initiate Additional PK Studies (1H)
	KP415	Report Additional PK Data (2H)
	KP415	Initiate Pivotal Efficacy Trial (2H)
	KP201/IR	Human Clinical Trial Initiation (Mid)
	KP201/IR	Intranasal HAL Study Data (2H)
2018	KP415	Pivotal Efficacy Trial Results (1Q)
	KP415	NDA Submission
	KP201/IR	NDA Submission with Priority Review
2019	KP511/ER & KP511/IR	NDA Submissions with Priority Review





KemPharm

Fourth Quarter & Year-End 2016 Results

March 9, 2017