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 26, 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 (Address of Principal Executive Offices)		**52241** (Zip Code)

Registrant's Telephone Number, Including Area Code: (319) 665-2575

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 8.01 Other Events.

On September 26, 2017, 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. 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 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: September 26, 2017

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Presentation titled "Management Presentation" dated September 2017.

Exhibit 99.1

Management Presentation

September 2017

Cautionary Note Regarding Presentation Information

This presentation contains forward-looking statements, including statements about our plans to develop and commercialize our product candidates, our planned clinical trials for our prodrug product candidates, the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including expectations about our ability to use the 505(b)(2) pathway and expedited FDA review, the clinical utility of our product candidates and our intellectual property position. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this presentation represent our views as of the date of this presentation. These and other risks concerning our business are described in additional detail in our Quarterly Report on Form 10-Q filed with the SEC on August 10, 2017, 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

LAT™ (Ligand Activated Therapy) 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 Clinical Product Pipeline

Category	Product Candidate	Parent Drug	Development Status	Next Milestone	Potential NDA Submission
ADHD	KP415	Methylphenidate (ER)	Clinical	PK + Efficacy Data	2018
	KP484	Methylphenidate (ER)	Clinical	PK + Efficacy Data	2019
PAIN	Apadaz	Hydrocodone/ APAP	NDA Resubmitted	PDUFA (2/23/18)	N/A
	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

Attention-Deficit/Hyperactivity Disorder:

KP415 and KP484
For the Treatment of ADHD

ADHD and ER Methylphenidate Market

- ~$13 billion ADHD market with prescriptions growing at >5% year-over-year
- Methylphenidate accounted for approximately 19.8 million TRx's and $3.8 billion in sales in 2016
- KemPharm believes ADHD key opinion leaders have significant interest in an ER methylphenidate product with:
  - Earlier onset (KP415)
  - Improved duration of action (KP415 & KP484)
  - Abuse-deterrent properties / lower abuse potential (KP415 & KP484)
- Branded products are being pressured by patent expirations
  - Vyvanse™ is the branded market share leader and loses patent exclusivity in 2024
  - Concerta™, Adderall™, Focalin™ are all brands which are off patent

Source: Symphony Health, PHAST 2016

KP415: ADHD Market Dynamics

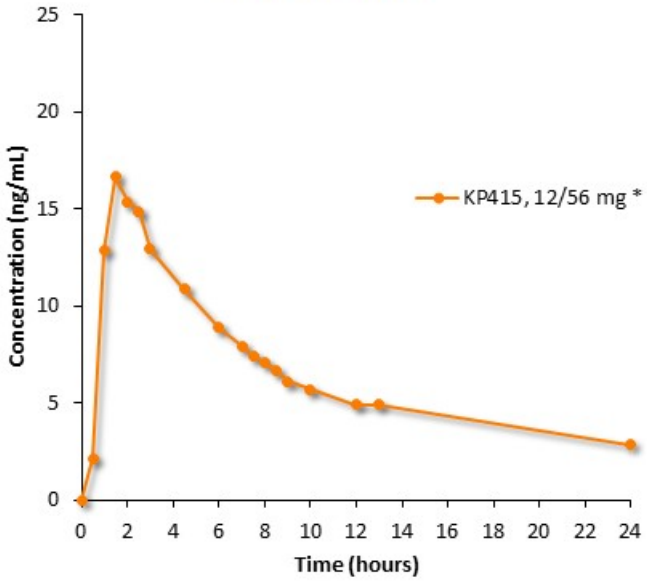
- In 2016, the branded ADHD market was ~$6.4B and more than 95% of these branded products are extended release[1]
- ADHD market has become more genericized, but many generics are priced closely to their branded comparator
- Recent ADHD new product launches have been based on delivery mechanisms alone; if approved, KP415 has the potential to be one of the first differentiated products launched into the ADHD market in some time
- Market research indicates prescribers see the following potential KP415 features as key advantages
  - Duration of action (60%)
  - Lower abuse potential (52%)
  - Early onset of action (43%)
- Market research indicates that prescribers estimate that methylphenidate is given as the preferred first line of therapy for children under the age of 13 approximately 60% of the time

