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): September 21, 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 8.01 Other Events.

On September 21, 2016, KemPharm, Inc., or 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 September 2016. A copy of the presentation is filed as Exhibit 99.1 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Presentation titled “Management Presentation” dated September 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: September 21, 2016

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

Exhibit Index

Exhibit No.	Description
99.1	Presentation titled “Management Presentation” dated September 2016.

Exhibit 99.1

KemPharm

Management Presentation

September 2016

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 August 11, 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
- 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	Feasibility	Phase 1	Phase 3	NDA	Next Milestone
ADHD	KP415	Methylphenidate (ER)					Proof-of Concept Data
PAIN	Apadaz™	Hydrocodone					FDRR Submission
	KP201/IR	Hydrocodone					IND Submission
	KP511/ER	Hydromorphone					Phase 3 Initiation
	KP606/IR	Oxycodone					Preclinical Development
	KP746	Oxymorphone					Preclinical Development
CNS	KP303	Quetiapine					Preclinical Development

Multiple Other Compounds in Pre-Discovery Stage

ADHD:

KP415
For the Treatment of ADHD

KP415 Product Overview

- Prodrug of methylphenidate
- Potential features and benefits
  - Extended release methylphenidate
    - Time to maximum plasma concentration is approximately three times longer than IR methylphenidate
  - Active metabolism may offer more consistent drug delivery
  - Suitable for more patient compliant dosage forms
    - Highly water soluble
    - Oral thin film, orally dissolving tablet, liquid, chewable
  - Reduced abuse potential
- No generic equivalent product
- Composition-based patent expires in 2032, and is potentially NCE eligible

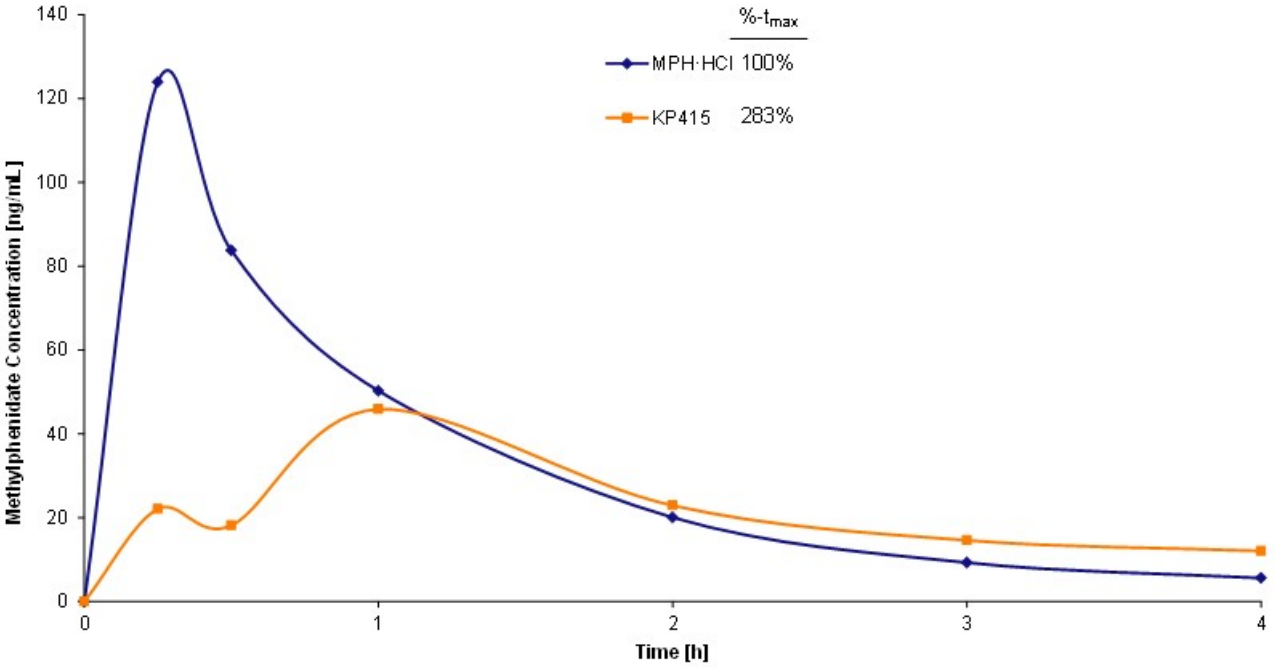
ADHD and ER Methylphenidate Market

- >$15 billion ADHD market
- ADHD market prescriptions are growing at ~5% year-over-year
- Methylphenidate accounted for approximately 19.7 million TRx's and $4.2 billion in sales in 2015
- Many physician specialties have increased their prescribing of ADHD products
- Branded products are being pressured by patent expirations
  - Vyvanse is the branded market share leader and growing; 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.

