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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 12, 2015**

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**KEMPHARM, INC.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of incorporation)

**001-36913**  
(Commission File No.)

**20-5894398**  
(IRS Employer Identification No.)

**2656 Crosspark Road, Suite 100**  
**Coralville, IA 52241**  
(Address of principal executive offices and zip code)

**Registrant's telephone number, including area code: (319) 665-2575**

(Former name or former address, if changed since last report.)

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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:

- 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 August 12, 2015, members of management of KemPharm, Inc., or the Company, will present at the Canaccord Genuity 35<sup>th</sup> Annual Growth Conference on, among other things, the Company's product candidate pipeline. A copy of this presentation is available on the Company's website at [www.kempharm.com](http://www.kempharm.com), and is filed as Exhibit 99.1 to this Current Report on Form 8-K, the contents of which are incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation titled "Canaccord Genuity 35 <sup>th</sup> Annual Growth Conference" dated August 12, 2015.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 12, 2015

**KEMPHARM, INC.**

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Presentation titled "Canaccord Genuity 35 <sup>th</sup> Annual Growth Conference" dated August 12, 2015.



**KemPharm**

**Canaccord Genuity 35th Annual Growth Conference**

**August 12, 2015**

## 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 KP201/APAP and our other 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 Registration Statement on Form S-1 (Registration No. 333-202660) declared effective April 15, 2015, and our other Periodic and Current Reports filed with the Securities and Exchange Commission. 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.

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. Any information in this presentation provided by IMS Health Incorporated (IMS) is an estimate derived from the use of information under license from the following IMS Health information service: IMS National Sales Perspectives and NPA Audits, in each case, for the period of January 2011 to September 2014. IMS expressly reserves all rights, including rights of copying, distribution and republication.



## KemPharm Overview

- Specialty pharmaceutical company discovering and developing novel **prodrugs**
- Leverage **LAT Platform Technology** to improve the attributes of approved drugs in large markets
  - **505(b)(2) pathway** reduces risk and expense
  - **Composition-of-matter** patent protection
- KP201/APAP has the potential to be the **first FDA approved** abuse-deterrent IR hydrocodone/APAP product (NDA submission in 2H 2015)
  - IR hydrocodone is the **highest prescribed** opioid in the U.S.
- Pipeline of **product candidates** in pain, ADHD and other CNS disorders



# Management Team

Travis C. Mickle, PhD  
President and CEO



Gordon K. Johnson  
CBO



Tracy M. Woody  
CCO



R. LaDuane Clifton  
CFO



Sven Guenther, PhD  
EVP of R&D



## 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
    - o Ligands – GRAS or demonstrated to be safe
    - o 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**