KP415 Product Overview

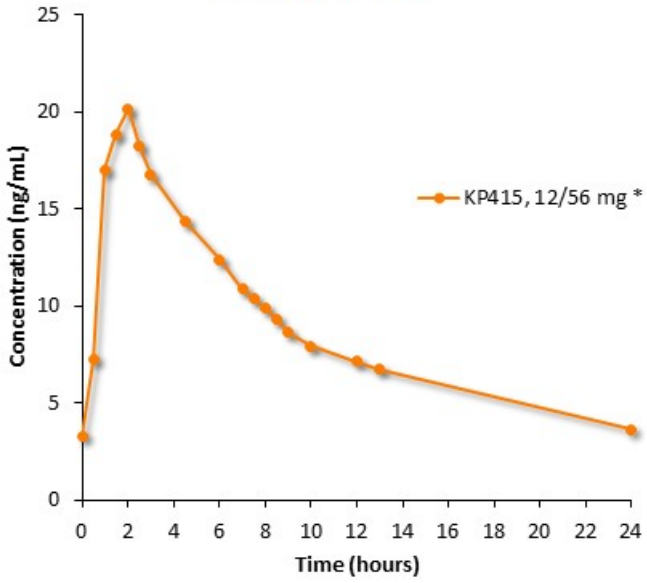
- Prodrug of d-methylphenidate (MPH) with intrinsic extended release properties, co-formulated with immediate release d-methylphenidate
- Potential KP415 features and benefits
  - Early onset of action
  - Potential longer total duration than current MPH therapies
  - Active metabolism may offer more predictable therapeutic effect
  - Lower abuse potential
  - Patient-friendly dosage form
    - Small capsule size (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

KP415 Single and Multiple Oral Dose PK

Anticipated KP415 Commercial Formulation Single Dose PK



Anticipated KP415 Commercial Formulation Steady State PK

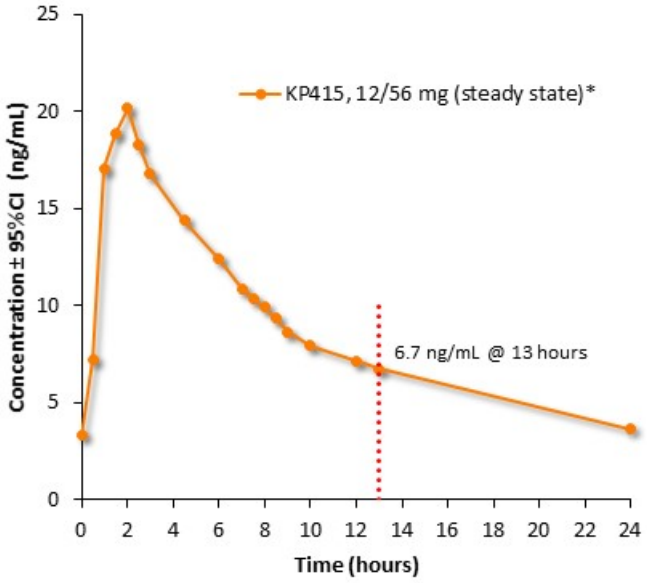


Note: Steady-state plasma concentrations collected after 7 days of once-per-day dosing.

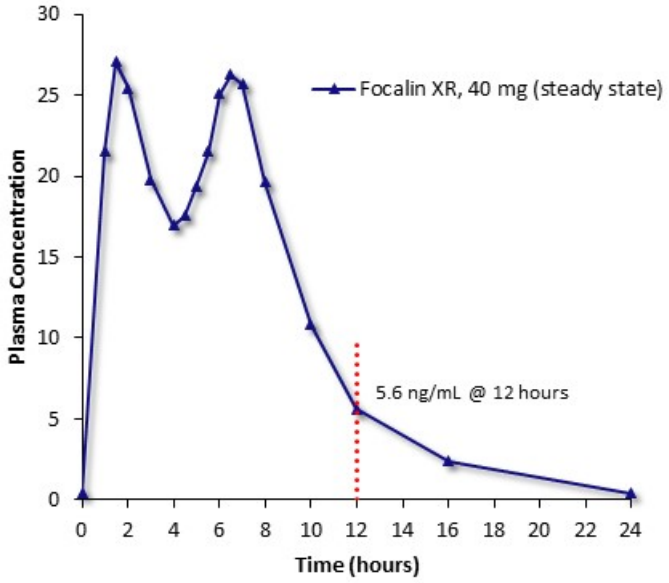
* Two subjects of the KP415, 12/56 mg treatment arm who appeared to be slow metabolizers of d-MPH were excluded from the analysis.

