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): January 9, 2017

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 7.01 Regulation FD Disclosure.

On January 9, 2017, KemPharm, Inc., or the Company, issued a press release announcing the results of its exploratory Phase 1, double-blind, single-dose, 2-treatment, 2-period, randomized, crossover study, or Study KP511.A01, intended to assess the pharmacokinetics, safety and intranasal abuse potential of KP511 Active Pharmaceutical Ingredient, or KP511 API, compared to equivalent doses of hydromorphone hydrochloride, or 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 pharmacokinetics of KP511 resulted in meaningful, statistically lower scores in the exploratory pharmacodynamic measures of "Drug Liking," "Feeling High," "Overall Drug Liking" and "Take Drug Again" when compared to HM API.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information set forth in this Item 7.01 and 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 the Company's filings under the Securities Act of 1933, as amended, or the Securities Act, 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 8.01 Other Events.

In the press release described above, on January 9, 2017, the Company announced the results of Study KP511.A01, its Phase I, double-blind, single-dose, 2-treatment, 2-period, randomized, crossover study of KP511. Study KP511.A01 was designed to assess the pharmacokinetics, safety and exploratory abuse potential of KP511 API compared to hydromorphone API after intranasal administration in twenty-six nondependent recreational opioid users who reported prior insufflation experience. The primary endpoint was pharmacokinetic evaluation of hydromorphone released from KP511 API and HM API. The secondary endpoint was safety. The exploratory endpoint was the abuse potential.

Mean peak hydromorphone exposure, or Cmax, was reduced by approximately 63% and median Tmax for hydromorphone was delayed by 30 minutes after insufflation of KP511 API when compared to HM API. Mean overall hydromorphone exposure with KP511 API was approximately 58% and 48% lower as measured by AUClast and AUCinf, respectively. In addition, mean cumulative hydromorphone exposures at time points following intranasal administration of KP511 were decreased from approximately 56% to 100% (higher reduction at earlier time points) with negligible hydromorphone plasma concentration prior to the 30-minute time point. The results demonstrated that KP511 prodrug may release hydromorphone at a significantly slower rate and lower extent after intranasal administration when compared to HM API. KemPharm believes the statistically significant reduction in hydromorphone exposure translated into statistically significant differences in the exploratory pharmacodynamic measures. Mean maximum scores, or Emax, of "Drug Liking" and "Feeling High" for KP511 were approximately 11.4 and 23.4 points lower, respectively. Additionally, mean "Overall Drug Liking" and "Take Drug Again" scores collected at 24 hours post-dose were approximately 16.0 and 13.3 points lower, respectively. Abuse measures were assessed on bipolar and unipolar ("Feeling High" only) visual analog scales.

In a retrospective assessment of drug preference after the last treatment, a significant majority of subjects (17 out of 26) preferred HM API over KP511 API indicating that KP511 may be less attractive for intranasal abuse. Several endpoints related to intranasal irritation including nasal burning, need to blow nose, nasal discharge and facial pain were higher (i.e., more severe) for KP511 versus HM API.

Also on January 9, 2017, the Company made available on the Company's website at www.kempharm.com, an investor presentation that includes, among other things, an update regarding the Company's product candidate pipeline. Management of the Company intends to deliver the presentation at investor meetings in January 2017. A copy of the presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K, the contents of which are incorporated herein by reference. The information contained in this Current Report on Form 8-K speaks only as the date hereof. While the Company may elect to update the information in this Current Report on Form 8-K in the future, the Company disclaims any obligation to do so except to the extent required by applicable law.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Exchange Act. 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, characteristics, development timeline and potential submission of NDAs for KP511/ER and KP511/IR. 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; the impact of competitive products and technological changes; obligations to third parties regarding the potential commercialization or sale of KP511/ER or KP511/IR; and the FDA approval process, including without limitation any timelines for related approval. 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 the Company's business are described in additional detail in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, and the Company's other Periodic and Current Reports filed with the Securities and Exchange Commission. The Company 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 Reports Positive Data from Phase 1 Intranasal Pharmacokinetic Study of KP511, An Investigational Prodrug of Hydromorphone for the Treatment of Pain” dated January 9, 2017.
99.2	Presentation titled "Management Presentation" dated January 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.

KEMPHARM, INC.

Date: January 9, 2017

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

Exhibit Index

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99.2	Presentation titled "Management Presentation" dated January 2017.

Exhibit 99.1

KemPharm Reports Positive Data from Phase 1 Intranasal Pharmacokinetic Study of KP511, An Investigational Prodrug of Hydromorphone for the Treatment of Pain

Statistically significant pharmacokinetic and pharmacodynamic differences of abuse potential were observed in the KP511.A01 Study

Coralville, IA – January 9, 2017 – KemPharm, Inc. (NASDAQ:KMPH), a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced the results of its exploratory Phase 1, double-blind, single-dose, 2-treatment, 2-period, randomized, crossover study (Study KP511.A01) intended to assess the pharmacokinetics, 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 pharmacokinetics of KP511 resulted in meaningful, statistically lower scores in the exploratory pharmacodynamic measures of "Drug Liking," "Feeling High," "Overall Drug Liking" and "Take Drug Again" when compared to HM API.