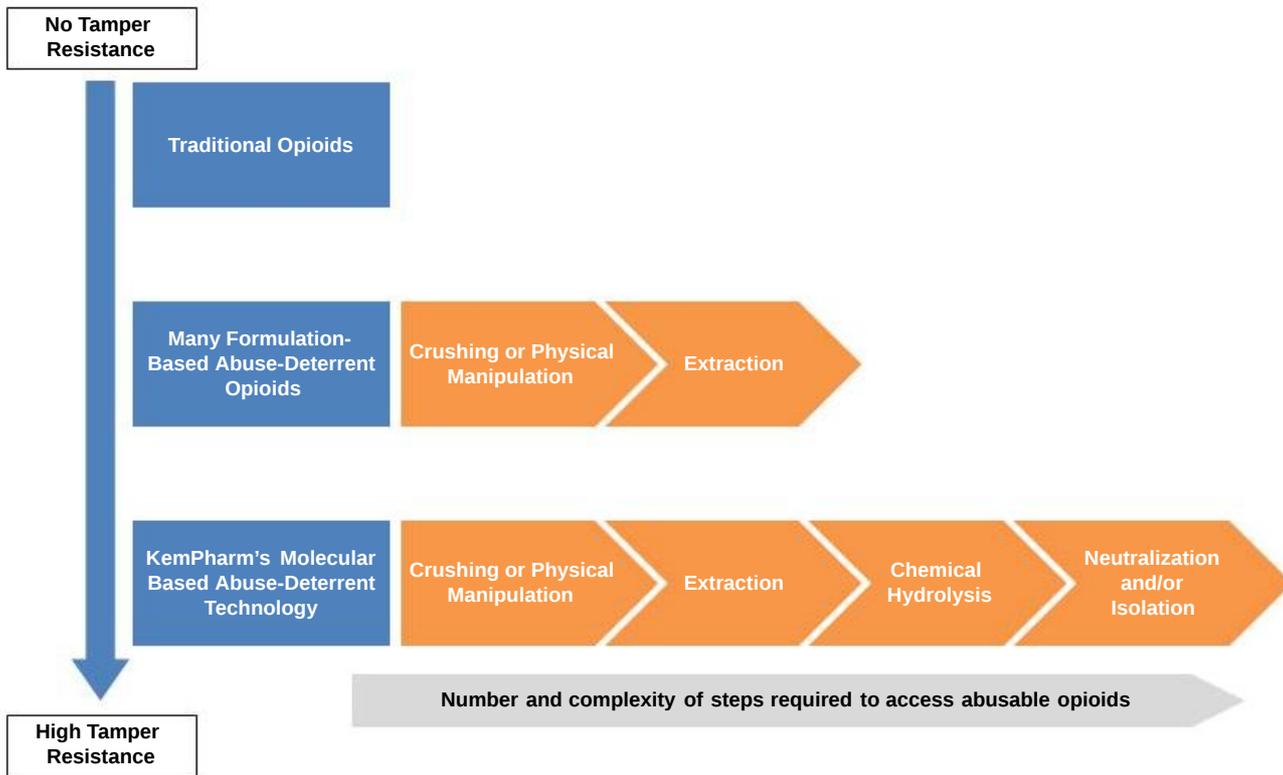
## Pipeline of Multiple Product Candidates

Selected KemPharm Prodrug Product Candidates			
Indication / Parent Drug	Product Candidate	Development Status	Key Milestone
<b>Pain</b>			
Hydrocodone (IR)	KP201/APAP	Clinical Trials	NDA Filing – 2H 2015
Hydromorphone (ER)	KP511/ER	Preclinical	Human POC Data – 2016
Oxycodone (ER)	KP606/ER	Preclinical	Human POC Data – 2017
<b>ADHD</b>			
Methylphenidate (controlled release)	KP415	Preclinical	Human POC Data – 2016
<b>Multiple CNS Disorders</b>			
Quetiapine	KP303	Preclinical	Preclinical Development

### Multiple Other Compounds in Pre-Discovery Stage



# Advancing Opioid Abuse-Deterrent Technology



## Opioid Abuse-Deterrent Landscape

	KemPharm Prodrugs	OxyContin	TARGINIQ	EMBEDA	Hysingla
Parent Drug	Multiple IR/ER Opioids	ER Oxycodone	ER Oxycodone	ER Morphine	ER Hydrocodone
Resists Physical Tampering	✓✓✓	✓	✓	✓	✓
Resists Non-Oral Abuse	✓✓✓	✓	✓	✓	✓
Molecular-Based Deterrence	✓	X	X	X	X
Prevents Common Solvent Extraction	✓	X	X	X	X
Potentially Prevents Oral Abuse	✓	X	X	X	X



# KP201/APAP Overview

Treatment of Acute Moderate to Moderately Severe Pain



## KP201/APAP Product Features

*Prodrug composed of hydrocodone and a generally regarded as safe (GRAS) ligand*

Molecular-Based Abuse-Deterrent Technology

Composition-of-Matter Patent Protection Until 2031

No Generic Equivalent Product (Benzhydrocodone)