KP415 Steady State PK at 13 Hours vs. Focalin XR

Anticipated KP415 Commercial Formulation Steady State PK



Focalin XR, 40 mg Steady State PK



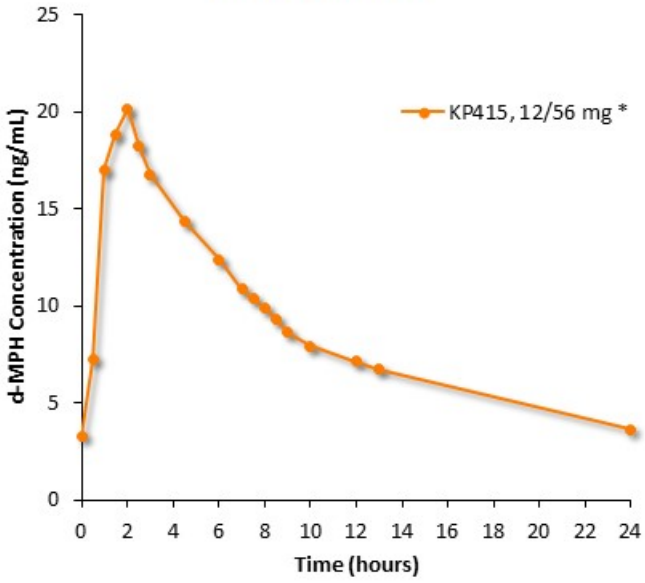
Note: Steady-state plasma concentrations collected after 7 days of once-per-day dosing.

* Two subjects of the KP415, 12/56 mg treatment arm who appeared to be slow metabolizers of d-MPH were excluded from the analysis.

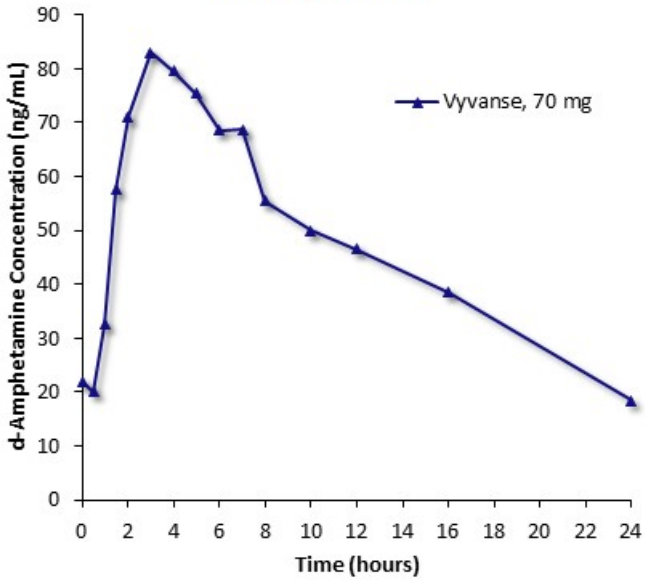
Focalin XR steady-state plasma concentrations were modeled based on Focalin XR single-dose data shown in product label. High-dose (40 mg) data were extrapolated from 20 mg data assuming dose proportionality

KP415 Steady State PK vs. Vyvanse[1]

Anticipated KP415 Commercial Formulation Steady State PK



Vyvanse, 70 mg Steady State PK



* Two subjects of the KP415, 12/56 mg treatment arm who appeared to be slow metabolizers of d-MPH were excluded from the analysis.

(1) Krishnan SM, Stark JG. Multiple daily-dose pharmacokinetics of lisdexamfetamine dimesylate in healthy adult volunteers. *Curr Med Res Opin.* **2008**;*24(1):33-40.*

KP484: Adult ADHD Market Dynamics

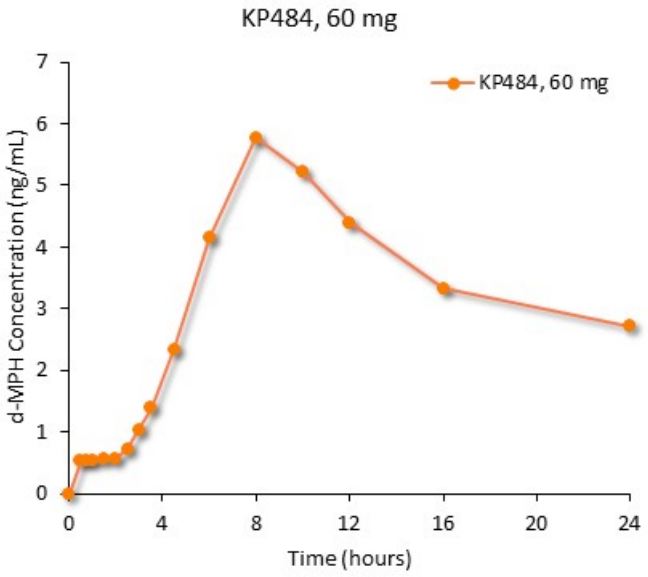
- Over 4% of U.S. adults, or approximately 10.5 million adults have ADHD[1,2]
- If approved, KP484 would launch into the high growth adult ADHD market
  - The adult ADHD market has grown at 11% YoY vs. 4% for the pediatric ADHD market for the last several years[1]
  - Adults are now the largest part of the ADHD market, comprising 53% of total TRx[1]
  - Despite the rapid growth in the adult market, the last 7 new ADHD products launched have been pediatric focused
  - Vyvanse™, the ADHD product known for its duration and abuse deterrent features has seen significant growth in the adult market averaging 22% YoY growth since 2009[1]
  - Shire's Mydayis™ was recently approved as a super long acting AXR in the amphetamine space (2-16 hour duration)
- KP484 could also provide the potential for other indications that have either been demonstrated by other stimulants or are currently unmet medical needs

