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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): December 8, 2015**

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**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.)

**2656 Crosspark Road, Suite 100  
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)

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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 (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 8.01 Other Events.**

On December 8, 2015, Travis C. Mickle, the president and chief executive officer of KemPharm, Inc., or the Company, will present at the 26th Annual Oppenheimer Healthcare 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. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation titled "26th Annual Oppenheimer Healthcare Conference" dated December 8, 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 thereunto duly authorized.

**KEMPHARM, INC.**

Date: December 8, 2015

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

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**Exhibit Index**

Exhibit No.

Description

99.1

Presentation titled "26<sup>th</sup> Annual Oppenheimer Healthcare Conference" dated December 8, 2015.



**KemPharm**

**26th Annual Oppenheimer Healthcare Conference**

**December 8, 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. 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. 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 anticipated in 4Q 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
    - 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**



## Pipeline of Multiple Product Candidates

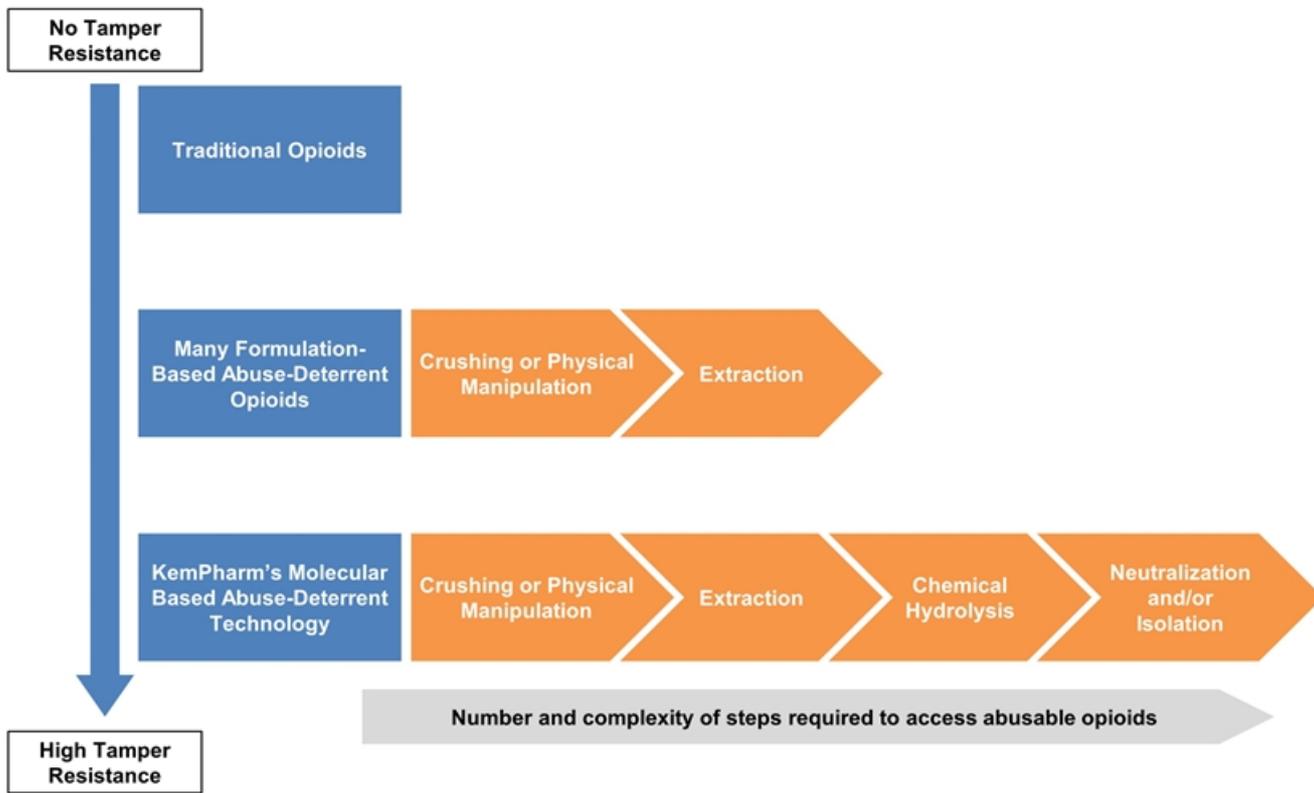
### Selected KemPharm Prodrug Product Candidates