Convenient Dosing

*Successfully completed bioequivalence trial in humans*

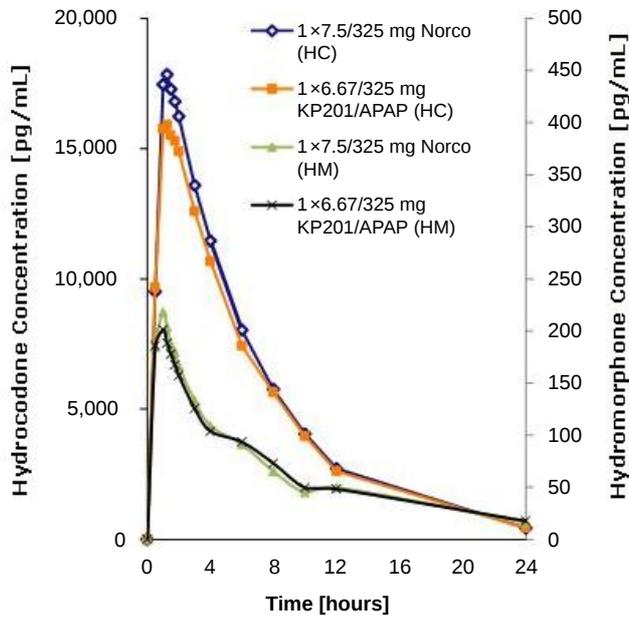


*Planned NDA submission in 2H 2015 with priority review anticipated*



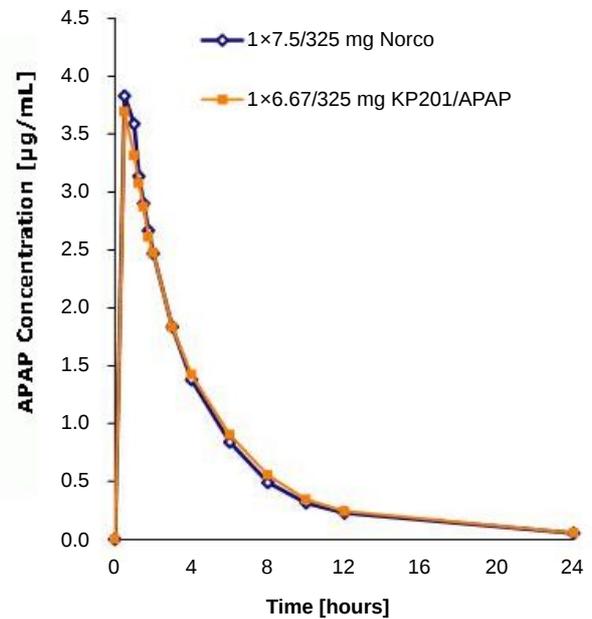
# Bioequivalence Study KP201.102 (KP201/APAP vs. Norco®)

## Hydrocodone/Hydromorphone



	C <sub>max</sub>	AUC <sub>0-t</sub>	AUC <sub>inf</sub>	T <sub>max</sub>
Hydrocodone	87%	94%	94%	102%
Hydromorphone	92%	100%	90%	120%

## Acetaminophen



	C <sub>max</sub>	AUC <sub>0-t</sub>	AUC <sub>inf</sub>	T <sub>max</sub>
APAP	92%	102%	99%	98%

Note: HC refers to hydrocodone.  
HM refers to hydromorphone, the active metabolite of hydrocodone.

## KP201/APAP Tamper Resistant Properties – In Vitro Studies

- Extraction of API (KP201) only yields inactive prodrug
- Hydrocodone not released through:
  - Physical manipulation (e.g., grinding)
  - Common solvent extraction (e.g., “alcohol dose dumping”, “cold water extraction”)
- KP201 is chemically stable under commonly applied “extraction methods”
- Hydrolysis under very harsh conditions is not practical
  - KP201 partially hydrolyzes under highly basic/acidic conditions
  - Poor solubility in blood, water and other solvents render it unsuitable for IV administration