"This study provides very strong preliminary evidence that KP511 imparts significant potential for deterring intranasal abuse when compared to currently marketed hydromorphone products" said Lynn Webster MD, Vice President Scientific Affairs, PRA Health Sciences, Salt Lake City Utah, following an independent review of the Study results. "While the promising results of this exploratory study will need to be confirmed in a pivotal intranasal human abuse potential study, they show that KP511 may provide improvement across multiple abuse measures relative to hydromorphone. It was particularly important to see that the "Take Drug Again" endpoint was significantly lower with KP511. The "Take Drug Again" measure plays an important role in the premarket assessment of abuse deterrent technologies for predicting their performance in the real world. The current data suggest that KP511 may be less likely snorted, which could be a potential public health benefit."

"We are pleased with the results of the Phase 1 study of KP511, which demonstrated that KP511 may, if the results are confirmed, provide clinically meaningful differences in intranasal abuse potential versus hydromorphone. If confirmed, this may give us the option to develop KP511 as an extended-release and immediate-release product candidate, and, if approved, could potentially provide an effective therapy to pain patients and offer a new hydromorphone product with meaningful abuse-deterrent properties," stated Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "The decrease in mean peak hydromorphone exposure by approximately 63% combined with the delay of 30 minutes in time to peak exposure translated into significant reduction in "Drug Liking," "Feeling High," "Overall Drug Liking" and "Take Drug Again" scores."

"Given the magnitude of the potential benefit, we intend to develop both an extended release (ER) and an immediate release (IR) version of KP511. The next phase in the development of KP511 is the completion of pivotal studies over the next two years, leading to potentially two New Drug Applications (NDAs) being submitted as early as 2019 with anticipated expedited review," added Travis. "Based on our estimates, in 2015, the combined ER and IR market for hydromorphone was more than $280 million, with over 3.2 million scripts written in that year. A market this large requires products with effective abuse deterrence."

Summary of the Preliminary Results from Study KP511.A01.

Study KP511.A01 was a Phase 1, double-blind, single-dose, 2-treatment, 2-period, randomized, crossover study intended to assess the pharmacokinetics, safety and exploratory intranasal abuse potential of KP511 API compared to hydromorphone API after intranasal administration in twenty-six nondependent recreational opioid users who reported prior insufflation experience. The primary endpoint was pharmacokinetic evaluation of hydromorphone released from KP511 API and HM API. The secondary endpoint was safety. The exploratory endpoint was the intranasal abuse potential.

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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 U.S. Food and Drug Administration (FDA)-approved drugs in the high need areas of pain, attention deficit hyperactivity disorder (ADHD)and other central nervous system (CNS) disorders. KemPharm’s co-lead clinical development candidates are KP415, an ER prodrug of methylphenidate for the treatment of ADHD, and KP201/IR, an acetaminophen (APAP)-free formulation of the company’s immediate release (IR) 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, characteristics, development timeline and potential submission of NDAs for KP511/ER and KP511/IR. 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; obligations to third parties regarding the potential commercialization or sale of KP511/ER or KP511/IR; and the FDA approval process, 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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Exhibit 99.2

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.

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 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 is **applicable across therapeutic areas**
- Amenable to **both immediate and extended release formulations**

KemPharm Prodrug Product Pipeline

Category	Product Candidate	Parent Drug	Development Status	Next Milestone	Potential NDA Submission
ADHD	KP415	Methylphenidate (ER)	Clinical	Efficacy Data	2018
PAIN	KP201/IR	Hydrocodone	Clinical	IN HAL Data	2018 with Priority Review
	KP511/ER	Hydromorphone	Clinical	POC in ER Formulation	2019 with Priority Review
	KP511/IR	Hydromorphone	Clinical	HAL and BE Data	2019 with Priority Review
	KP606/IR	Oxycodone	Preclinical	Preclinical Development	TBD
	KP746	Oxymorphone	Preclinical	Preclinical Development	TBD
CNS	KP303	Quetiapine	Preclinical	Preclinical Development	TBD

Multiple Other Compounds in Pre-Discovery Stage

Attention-Deficit/Hyperactivity Disorder:

KP415

For the Treatment of ADHD

KP415 Product Overview

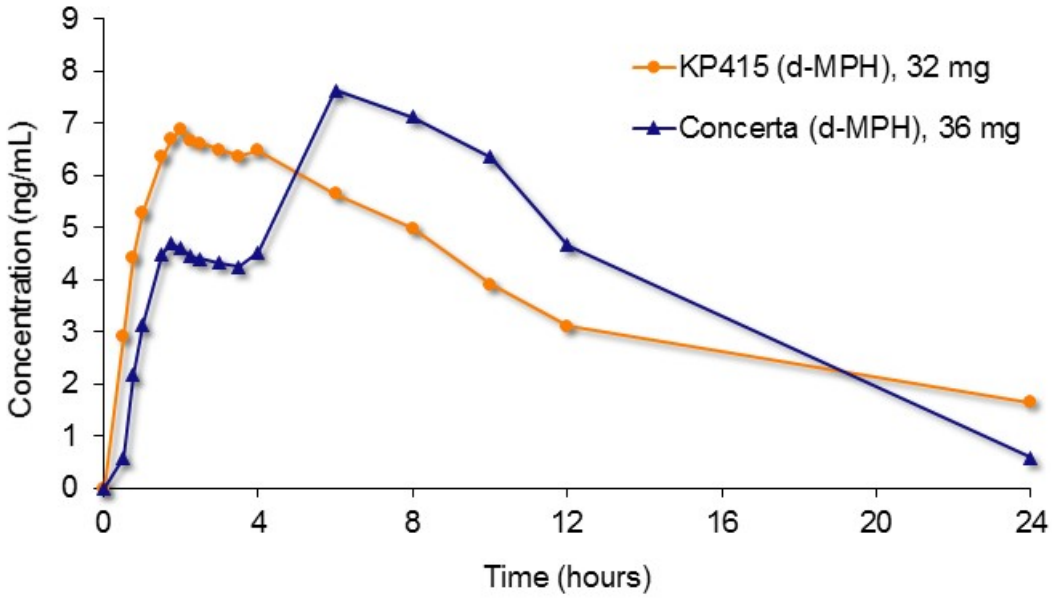
- Prodrug of d-methylphenidate with extended release properties
- Potential KP415 features and benefits
  - Earlier onset of action
  - Once-daily dosing
  - Active metabolism may offer more predictable therapeutic effect
  - Reduced abuse potential
  - Patient-friendly dosage form
    - Small capsule size (Size 4, same as Vyvanse), easily swallowed
    - May be opened and contents sprinkled on food or mixed into liquids for easier ingestion
- No generic equivalent product
- Composition-based patent expires in 2032, and is potentially NCE eligible

ADHD and ER Methylphenidate Market

- >$15 billion ADHD market with prescriptions growing at ~5% year-over-year
- Methylphenidate accounted for approximately 19.7 million TRx's and $4.2 billion in sales in 2015
- KemPharm believes ADHD key opinion leaders have significant interest in an ER methylphenidate product with:
  - Earlier onset
  - Improved duration of action
  - Abuse-deterrent properties
- Branded products are being pressured by patent expirations
  - Vyvanse is the branded market share leader and loses patent exclusivity in 2023
  - Concerta, Adderall, Focalin are all large brands which are all off patent

All market data is based on management estimates.

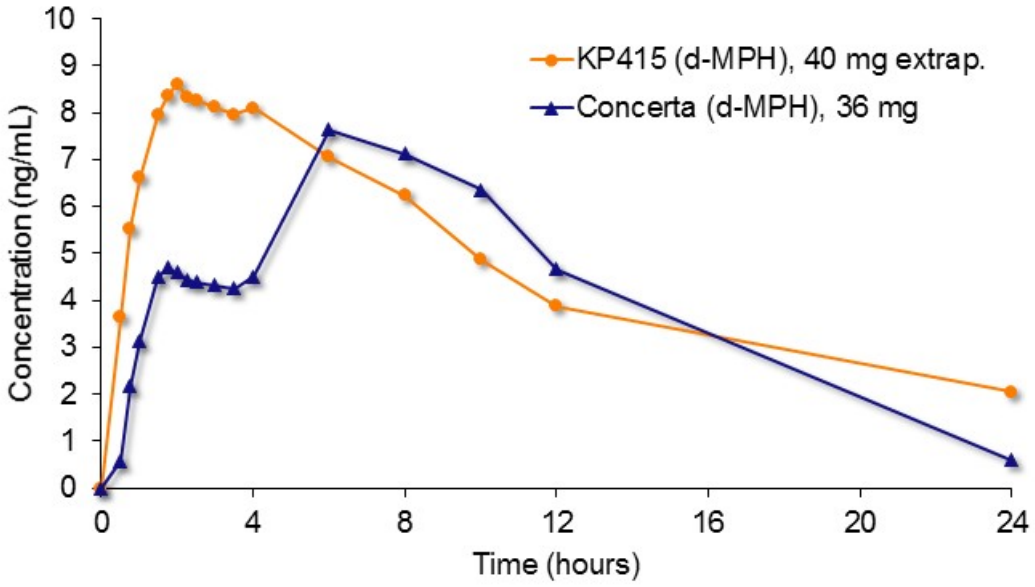
Clinical Study Results of KP415.101 – Oral PK in Humans



PK Parameter	N	KP415, 32 mg Mean (SD)	N	Concerta®, 36 mg Mean (SD)
C_{max} (ng/mL)	24	8.20 (5.11)	24	7.97 (2.26)
AUC_{last} (h*ng/mL)	24	89.1 (32.3)	24	97.0 (30.8)
AUC_{inf} (h*ng/mL)	24	119.7 (41.2)	24	101.5 (33.7)
T_{max} (h) (median, range)	24	3 (1, 8)	24	6 (6, 10)

Note: The 32 mg dose of KP415 was approximately 10.5% lower than 36 mg of Concerta® with respect to d-MPH.