Indication / Parent Drug	Product Candidate	Development Status	Anticipated NDA Filing
<b>Pain</b>			
Hydrocodone (IR)	KP201/APAP	Clinical	NDA Filing – 4Q 2015
Hydrocodone (IR)	KP201/IR (APAP-free)	Clinical	NDA Filing – 2017
Hydromorphone (ER)	KP511/ER	Preclinical	NDA Filing – 2018
Oxycodone (IR)	KP606/IR	Preclinical	NDA Filing – 2019
<b>ADHD</b>			
Methylphenidate (controlled release)	KP415	Preclinical	NDA Filing – 2019

### 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	✓	✗	✗	✗	✗
Prevents Common Solvent Extraction	✓	✗	✗	✗	✗
Potentially Prevents Oral Abuse	✓	✗	✗	✗	✗



# 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)

Bioequivalent, No Food Effect, Convenient Dosing

*Recently completed Human Abuse Liability Program in humans* ✓

*Planning NDA submission in 4Q 2015 with priority review anticipated*



## Large Market Opportunity

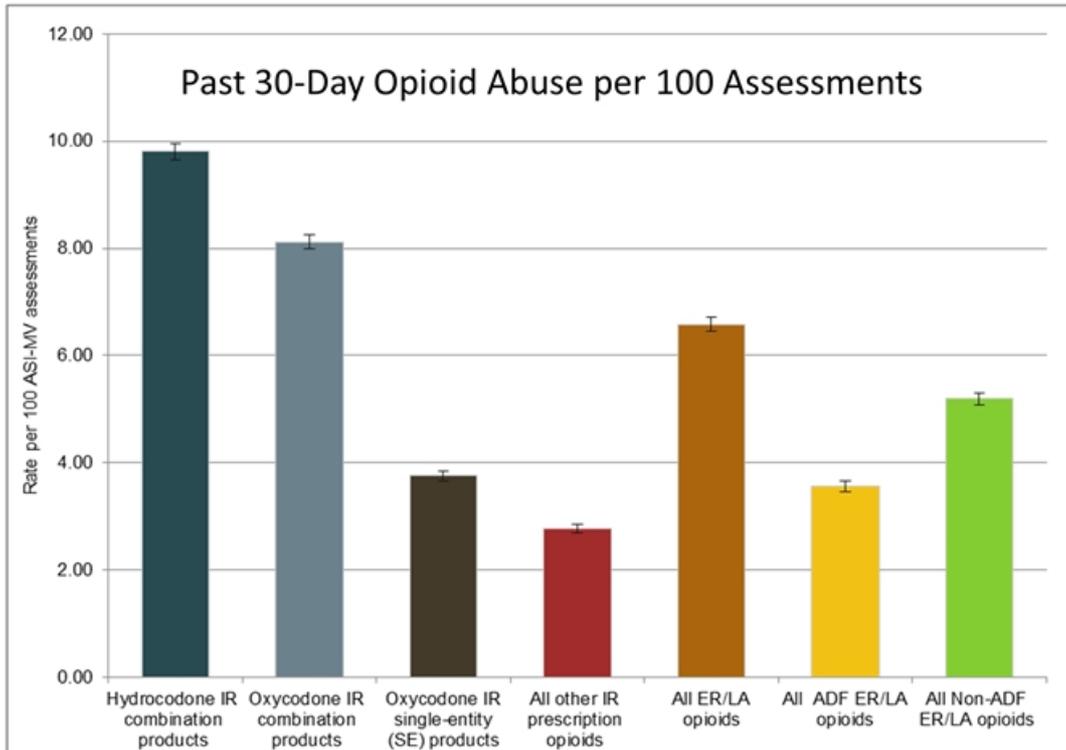
- Hydrocodone is associated with more drug abuse and diversion than any other licit or illicit opioid<sup>(1)</sup>
- IR hydrocodone in combination with acetaminophen is the most frequently prescribed opioid in the U.S.<sup>(2)</sup>
  - IR hydrocodone/APAP products accounted for 127.4 million prescriptions 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.