## KP201 Solvent Hydrolysis Studies

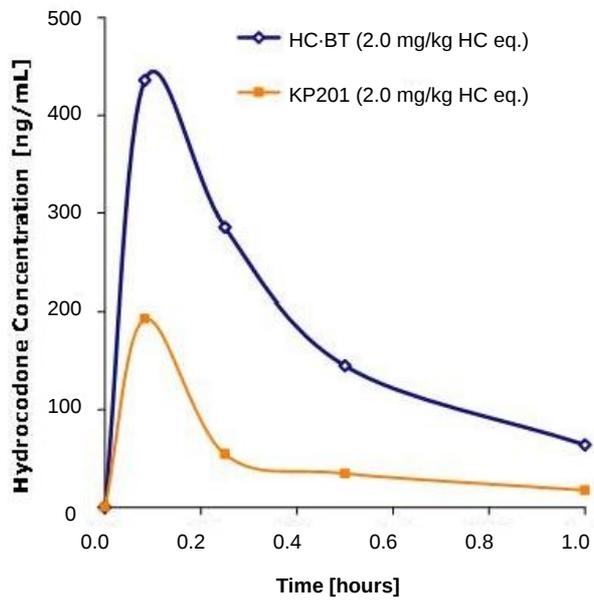
*Preliminary results suggest that KP201 remains intact and does not hydrolyze or break down into its components in commonly available solvents*

Solvent	% Release of Hydrocodone					
	Ambient Temperature			At Boiling Point		
	0.5 hours	1 hour	4 hours	0.5 hours	1 hour	4 hours
Water	0	0	0	0	0	0
Ethanol	0	0	0	0	0	0
Methanol	0	0	0	0	0	0
Acetone	0	0	0	0	0	0
Ethyl acetate	0	0	0	0	0	0
Toluene	0	0	0	0	0	0
Xylene	0	0	0	0	0	0
Tetrahydrofuran	0	0	0	0	0	0
Methyl ethyl ketone	0	0	0	0	0	0
Octane	0	0	0	0	0	0
Petrol ether	0	0	0	0	0	0

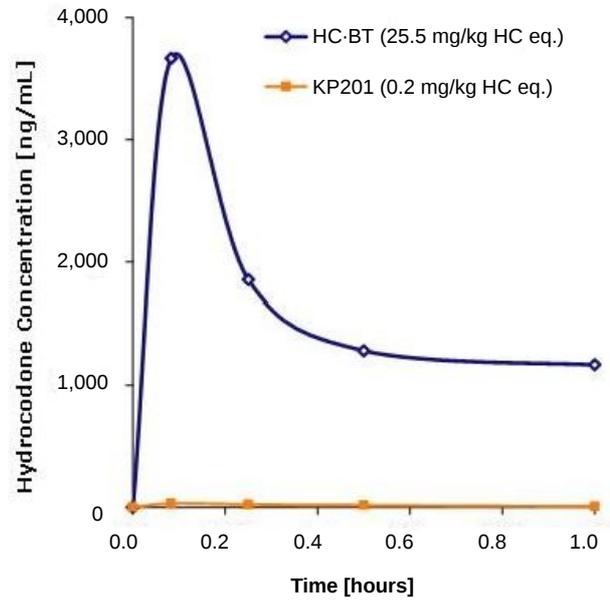


# KP201 Abuse-Deterrent Properties in Rat Studies

## Intranasal



## Intravenous



Note: HC-BT refers to hydrocodone bitartrate.

## Recently Completed KP201.A01 Human Abuse Liability Trial

- Oral Human Abuse Liability Trial
  - Compared the drug likability, exposure levels and safety of KP201/APAP compared to Norco after oral administration
  - Single-center, randomized, double-blind, active- and placebo-controlled crossover trial (62 subjects completed the study)
- Positive data announced on June 11, 2015
  - Lower exposure to hydrocodone at the highest dose levels
  - Lower incidence of hypoxia across the same dosage levels, suggestive of the potential for improved safety
  - Liking data was similar at each equivalent dose level, as expected