Predicted Oral Exposure for Commercial Dosage Strength



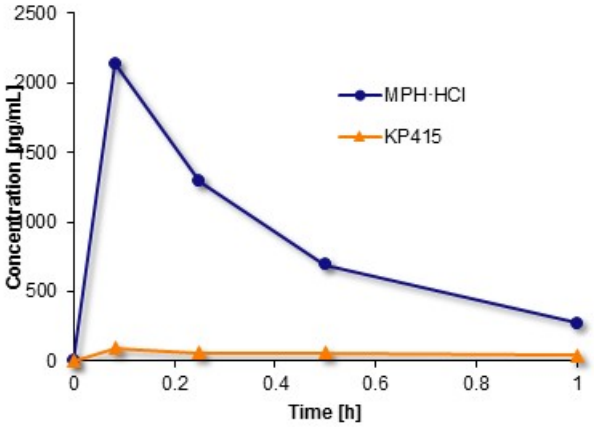
Note: KP415 (40 mg) plasma concentrations were extrapolated by KemPharm from data for the 32 mg dose administered in KP415.101 assuming dose linearity.

The 40 mg dose of KP415 is approximately 11.8% higher than 36 mg of Concerta® with respect to d-MPH.

KP415 Reduced IN and IV Pharmacokinetics in Rats

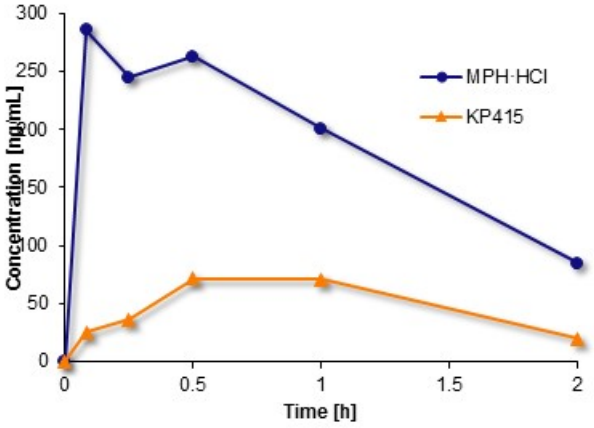
Intranasal PK Curves

	%AUC	$\%C_{max}$
KP415/MPH	7%	5%



Intravenous PK Curves

	%AUC	$\%C_{max}$
KP415/MPH	27%	25%



Dose Reference	Dose	
	KP415	MPH
Test Article (mg/kg)	4.75	2.39
MPH Content (mg/kg)	2.06	2.06
HED (mg/kg)	0.8	0.4

Note: MPH·HCl methylphenidate hydrochloride
HED = human equivalent dose

KP415 Clinical Update and Development Timeline

- Completion of a Pre-Investigational New Drug (Pre-IND) review of KP415 announced on July 14, 2016
- KP415 IND acceptance announced on October 11, 2016
- Results from KP415 Phase 1 proof-of-concept trial announced on December 14, 2016
- KP415 efficacy studies anticipated to commence in 2H 2017 with final data expected as early as 1H 2018
- KP415 NDA anticipated to be filed as early as 2018

Pain:

KP201/IR (APAP-free)
For the Short-Term Treatment of Acute Pain

KP201/IR (APAP-free) Product Overview

- IR formulation of benzhydrocodone without APAP
- Potentially the first IR hydrocodone-related/APAP free product in the U.S.
- An abuse-deterrent opioid that offers comparable efficacy to Vicodin, Norco and Lortab, but with the potential safety advantage of having no added APAP
  - According to the FDA, overdoses of APAP are the most common cause of drug-related liver injury
  - In 2011, the FDA limited the amount of APAP in prescription combination products and required warnings to be added to the labels of all APAP prescription products
- Molecular-Based Abuse-Deterrent Technology
- No generic equivalent product
- Composition-based patent expires in 2031
- Anticipated 505(b)(1) NDA submission with priority review

KP201/IR (KP201 API) Intranasal PK Trial

- KP201/IR (KP201 API or benzhydrocodone) compared to hydrocodone bitartrate (HB) after intranasal administration for drug exposure levels, safety and drug likability in single-center, randomized, double-blind trial (n=51)

- Significant differences observed include:

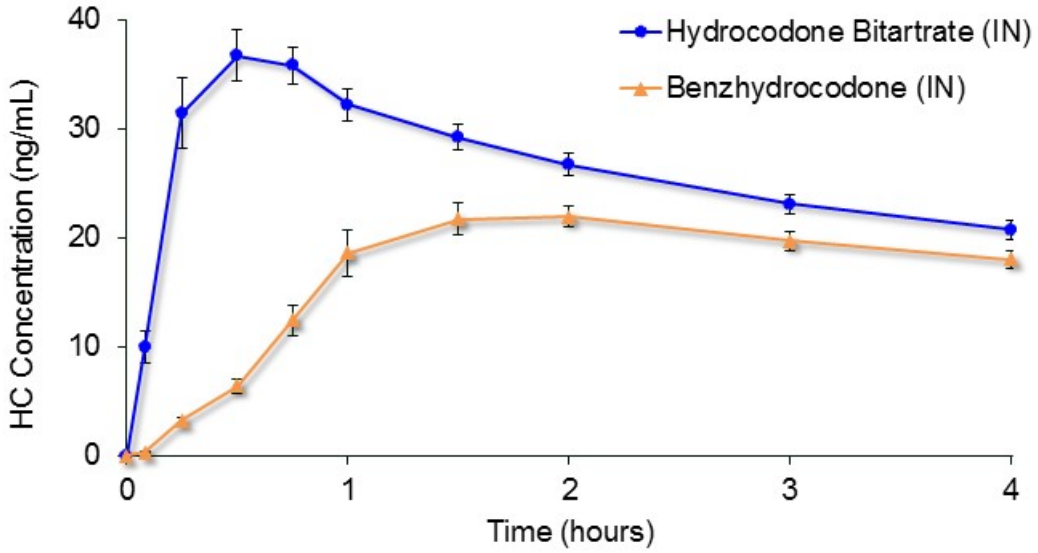
  - Significantly lower drug liking and pupil dilation for KP201/IR as well as greater difficulty in snorting KP201/IR vs. HB

  - 36% decrease in peak hydrocodone exposure (C_{max}) for IN KP201/IR vs. IN HB

  - Time to peak hydrocodone exposure (T_{max}) for IN KP201/IR delayed by one hour vs. IN HB

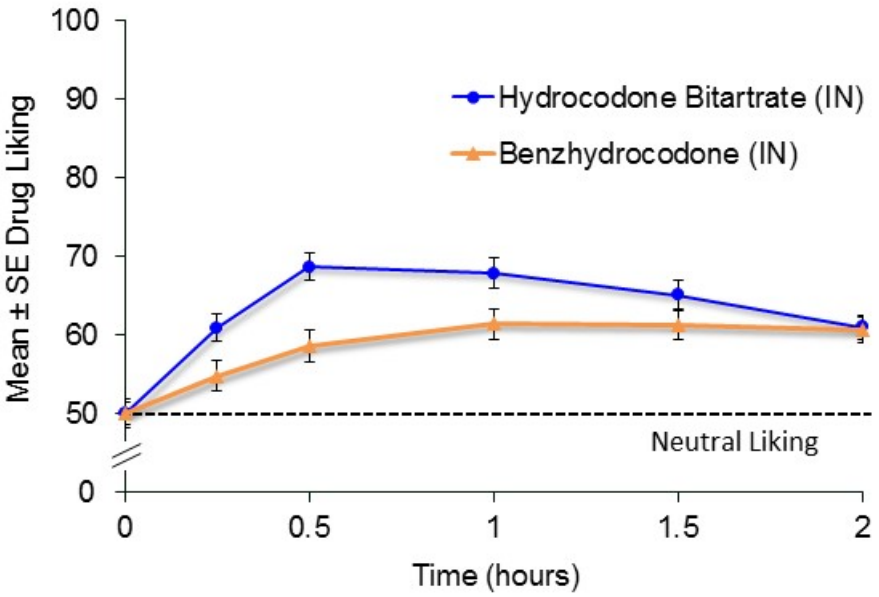
  - Decreased overall exposure to hydrocodone released from IN KP201/IR vs. IN HB (AUC_{last} and AUC_{inf} were 20.3% and 19.5% lower, respectively, p-value <0.0001 for each ratio)

Intranasal Administration of Benzhydrocodone API (KP201) and Hydrocodone Bitartrate API (Study A03)



PK Parameter	N	Benzhydrocodone, 13.34 mg Mean (SD)	N	Hydrocodone Bitartrate, 15 mg Mean (SD)	Benzhydrocodone vs Hydrocodone Bitartrate	
					GLSM Diff	P Value
C_{max} (ng/mL)	24	25.6 (6.4)	24	40.4 (11.8)	-36.0%	<0.0001
AUC_{last} (h*ng/mL)	24	185.5 (50.5)	24	231.1 (54.6)	-20.3%	<0.0001
AUC_{inf} (h*ng/mL)	24	194.7 (55.7)	24	239.4 (58.4)	-19.5%	<0.0001
T_{max} (h) (median, range)	24	1.75 [0.75, 4.00]	24	0.50 [0.25, 2.02]	–	–