KP415 Oral PK Profile in Rats

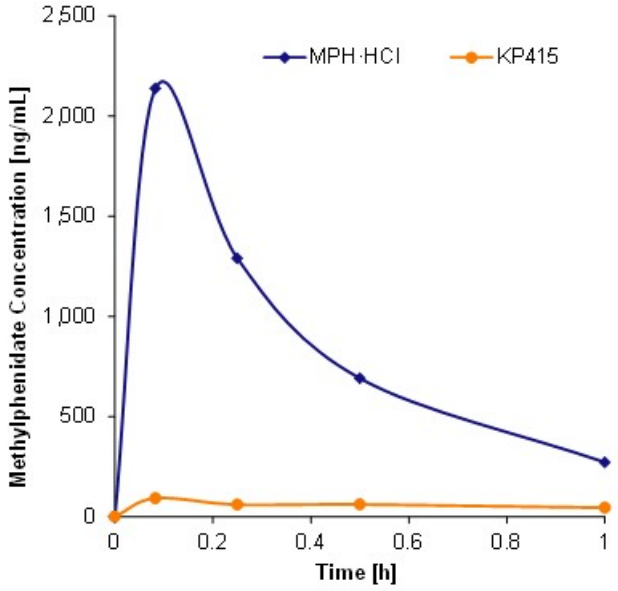
Oral PK Curves



Note: MPH·HCl refers to methylphenidate hydrochloride.
Studies conducted in rats.

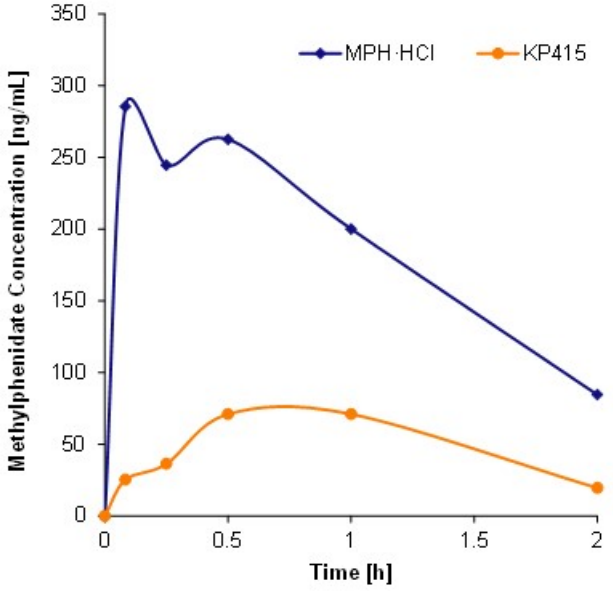
KP415 Reduced Abuse Potential

Intranasal PK Curves



	%-AUC	%-C_{max}
KP415	7%	5%

Intravenous PK Curves



	%-AUC	%-C_{max}
KP415	27%	25%

Note: MPH·HCl refers to methylphenidate hydrochloride.
Studies conducted in rats.

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 filing announced on September 19, 2016
- Human clinical trials of KP415 expected to begin in 4Q 2016
- Results from KP415 Phase 1 proof-of-concept trial expected to be announced by year-end 2016
- KP415 NDA expected to be filed in 2018

Pain:

Apadaz™ End of Review Meeting Update

End of Review Meeting with FDA

- Primary goals for the End of Review meeting were to gain greater clarity into the issues identified by the FDA in the Apadaz NDA and to achieve a potential path forward for an Apadaz product label that could include abuse deterrence claims

- Discussed fundamental questions pertaining:
  - Hydrocodone-acetaminophen combination products
  - Abuse deterrence in relation to the broader immediate-release (IR) prescription opioid market
  - Published industry guidance from the FDA concerning the evaluation and labeling of abuse deterrent opioids