## Ongoing Human Abuse Liability and PK Trials

- Intranasal Human Abuse Liability Trial
  - Assesses the drug likability, exposure levels and safety of KP201/APAP compared to Norco after crushing and intranasal administration
  - Single-center, randomized, double-blind trial (n=40)
  - Data in 3Q 2015
- Intranasal KP201 (API) PK Trial
  - Assesses the drug exposure levels of KP201 (API) compared to hydrocodone bitartrate after intranasal administration
  - Single-center, randomized, double-blind trial (n=24)
  - Data in 3Q 2015



# KP201/APAP Potential Abuse-Deterrent Label Claims

## FDA Guidance

FDA is committed to retaining a flexible, adaptive approach to evaluating potentially abuse-deterrent opioid drug products. In some cases, data from all three categories or "tiers" of studies noted below may not be necessary. In most cases, however, in order to obtain a full and scientifically rigorous understanding of the impact of a technology or technologies on a product's abuse potential, data from each of the following three categories of re-marketing

1. Laboratory manipulation and extraction studies (Category 1)
2. Pharmacokinetic studies (Category 2)
3. Clinical abuse potential studies (Category 3)

The results of Category 1 studies influence the design of Category 2 pharmacokinetic studies, and the results of Category 2 studies influence the need for Category 3 studies of human abuse potential and the design and goals of these studies.



There are four general categories of claims available to describe the potential abuse-deterrent properties of a product. Depending on product and study data, a combination of categories can be included in the label claims. The FDA Guidance lists the following theoretical examples:

- Category 1: In vitro data demonstrate the product has physical and chemical properties that are expected to deter intravenous abuse.<sup>1</sup>
- Category 1 and 2: In vitro data demonstrate that the product has physical and chemical properties that are expected to deter oral, nasal and intravenous abuse.<sup>1</sup>
- Category 2 and 3: Pharmacokinetic and clinical abuse potential studies indicate that the product has properties that are expected to deter abuse via the oral, intranasal and intravenous routes.<sup>1</sup>
- Category 4: Data demonstrated a reduction in the abuse of the product in the community.<sup>1</sup>

<sup>1</sup> Abuse of the product is still possible by other routes

- The FDA outlines 3 types of studies that may translate into 4 categories of label claims
- KemPharm's abuse liability program is consistent with the FDA Guidance:

- Extraction/hydrolysis study
- Oral abuse liability trial (with pharmacokinetics)
- Intranasal abuse liability trial (with pharmacokinetics)

- KP201/APAP will be compared with Norco® in all studies
- Studies will be completed before filing of NDA
- If data is positive, label may include claims for up to 3 categories at approval



## Large Market Opportunity

- Hydrocodone is associated with more drug abuse and diversion than any other licit or illicit opioid<sup>(1)</sup>
- IR hydrocodone in combination with acetaminophen is the most frequently prescribed opioid in the U.S.<sup>(2)</sup>
  - IR hydrocodone/APAP products accounted for 127.4 million prescriptions in the U.S. in 2013 <sup>(2)</sup>
  - Assuming 14 days therapy prescribed and QID dosing, 127.4 million prescriptions translates into over 7 billion tablets per year

(1) DEA website.

(2) IMS Health Incorporated.

## KP201/APAP Commercial Strategy

*KemPharm has many potential avenues to commercialize KP201/APAP, including but not limited to, a collaboration or establishing a specialist U.S. sales force*