Intranasal Administration of Benzhydrocodone and Hydrocodone Bitartrate – Drug Liking Scores (Study A03)



Parameter Mean (SE)	Benzhydrocodone 13.34 mg	HB 15 mg	Benzhydrocodone vs HB P Value
E_{max}	67.5 (1.8)	73.2 (1.8)	0.004
TE_{max} (hours)	1.5 (0.1)	0.9 (0.1)	0.0039

Note: HB = hydrocodone bitartrate

Differences Observed in Drug Liking and Ease of Insufflation of KP201 (API) vs. Hydrocodone (API)

Parameter	LS Mean		P-value
	KP201 (API)	Hydrocodone Bitartrate	
Drug Liking E_{max}	67.5	73.2	0.004
Ease of Insufflation[1]	78.5	65.8	0.0004

1. Higher score indicates increased difficulty with insufflation
Study A03: Intranasal HAP Study of APIs (N=51)

KP201/IR Clinical Update and Development Timeline

- Completed KP201/IR End-of-Phase 1 (EOP1) meeting with the FDA on June 23, 2016
- Licensing agreement with Acura Pharmaceuticals for Aversion® abuse-deterrent technology announced on October 18, 2016
- KP201/IR IND acceptance announced on November 29, 2016
- KP201/IR "Fast Track" designation announced on December 20, 2016
- Human clinical trials of KP201/IR anticipated to commence in 1H 2017 with final IN HAL study data expected as early as prior to year end 2017
- KP201/IR NDA anticipated to be filed as early as 2018
- Priority Review status expected

Pain:

KP511/ER and KP511/IR
For the Treatment of Severe Pain

KP511/ER and IR: Product Overview

- KP511 is a prodrug of hydromorphone
  - KP511/ER is designed as an Extended Release (ER) formulation
  - KP511/IR is designed as an Immediate Release (IR) formulation
- Potential KP511 abuse-deterrent features based on clinical and preclinical trials
  - Significantly reduced IN and IV bioavailability
  - Significantly reduced IN drug liking VAS, drug HIGH VAS and take drug again VAS
  - Highly tamper resistant
  - Limited oral bioavailability at high doses (potential overdose protection)
- No generic equivalent product
- Composition-based patent expires in 2032
- Anticipated 505(b)(2) NDA submission with priority review

Hydromorphone Market

- Nearly a $280 million combined ER and IR hydromorphone market in 2015
- Almost 3.2 million total prescriptions in 2015
- Hydromorphone prescribers:
  - ~3,500 branded prescribers
  - ~140,000 generic prescribers
- The top 4 specialties make up over 50% of the prescription base
- Prescription data suggests an increased writer base since a generic hydromorphone ER product was launched in Q2 2014
- Neither Exalgo nor Dilaudid, the only branded hydromorphone ER and IR products, respectively, have AD labeling

All market data is based on management estimates.

KP511 (API) Intranasal PK and Pilot HAL Studies

- KP511 API compared to molar-equivalent dose of hydromorphone (HM) API after intranasal administration for drug exposure levels, safety and drug likability in single-center, randomized, double-blind trial (n=26)

- Significant differences observed include:

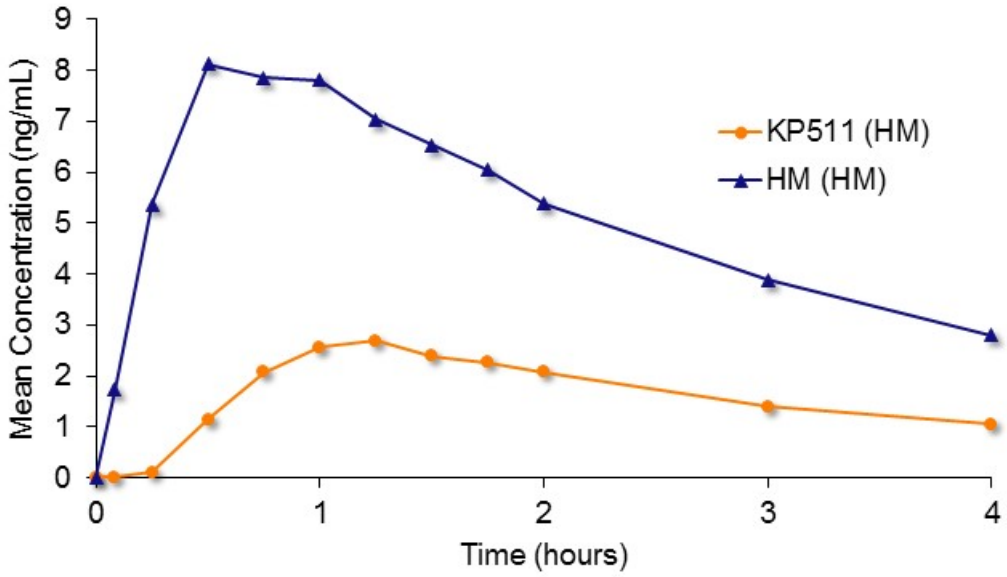
  - Significantly lower drug liking, feeling high, and take drug again VAS scores for KP511 vs. HM