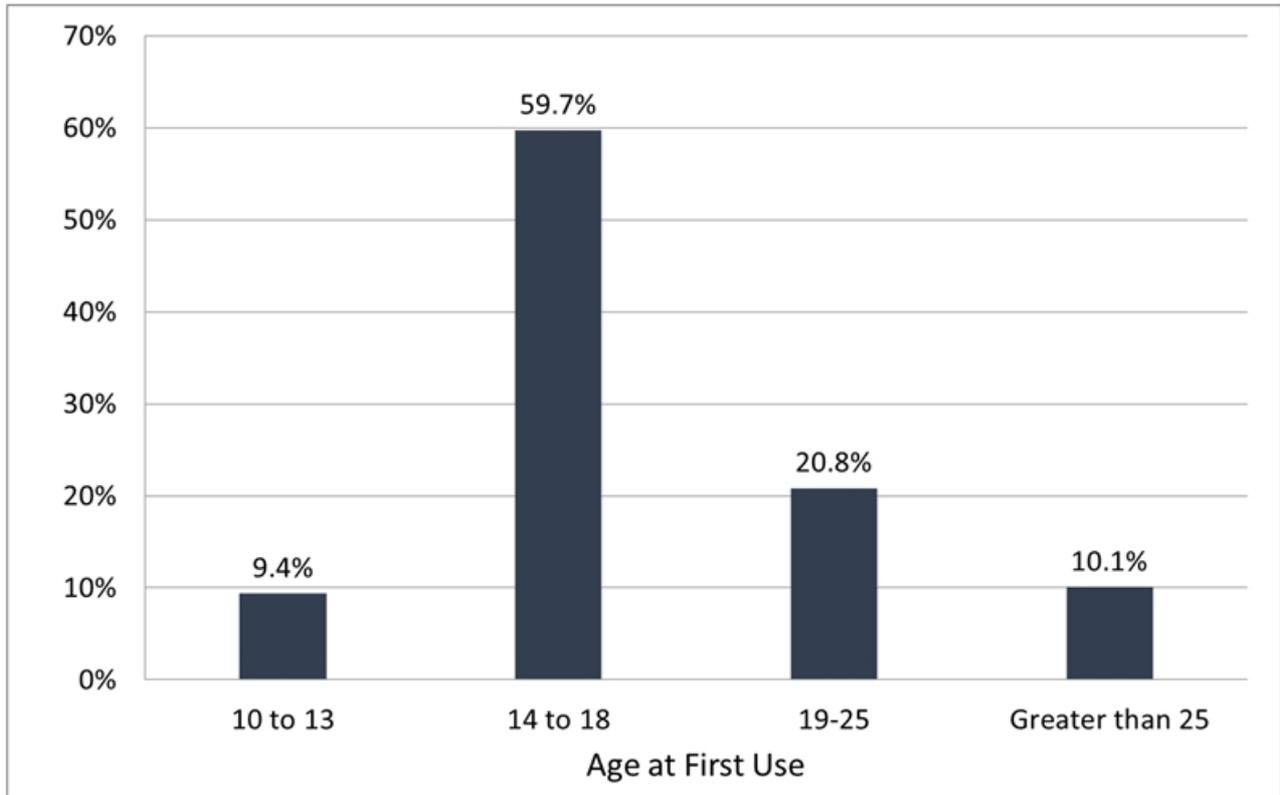


# Survey Data Indicates Large Hydrocodone Abuse Problem\*



\*Surveyed from January 2012 through September 2014. Total sample included 151,704 adult assessments from 743 centers located in 42 states. Abuse prevalence and patterns for immediate-release hydrocodone combination products. Theresa A. Cassidy, MPH, Eileen M. Thorley, MPH, Taryn Dailey, Stephen F. Butler, PhD; Inflexion, Inc., Newton MA; Presented at PAINWeek2015, September 8-12, 2015, Las Vegas, NV. Prepared by Inflexion, Inc. with support from KemPharm Inc.