- Also reviewed proposed short duration "blister" packaging for Apadaz, which was put forth as part of the Amendment Request to the Apadaz NDA
  - Blister packaging intended to align with the CDC's Guideline for Prescribing Opioids for Chronic Pain

Formal Dispute Resolution Request (FDRR)

- The intent of a FDRR submission is to provide a pathway by which applicants seek to resolve scientific and/or medical policy disputes that cannot be resolved at the Division level within the FDA
- If an issue is not resolved at the Division level, the applicant may request that the matter be reviewed at the next higher management level
- The sole issue for the FDRR is the different valuations of the abuse-deterrence data filed for Apadaz in the context of what is appropriate, fair and balanced abuse-deterrence label information for physicians and patients
- The EoR meeting minutes have confirmed that the Division is focused primarily on Category 3 data in determining whether an IR opioid product is eligible for any abuse-deterrent label claims

Pain:

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

KP201/IR (APAP-free) Product Overview

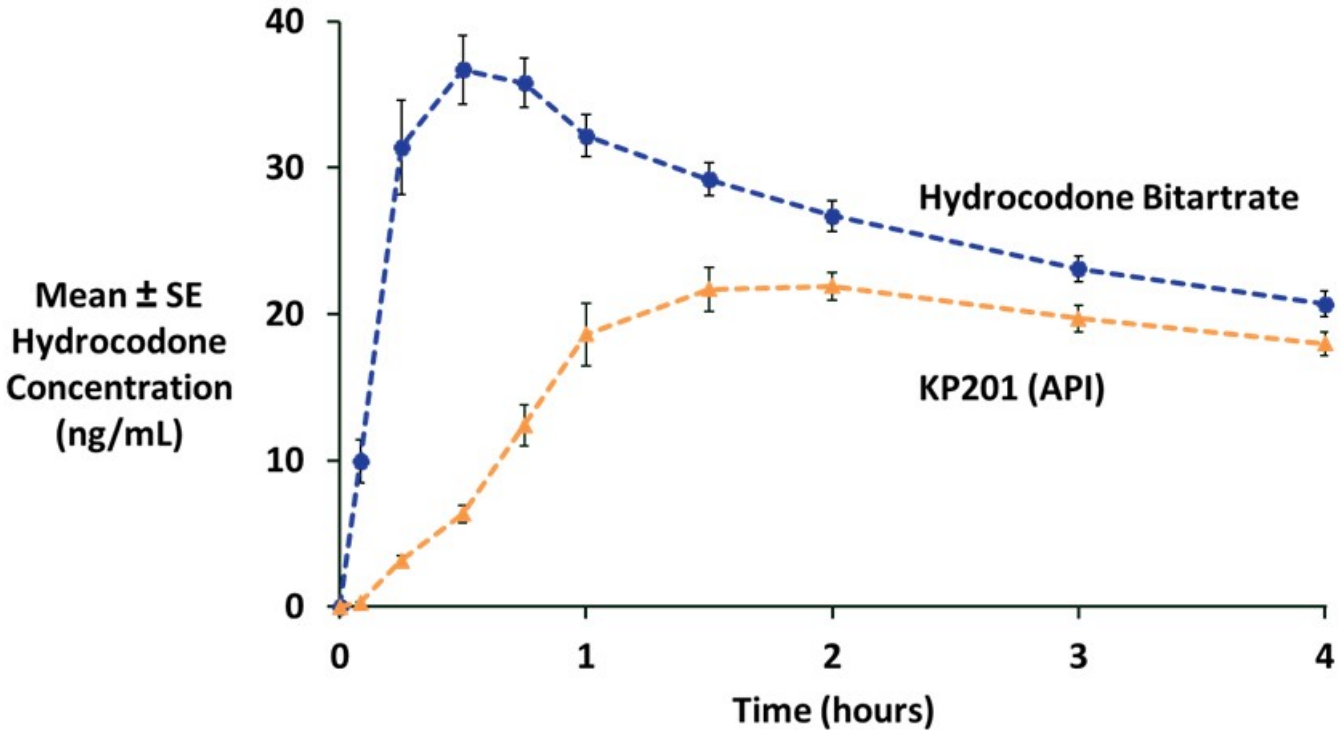
- IR formulation of benzhydrocodone without APAP
- Potentially the first IR hydrocodone-related product without APAP in the U.S.
- An abuse-deterrent opioid that offers comparable efficacy to Vicodin, Norco and Lortab, but with the potential safety advantage of having no added APAP
  - According to the 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 Intranasal PK Trial