  - Approximately 63% decrease in peak hydromorphone exposure (C_{max}) for IN KP511 vs. IN HM

  - Time to peak hydromorphone exposure (T_{max}) for IN KP511 delayed by 30 minutes vs. IN HM

  - The mean systemic exposure ($AUC_{0\text{-}inf}$) to hydromorphone released from IN KP511 was only 20.0 ng*hr/mL as compared to 38.8 ng*hr/mL following IN HM

Study KP511.A01 – Intranasal Pharmacokinetics



PK Parameter	N	KP511, 16.1 mg Mean (SD)	N	HM·HCl 8 mg Mean (SD)
C_{max} (ng/mL)	26	3.46 (1.57)	26	9.25 (2.99)
AUC_{last} (h*ng/mL)	26	14.45 (5.03)	26	34.23 (9.47)
AUC_{inf} (h*ng/mL)	26	19.79 (7.87)	26	38.16 (9.78)
T_{max} (h) (median, range)	26	1.25 (0.5, 2.0)	26	0.75 (0.25, 1.25)

Note: 16.1 mg of KP511 are equivalent to 8 mg of HM·HCl with respect to hydromorphone content.

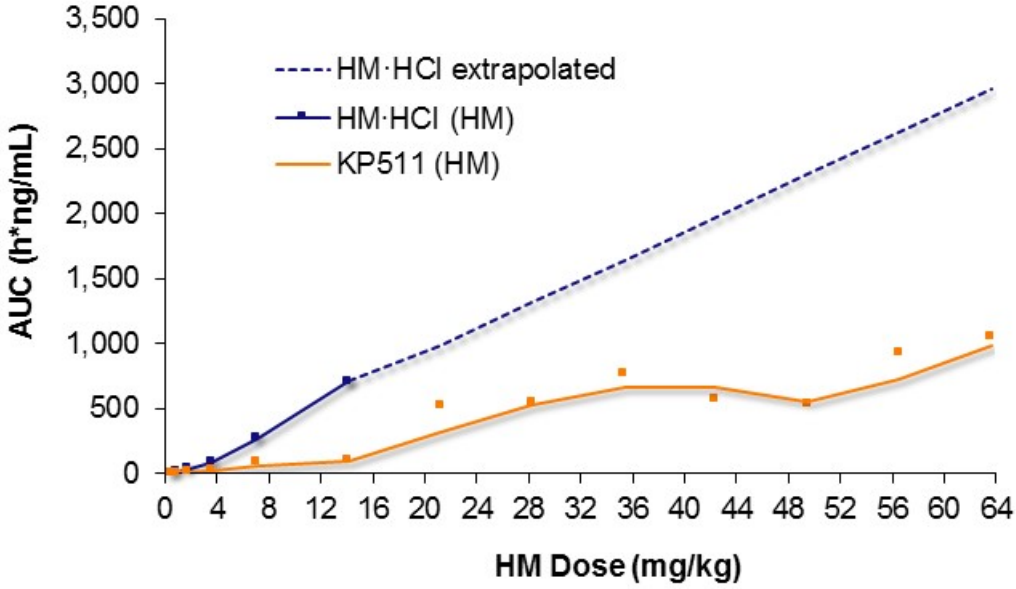
HM·HCl = hydromorphone hydrochloride

Differences Observed in Drug Liking, Feeling High and Take Drug Again of KP511 (API) vs. Hydromorphone (API)

Parameter	LS Mean		P-value
	KP511 (API)	Hydromorphone (API)	
Drug Liking E_{max}	67.2	78.7	0.0017
Feeling High E_{max}	44.8	68.2	0.0002
Take Drug Again (12 hours)[1]	62.7	74.1	0.0094

1. Mean Take Drug Again scores at 8, 12, and 24 hours post dosing were very similar
Study KP511.A01: Intranasal Pilot HAL Study of APIs (N=26)

KP511 Potential Oral Overdose Protection



Note: HM·HCl refers to hydromorphone hydrochloride.
Studies conducted in rats.