## Age at First IR Hydrocodone Use Among Lifetime Users\*



\*Survey participants were recruited between December 2014 and March 2015 on [Bluelight.org](http://Bluelight.org).  
Patterns of abuse of hydrocodone combination products: Results from an internet survey of recreational drug users. Theresa A. Cassidy, MPH, Natasha K. Oyedele, MPH, Jared Beaumont, MPH, Stephen F. Butler, PhD; Inflexxion, Inc., Newton MA; Presented at PAINWeek2015, September 8-12, 2015, Las Vegas, NV. Prepared by Inflexxion, Inc. with support from KemPharm Inc.



## KP201.T01, KP201.T02 and KP201.T03 Tampering Studies

- KP201/APAP tampering studies designed to evaluate:
  - The potential of extraction of the KP201 prodrug from the tablet formulation and its conversion into active hydrocodone
  - The properties that reduce the likelihood of IV abuse of KP201/APAP
  - The potential to abuse KP201/APAP by smoking
- Data announced on September 30, 2015
  - Under all conditions tested (>1,000), the amount of hydrocodone released from KP201 was less than the amount of hydrocodone released from HB/APAP tabs
  - Extraction from KP201/APAP yielded mostly inactive KP201, while hydrocodone was efficiently extracted from HB/APAP under the same conditions



## KP201.T01, KP201.T02 and KP201.T03 Tampering Studies (cont'd)

- Greater than 90% of all conditions tested for extraction yielded no hydrocodone released from KP201/APAP
- Conditions that led to any release of hydrocodone from KP201/APAP required harsh chemicals and usually heat, by comparison, hydrocodone was extracted from HB/APAP tablets with only water
- Traditional means of preparing a drug for injection were not suitable for KP201/APAP, yielding only inactive KP201, while up to 100% of hydrocodone could be extracted from HB/APAP by the same process
- Cold water extraction yielded no free hydrocodone from KP201/APAP
- Smoking or freebasing of KP201/APAP tablets was not possible
- Smoking of the KP201 API itself after extraction yielded no hydrocodone, by comparison, it was possible to smoke the hydrocodone API



## 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)
- 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



## KP201.A02 Human Abuse Liability Trial

- Intranasal KP201/APAP Human Abuse Liability Trial
  - Assessed the drug likability, exposure levels and safety of KP201/APAP compared to Norco after crushing and intranasal (IN) administration
  - Single-center, randomized, double-blind trial (n=42)
- Data announced on October 21, 2015
  - Significant PK differences for IN KP201/APAP vs. IN Norco®:
    - Increase in time to achieve peak exposure ( $T_{max}$ )( $p = 0.0001$ )
    - Lower peak hydrocodone exposure ( $C_{max}$ ) for KP201/APAP ( $p = 0.0027$ )
    - Statistically significant reduction in hydrocodone exposure through peak drug effect
    - Drug liking through peak effect (2.0 hours) was lower for IN KP201/APAP vs. IN Norco® ( $p < 0.0001$ )



## KP201.A03 Intranasal PK Trial

- 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 announced on August 13, 2015
  - 36% decrease in peak hydrocodone exposure (C<sub>max</sub>) for KP201 compared to hydrocodone bitartrate (HB) when taken intranasally
  - Time to peak hydrocodone exposure (T<sub>max</sub>) delayed by one hour
  - Decreased overall exposure to hydrocodone released from KP201 vs. HB especially in early time points (82% decrease in AUC<sub>0-0.5h</sub> and 63% decrease in AUC<sub>0-1.5h</sub>)



## Summary Trial Results: Abuse Quotient (AQ)<sup>1</sup>

Rank <sup>2</sup>	Treatment	RoA	Dose Units (mg)	AQ (SD) <sup>3</sup> (ng/mL/hrs)
1	KP201 API	IN	2 (13.34)	17.0 (11.6)
2	KP201/APAP	IN	2 (13.34/650)	31.9 (18.4)
3	HB/APAP	PO	2 (15/650)	34.5 (23.3)
4	KP201/APAP	PO	2 (13.34/650)	38.6 (21.8)
5	HB/APAP	IN	2 (15/650)	56.5 (43.8)
6	HB API	IN	2 (15)	87.3 (69.0)
7	KP201/APAP	PO	4 (26.68/1300)	99.6 (58.9)
8	HB/APAP	PO	4 (30/1300)	99.7 (57.1)
9	KP201/APAP	PO	8 (53.36/2600)	204.8 (125.2)
10	HB/APAP	PO	8 (60/2600)	222.7 (125.1)
11	KP201/APAP	PO	12 (80.04/3900)	287.8 (189.8)
12	HB/APAP	PO	12 (90/3900)	329.7 (201.9)