KP484 Product Overview

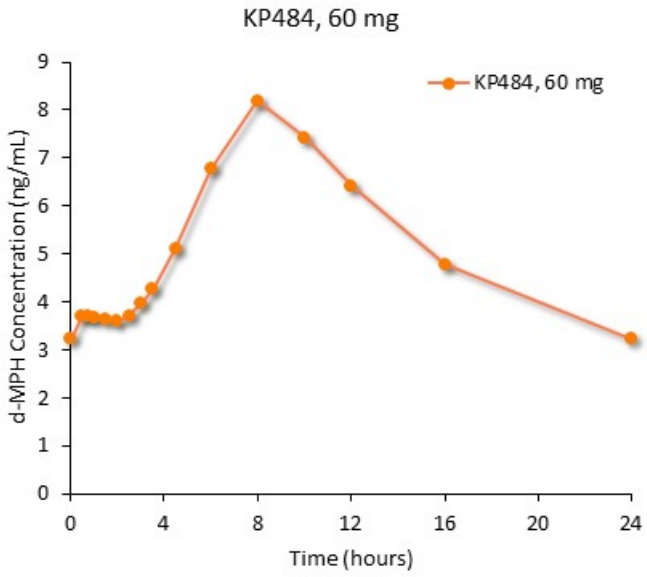
- Prodrug of d-methylphenidate with extended release properties
- Potential KP484 features and benefits
  - True once-daily dosing
  - Potentially longer duration than other super-extended release ADHD products
  - Active metabolism may offer more predictable therapeutic effect
  - Lower abuse potential
  - Patient-friendly dosage form
    - Small capsule size (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