KP511 Clinical Update and Development Timeline

- KP511/ER IND acceptance announced on March 28, 2016 and "Fast Track" designation was announced on May 10, 2016
- Results from KP511 API Phase 1 proof-of-concept trial announced on June 28, 2016
- Results from intranasal PK and pilot HAL studies of KP511 API announced on January 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 anticipated to be submitted in 2019
- Priority Review status expected for both NDAs

Central Nervous System Disorders:

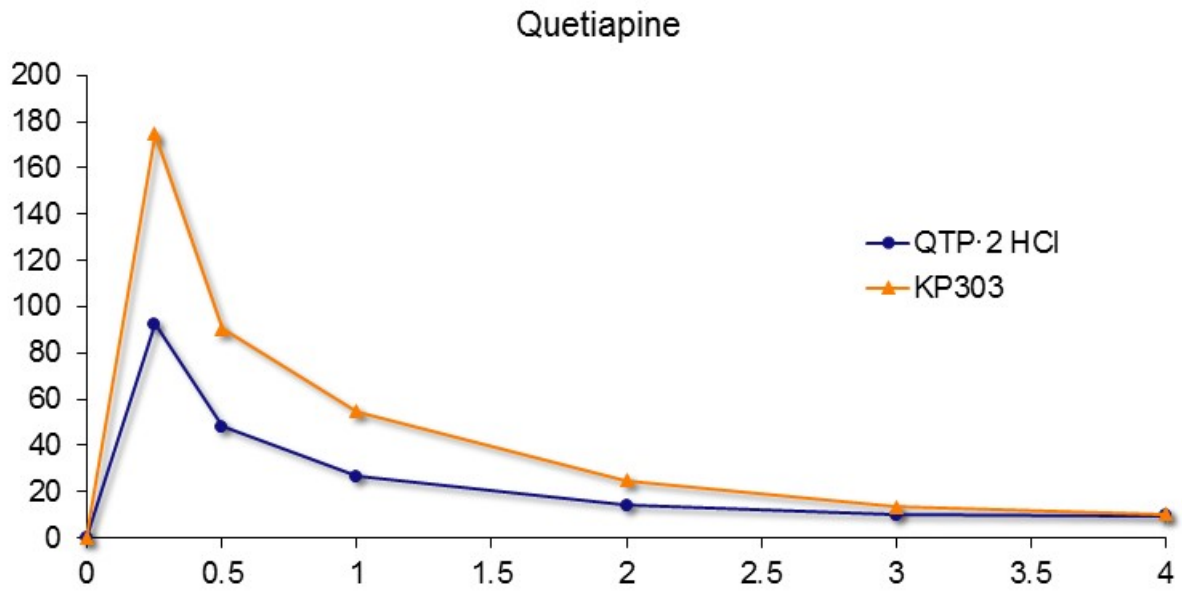
KP303

For the Treatment of Schizophrenia and Other CNS Disorders

KP303 Product Overview

- Prodrug of quetiapine (Seroquel®)
- Quetiapine is heavily metabolized by CYP450 in the liver
- High interpatient variability (due to differences in hepatic enzymes)
- KP303 has been observed to have significantly higher oral bioavailability in rats compared to quetiapine
- Potential clinical benefits may include:
  - Improved efficacy
  - Decreased interpatient variability (i.e. more consistent effect)
  - Fewer or less severe adverse reactions due to potentially reduced problematic metabolites
- Potential for utilization of the 505(b)(2) regulatory pathway
- Composition-based patent expires in 2030, and is potentially NCE eligible

KP303 Oral PK Profile in Rats



PK Parameter	KP303 vs QTP·2 HCl Mean Diff
C_{max} (ng/mL)	+90%
AUC_{0-4h} (h*ng/mL)	+68%

Note: KP303 (N=22) and QTP·2 HCl (N=28) were administered at equimolar doses of 6.92 and 5.34 mg/kg, respectively. Both contain approximately 4.5 mg/kg of quetiapine.

KemPharm Expected News Flow

Product	Event	Date
KP511 (API)	Intranasal PK and Pilot HAL Study Data	1Q 2017
KP415	Initiate Efficacy Trials	2H 2017
KP201/IR	Intranasal HAL Study Data	2H 2017
KP415	Efficacy Trial Results	1H 2018
KP415	NDA Submission	2018
KP201/IR	NDA Submission with Priority Review	2018
KP511/ER	NDA Submission with Priority Review	2019
KP511/IR	NDA Submission with Priority Review	2019

Q3 2016 Financial Update

- Total cash, cash equivalents, restricted cash, marketable securities and long-term investments of $92.0M as of September 30, 2016
    - Represents a decrease of $10.6M from June 30, 2016
- Q3 2016 net loss of ($13.4M), or ($0.92) per basic and diluted share vs. Q3 2015 net loss of ($9.7M), or ($0.68) per basic and diluted share
    - Net loss for Q3 2016 driven by a loss from operations of ($10.4M), net interest expense of $1.7M, and non-cash fair value adjustment expense of $1.3M
- Operating loss for Q3 2016 was ($10.4M) vs. ($6.5M) for Q3 2015
    - Primarily due to $3.0M of severance expense related to deferral of commercial operations and an increase in G&A costs of $0.9M due to an increase in headcount
- 14,646,982 common shares outstanding at September 30, 2016

KemPharm

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