- KP201/IR (benzhydrocodone API) 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)

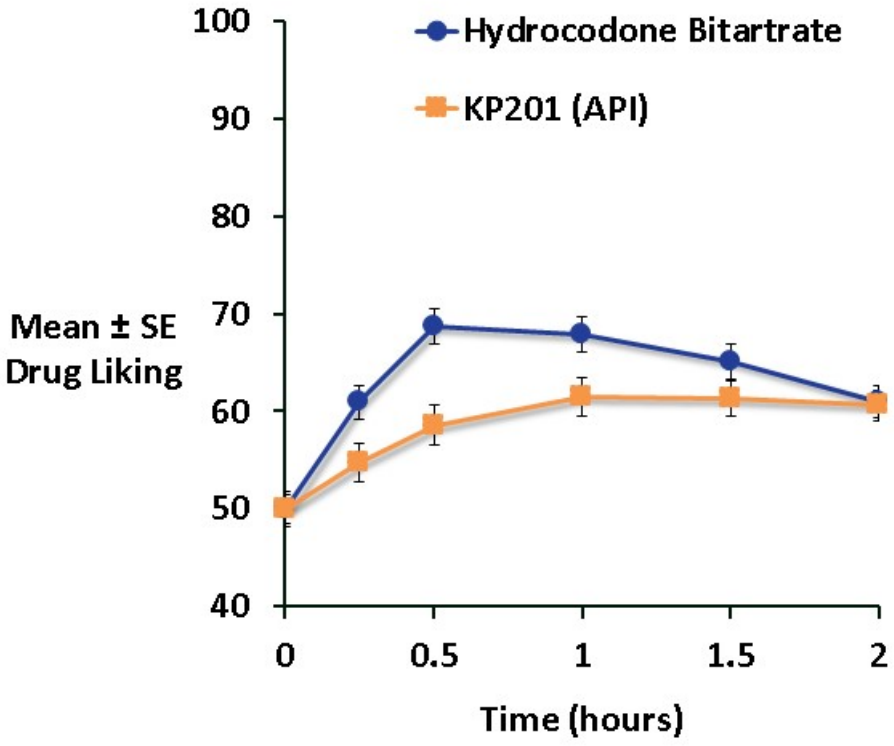
- Significant differences for IN KP201/IR vs. IN HB:
  - Significantly lower drug liking and pupil dilation for KP201/IR as well as greater difficulty in snorting KP201/IR vs. HB
  - 36% decrease in peak hydrocodone exposure (Cmax) for IN KP201/IR vs. IN HB
  - Time to peak hydrocodone exposure (Tmax) 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)

IN Administration of KP201 (API) Demonstrated Lower HC Release



Study A03: Intranasal HAP Study of APIs (N=24)

Differences in Drug Liking Over Time Mirrored PK Findings



Study A03: Intranasal HAP Study of APIs (N=51)

Differences Observed in Drug Liking E_{max} and Ease of Insufflation of KP201 (API) vs. Hydrocodone Bitartrate

Parameter	Mean		P-value
	KP201 (API)	Hydrocodone Bitartrate	
Drug Liking E_{max}	67.4	73.2	0.004
Ease of Insufflation	79	66	0.004

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
- KP201/IR IND filing expected in Q4 2016
- Human clinical trials of KP201/IR expected to begin in Q1 2017
- KP201/IR NDA expected to be filed in 2018
- Priority Review status expected

Pain:

KP511/ER
For the Treatment of Severe Pain

KP511/ER Product Overview

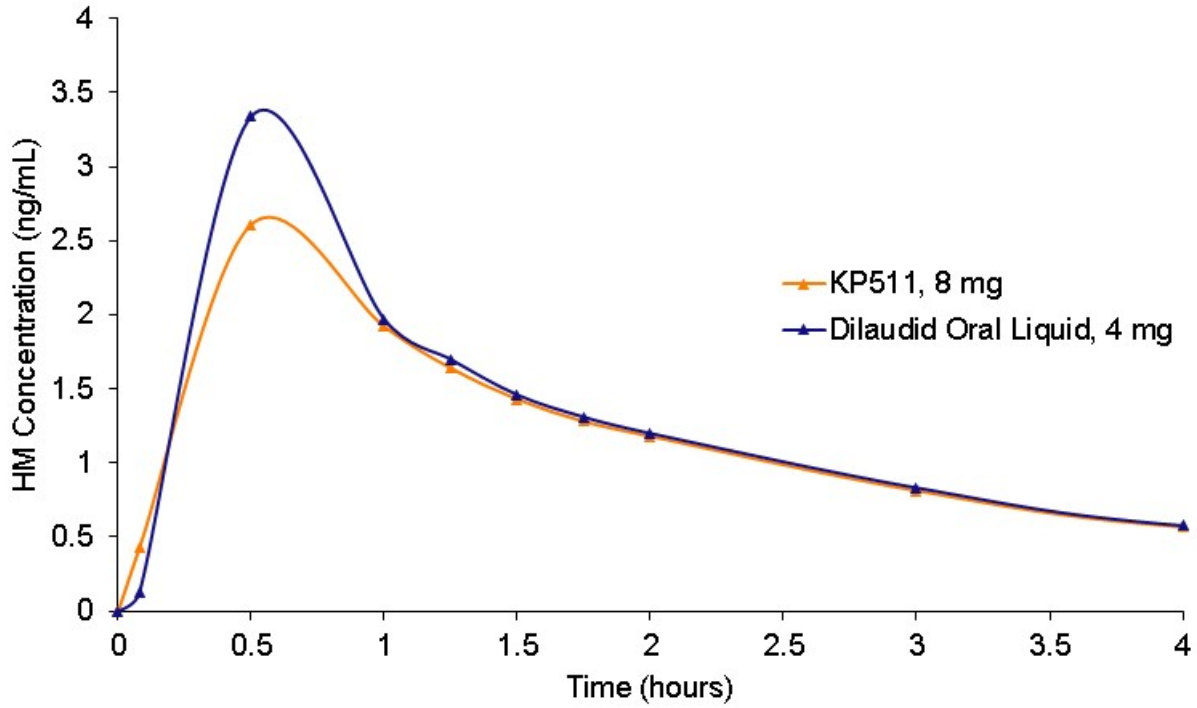
- KP511/ER is an ER formulation of KP511, a prodrug of hydromorphone
- Demonstrated comparable hydromorphone exposure vs. equimolar dose of Dilaudid™ in oral human proof-of-concept trial
- Potential valuable properties based on preclinical data
  - Significantly reduced IN and IV bioavailability (abuse deterrence)
  - Highly tamper resistant
  - Limited oral bioavailability at high doses (overdose protection)
- Composition-based patent expires in 2032
- Anticipated 505(b)(2) NDA submission with priority review

Hydromorphone ER Market

- Nearly a $350 million dollar hydromorphone market in 2015
- Almost 3.2 million total prescriptions in 2015
- Prescription data suggests an increased writer base since a generic hydromorphone ER product was launched in Q2 2014
- Hydromorphone prescribers:
  - ~3,500 branded prescribers
  - ~140,000 generic prescribers
- The top 4 specialties make up over 50% of the prescription base
  - Primarily: Pain, Anesthesiology and Rehab
- Exalgo, the only branded hydromorphone ER, does not have AD labeling

All market data is based on management estimates.

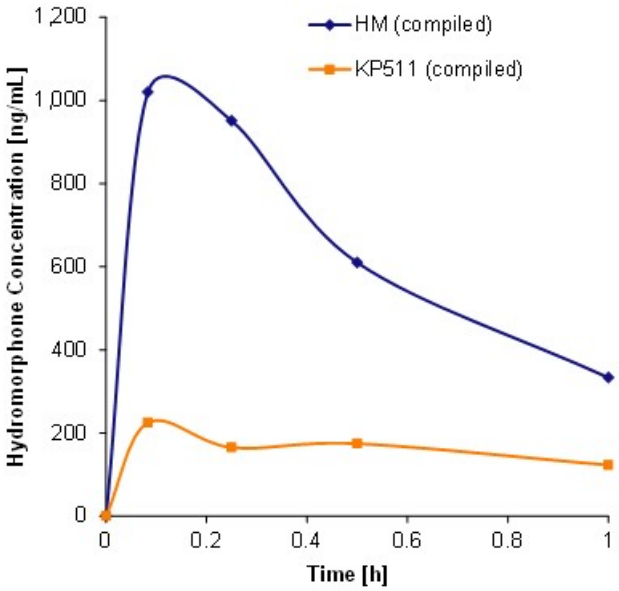
Clinical Study KP511.101 – Oral PK in Humans