### Collaboration

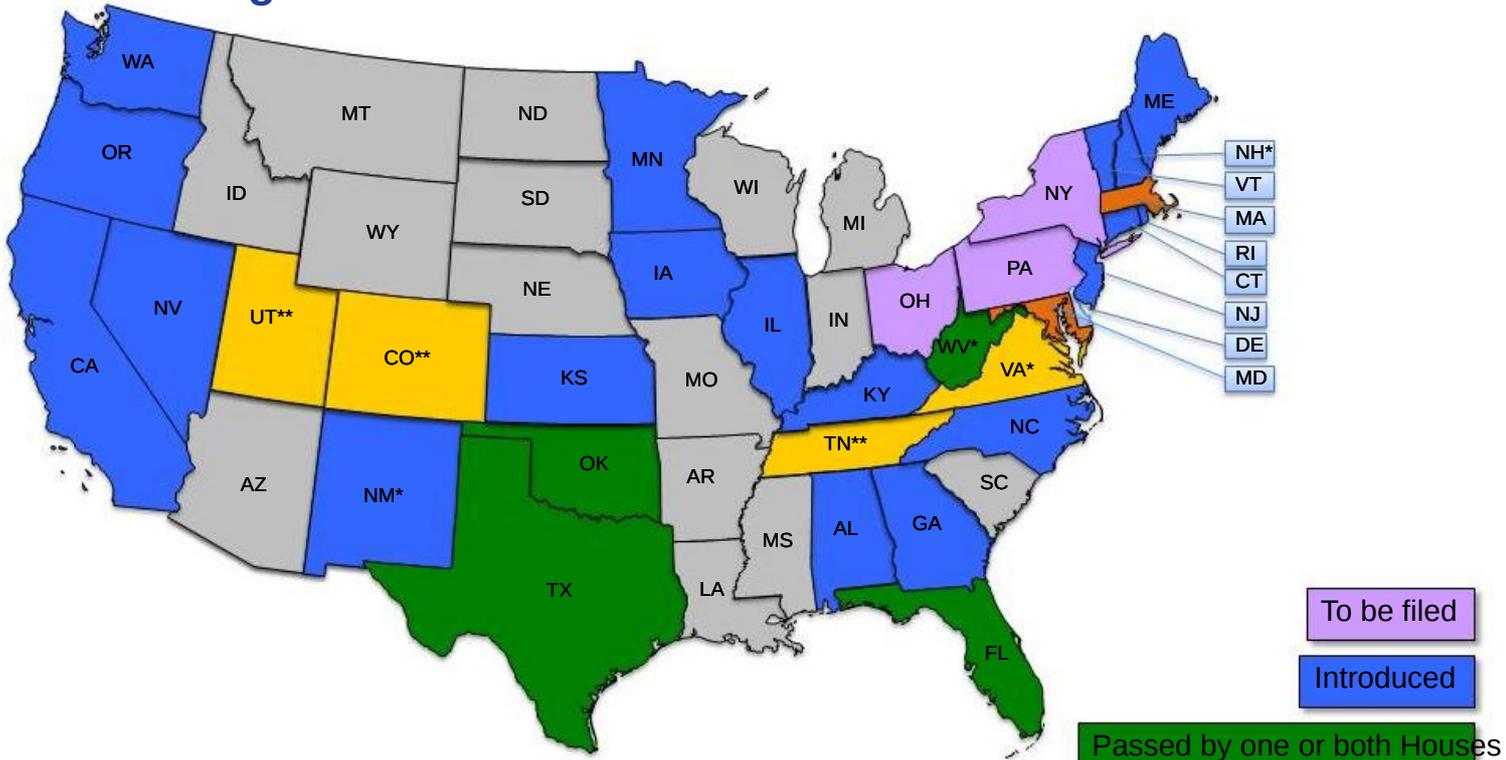
- Potential global / U.S.-based deal targeting large prescriber base, including primary care physicians
- Utilize contract sales force(s)

### Specialist U.S. Sales Force

- Specialist sales force targeting pain thought leaders, pain management specialists and high prescribing health care professionals
- License international commercial rights to one or more collaborators



# State Legislative Initiatives



\* Bill would require a study of AD inclusion on formularies  
 \*\* Bill has been converted or deferred to a study

Source: Presentation by Dan Cohen, CBI's Abuse Deterrent Formulations Conference, May 19-20, 2015, "Working with Policymakers and Payers to Improve the Incentives for ADFs" and company data.