1. Abuse Quotient (AQ) = C<sub>max</sub>/T<sub>max</sub>.

2. All treatments from studies KP201.A01, KP201.A02 and KP201.A03 are ranked from the smallest to largest abuse quotient.

3. Standard Deviation (SD).



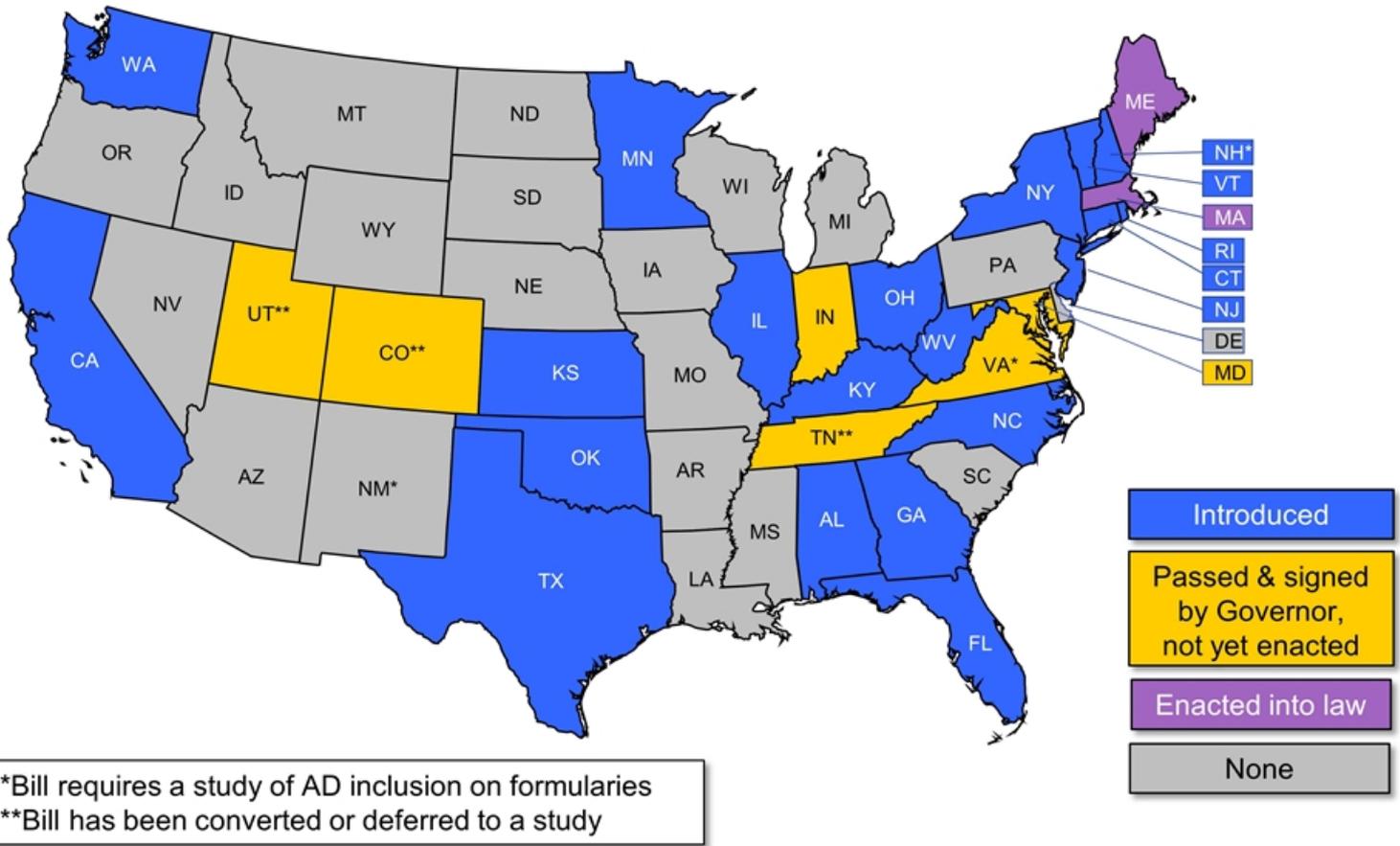
## KP201/APAP Commercial Strategy

*If approved for marketing, 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	Specialist U.S. Sales Force
<ul style="list-style-type: none"><li data-bbox="132 483 703 658">• Potential global / U.S.-based deal targeting large prescriber base, including primary care physicians</li><li data-bbox="132 719 687 757">• Utilize contract sales force(s)</li></ul>	<ul style="list-style-type: none"><li data-bbox="831 483 1409 703">• Specialist sales force targeting pain thought leaders, pain management specialists and high prescribing health care professionals</li><li data-bbox="831 763 1453 887">• License international commercial rights to one or more collaborators</li></ul>



# State Legislative Initiatives



Source: Legiscan.com November 2015

## KP201/APAP Milestones

Human Bioequivalence



Preclinical Abuse Deterrence / Tamper Resistance



Oral Human Abuse Liability Trial



Intranasal Human Abuse Liability Trial



Intranasal PK Trial



Anticipated NDA Submission

4Q 2015

Anticipated NDA Approval (with priority review)