Note: Dilaudid Oral Liquid is an oral solution of hydromorphone hydrochloride at a concentration of 1 mg/mL.
KP511, 8 mg is the molar equivalent of Dilaudid Oral Liquid, 4 mg.

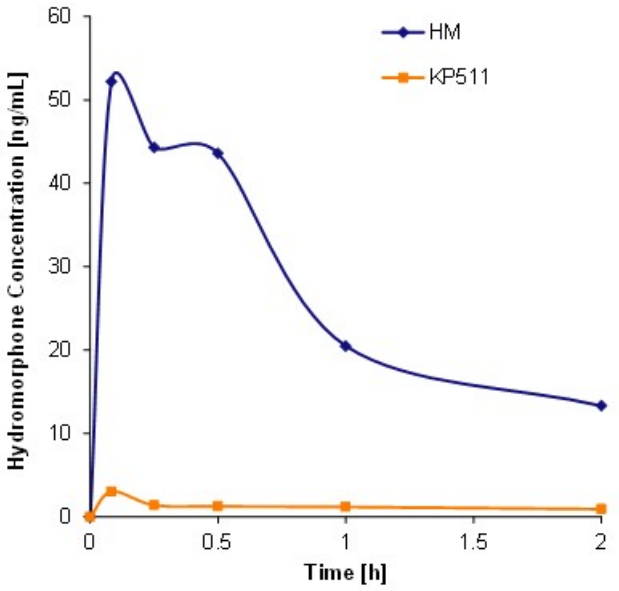
KP511/ER Reduced Abuse Potential

Intranasal PK Curves



- 2.0 mg/kg (hydromorphone eq.)
- Average data from 2 studies (N=10)
- %-AUC = 25%
- %-C_{max} = 22%