## KP201/APAP Milestones

Human Bioequivalence	✓
Preclinical Abuse Deterrence / Tamper Resistance	✓
Oral Human Abuse Liability Trial	✓
Intranasal Human Abuse Liability Trial	3Q 2015
Intranasal PK Trial	3Q 2015
NDA Submission	2H 2015
NDA Approval (with priority review)	As Early As Mid-2016
DEA Scheduling and Product Launch	As Early As 2017



# KP511/ER Overview

## Treatment of Moderate to Severe Pain



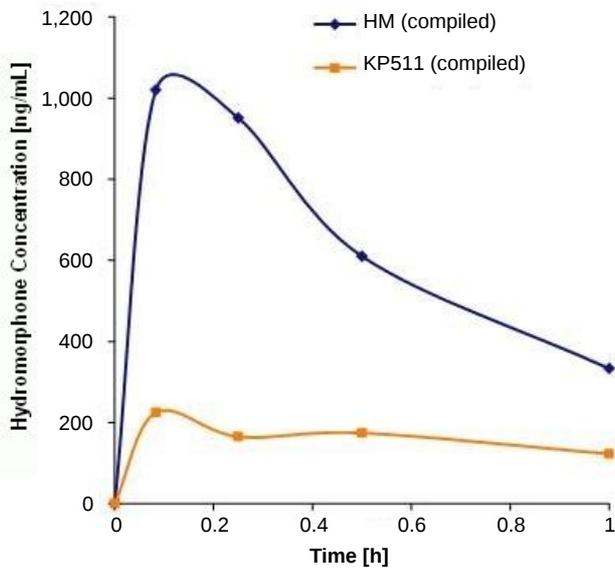
## KP511/ER Product Overview

- KP511/ER is an ER formulation of KP511, a prodrug of hydromorphone
- IR bioequivalent release of hydromorphone demonstrated in rats
- 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
- Potential for POC data in 2016 and utilization of the 505(b)(2) regulatory pathway



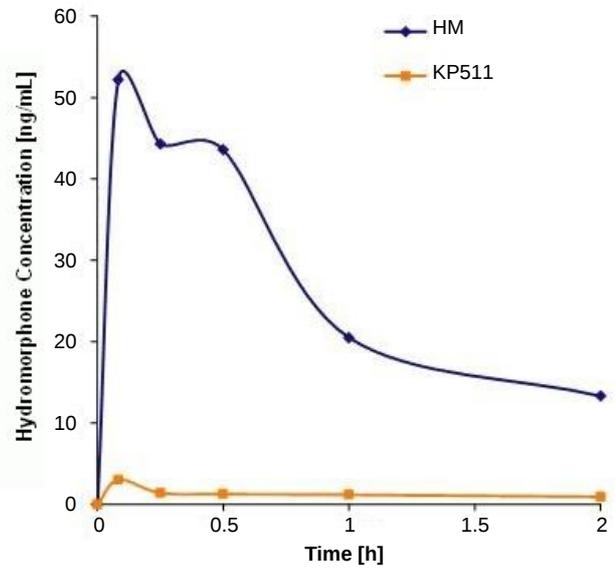
# KP511/ER Reduced Abuse Potential

Intranasal PK Curves



- 2.0 mg/kg (hydromorphone eq.)
- Average data from 2 studies (N=10)
- %-AUC = 25%
- %-C<sub>max</sub> = 22%