As Early as Mid-2016

Anticipated DEA Scheduling and Product Launch

As Early as 2017



# KP511/ER Overview

Treatment of Moderate to Severe Pain



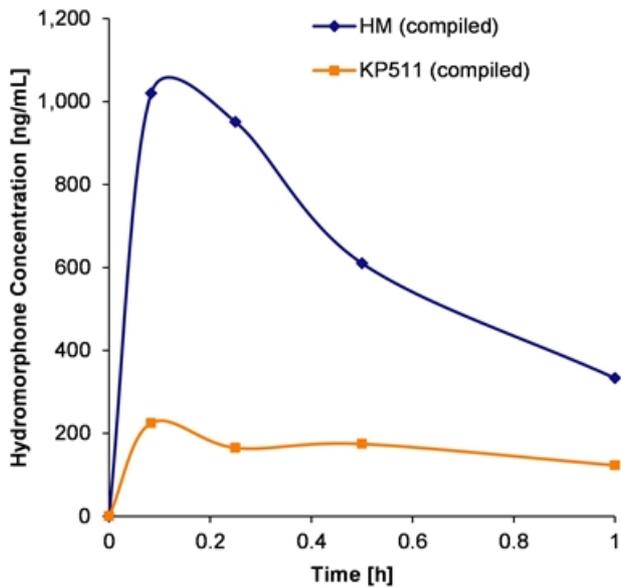
## KP511/ER Product Overview

- 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

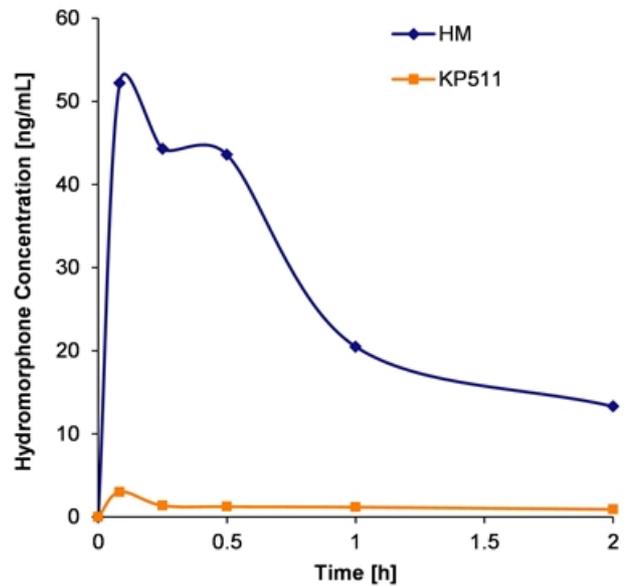
## Intranasal PK Curves



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

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

## Intravenous PK Curves

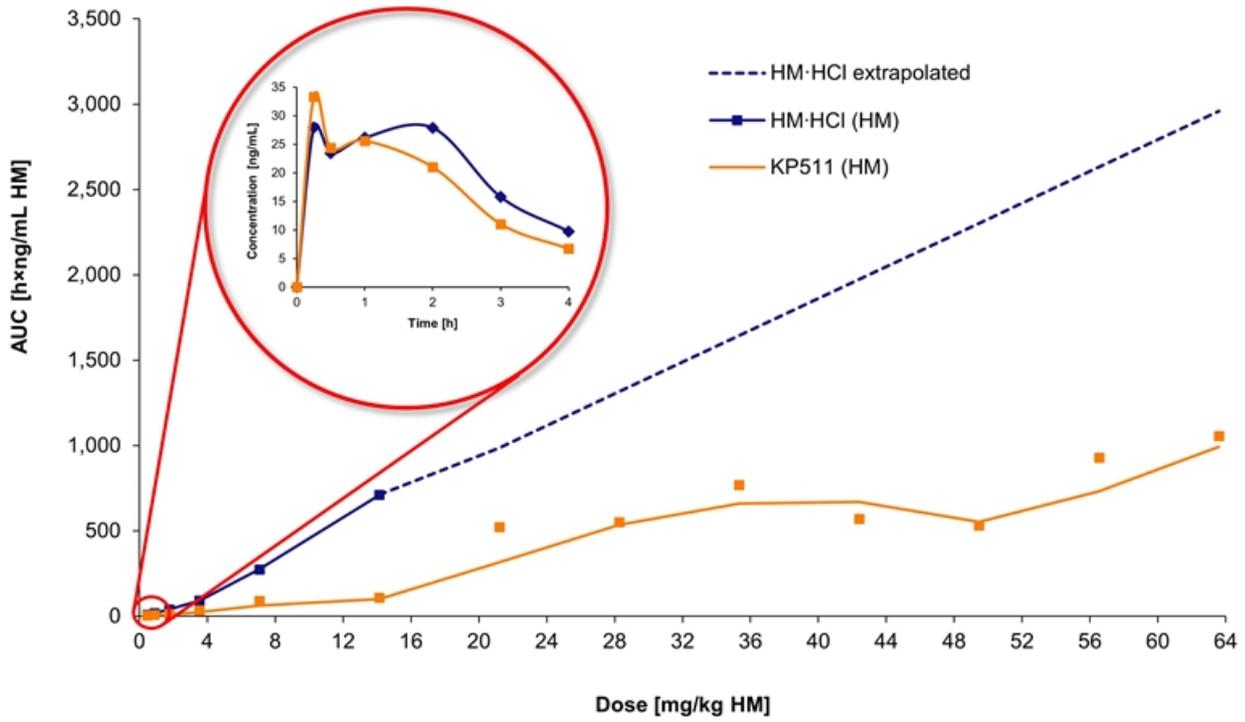


- 0.2 mg/kg (hydromorphone eq.)
- 1 study (N=5)
- %-AUC = 5%
- %-C<sub>max</sub> = 6%



# 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	NDA Submission	4Q 2015
KP201/IR (APAP-free)	IND Filing	2Q 2016
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/IR	Human POC	2017
KP201/IR (APAP-free)	NDA Submission	2017



## 3Q 2015 Update

- Cash and cash equivalents of \$59.0 million as of September 30, 2015
  - A decrease of \$5.2 million vs. \$64.2 million as of June 30, 2015
- 3Q 2015 net loss was \$9.7 million vs. \$7.1 million for 3Q 2014
  - Increase in net loss year-over-year primarily due to KP201/APAP R&D, increased G&A expense and increase in non-cash interest expense
- \$35 million available under the \$60 million Deerfield facility:
  - \$10 million optionally available upon NDA acceptance
  - \$25 million optionally available upon NDA approval
- 14,241,562 common shares outstanding at September 30, 2015





**KemPharm**

**For additional information please contact:**

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

**321-939-3416**