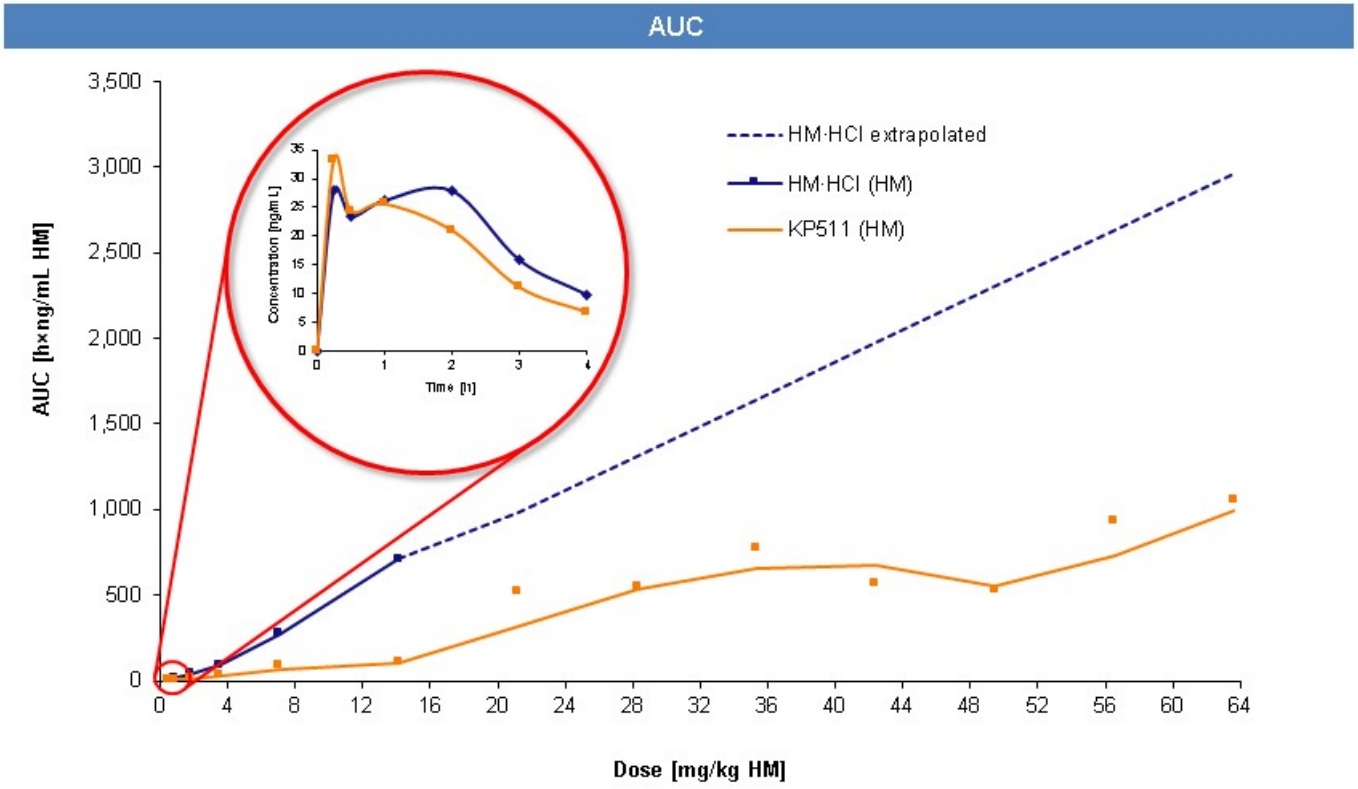
Intravenous PK Curves



- 0.2 mg/kg (hydromorphone eq.)
- 1 study (N=5)
- %-AUC = 5%
- %-C_{max} = 6%

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

KP511/ER Potential Oral Overdose Protection



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

KP511/ER Clinical Update and Development Timeline

- IND application accepted by the FDA in March 2016 and "Fast Track" designation granted in May 2016
- Positive results reported from Phase 1 proof-of-concept trial in June 2016
  - Comparable hydromorphone exposure between 4 mg Dilaudid™ Oral Liquid and an equimolar 8 mg dose of KP511 API
- Planning to initiate human abuse liability (HAL) studies to assess tamper and extraction resistance, intranasal and intravenous abuse potential, and the potential to limit oral abuse and/or overdose
  - Data from intranasal HAL studies of KP511 API expected in 1Q 2017
- Also intend to investigate KP511's potential to limit oral abuse and/or overdose and improve or reduce opioid-induced constipation (OIC)
- KP511/ER NDA expected to be filed in 2019
- Priority Review status expected

CNS:

KP303
For the Treatment of Schizophrenia and Other CNS Disorders

KP303 Product Overview

- Prodrug of quetiapine (Seroquel®)
- Potential for utilization of the 505(b)(2) regulatory pathway
- Composition-based patent expires in 2030, and is potentially NCE eligible

KemPharm Expected News Flow

Product	Event	Date
KP201/IR	IND Filing	4Q 2016
KP415	Human POC Data	4Q 2016
KP511 (API)	Intranasal PK and HAL Study Data	1Q 2017
KP415	Initiate Phase 3 Trials	2H 2017
KP201/IR	Intranasal HAL Study Data	2H 2017
KP415	Phase 3 Trial Results	1H 2018
KP415	NDA Submission	2018
KP201/IR	NDA Submission with Priority Review	2018
KP511/ER	NDA Submission with Priority Review	2019

Q2 2016 Financial Update

- Total cash and cash equivalents, restricted cash, marketable securities and long-term investments of $102.6M as of June 30, 2016
    - Represents a decrease of $8.4M from March 31, 2016
- Q2 2016 net income of $9.8M, or $0.59 per basic share, and ($0.58) net loss per diluted share vs. Q2 2015 net loss of ($29.7M), or ($2.45) per basic and diluted share
    - Net income for Q2 2016 driven by a $20.8M decrease in the fair value of the Company's derivative and warrant liability
- Operating loss for Q2 2016 were $9.3M vs. $6.0M for Q2 2015
    - Driven by an increase in R&D costs of $2.2M primarily related to activity for KP511 and KP415, and an increase in G&A costs of $1.1M due to an increase in headcount and commercial activities
- 14,646,982 common shares outstanding at June 30, 2016

KemPharm

For additional information please contact:

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