Intravenous PK Curves

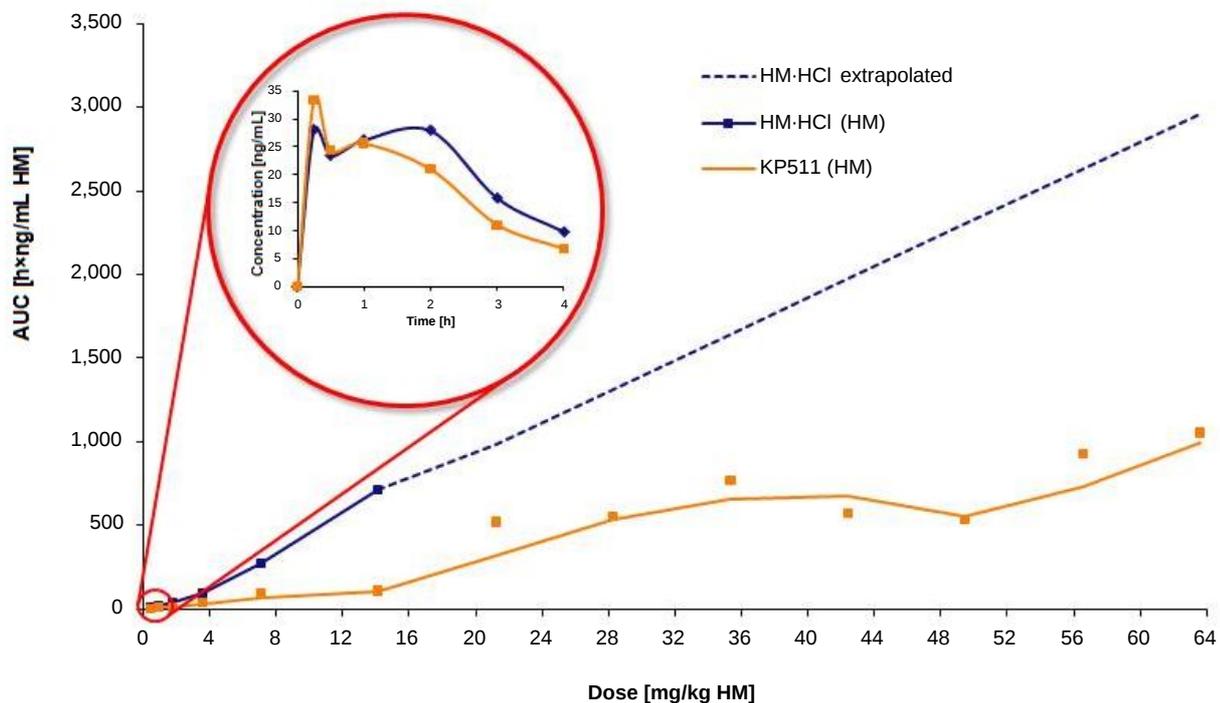


- 0.2 mg/kg (hydromorphone eq.)
- 1 study (N=5)
- %-AUC = 5%
- %-C<sub>max</sub> = 6%

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

# KP511/ER Potential Oral Overdose Protection

## AUC



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

# KP415 Overview

Treatment for ADHD



## KP415 Overview

- Prodrug of methylphenidate
- Branded formulations of methylphenidate (Concerta, Focalin and Ritalin) accounted for sales of \$1.1 billion in 2014<sup>(1)</sup>
- Potential features and benefits
  - Controlled release methylphenidate
  - Reduced abuse potential
  - Suitable for more patient compliant dosage form
    - Highly water soluble
    - Oral thin film, orally dissolving tablet, liquid, chewable
- Potential for POC data in 2016

(1) Public filings.

## KemPharm Expected News Flow

Product	Event	Date
KP201/APAP	Intranasal Human Abuse Liability Trial – Clinical Results	3Q 2015
KP201 (API)	Intranasal PK Trial – Clinical Results	3Q 2015
KP201/APAP	NDA Submission	2H 2015
KP201/APAP	NDA Approval (Priority Review)	As Early As Mid-2016
KP201/APAP	DEA Scheduling and Product Launch	As Early As 2017
KP511/ER	Human POC	2016
KP415	Human POC	2016
KP606/ER	Human POC	2017



## 1Q 2015 Update

- Cash of \$10.3 million as of March 31, 2015
- Net proceeds from IPO in April/May 2015 of \$59.9 million, net of underwriting discounts and commissions
- 1Q 2015 net loss was \$6.0 million vs. \$1.9 million for 1Q 2014
  - Increase in net loss year-over-year primarily due to IPO expenses and KP201/APAP R&D
- \$35 million available under the \$60 million Deerfield facility:
  - \$10 million optionally available upon NDA acceptance
  - \$25 million optionally available upon NDA approval





**KemPharm**

**For additional information please contact:**

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**[rjohnson@kempharm.com](mailto:rjohnson@kempharm.com)**

**319-665-2575**