KP484 Single and Predicted Multiple Oral Dose PK

KP484 – Oral PK, Single Dose



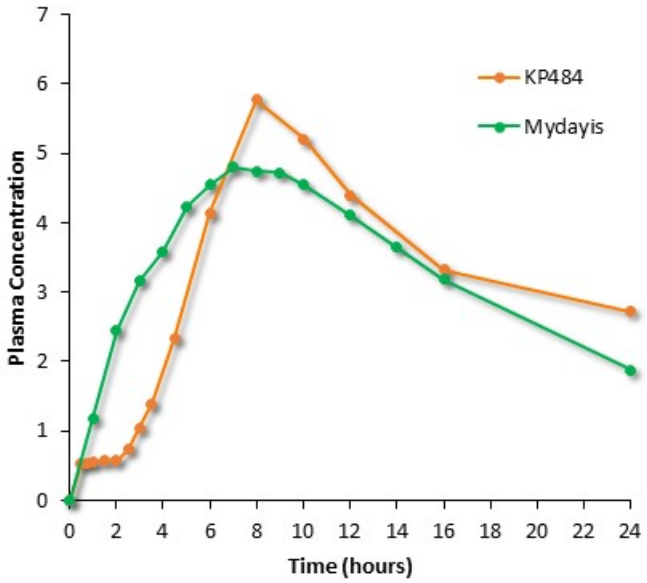
KP484 – Predicted Oral PK, Steady State



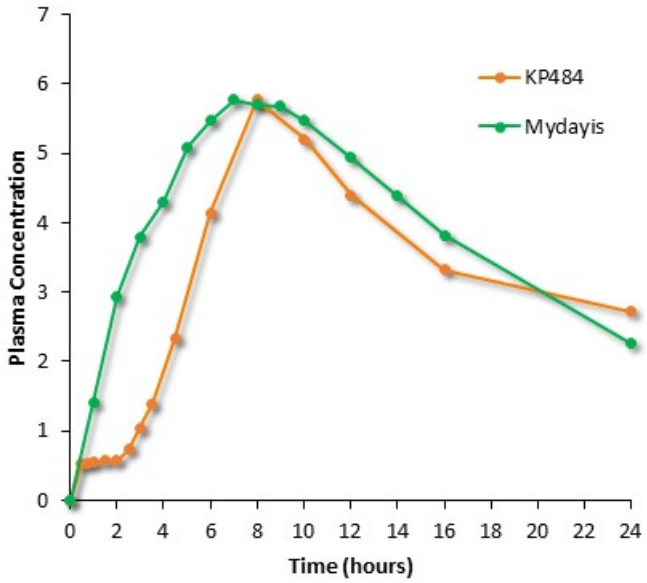
Note: Steady-state plasma concentrations were modeled based on single-dose data.

KP484 Single Oral Dose PK vs. Mydayis[1]

KP484 vs. Mydayis – AUC_{0-24} Normalized



KP484 vs. Mydayis – C_{max} Normalized

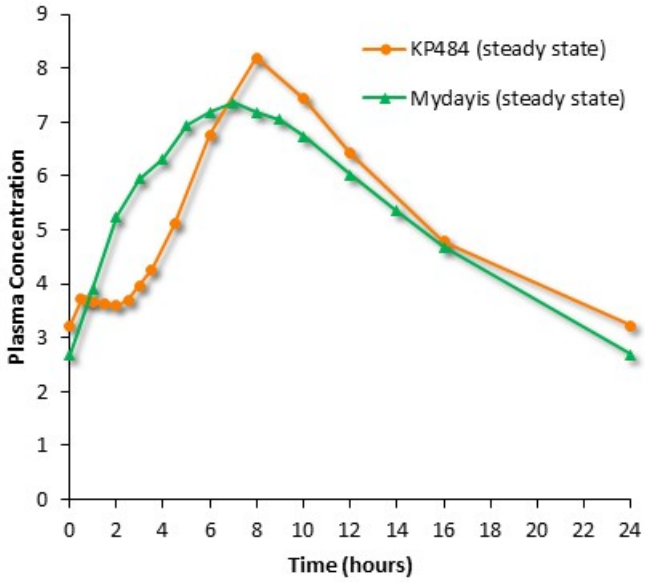


Disclaimer: Data for Mydayis(1) were normalized so that the mean AUC_{0-24}/C_{max} for d-amphetamine released from Mydayis matches the mean AUC_{0-24}/C_{max} for d-methylphenidate released from KP484. The representation is not intended for predictions or direct comparison of efficacy between the two drugs. Methylphenidate and amphetamine are different stimulants with different potency and MOA.

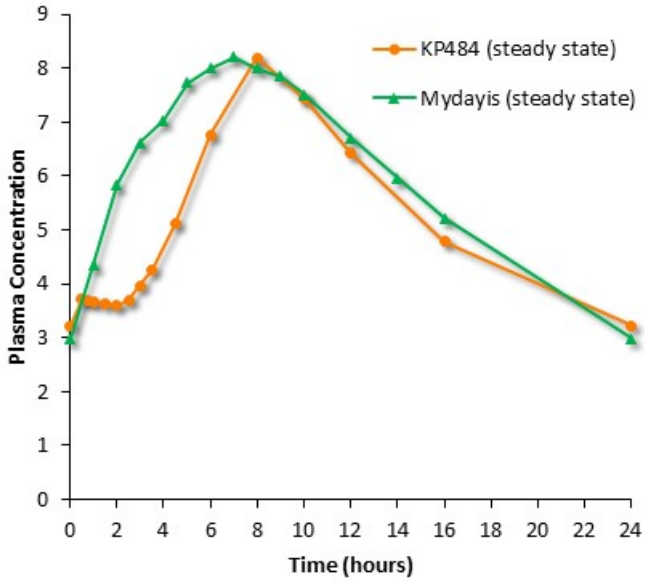
(1) Spencer TJ, Adler LA, Weisler RH, Youcha SH. Triple-Bead Mixed Amphetamine Salts (SPD465), a Novel, Enhanced Extended-Release Amphetamine Formulation for the Treatment of Adults with ADHD: A Randomized, Double-Blind, Multicenter, Placebo-Controlled Study. *J Clin Psychiatry*. **2008**;69*(9)*:1437-48.

KP484 Steady State PK vs. Mydayis[1]

KP484 vs Mydayis – AUC_{0-24} Normalized



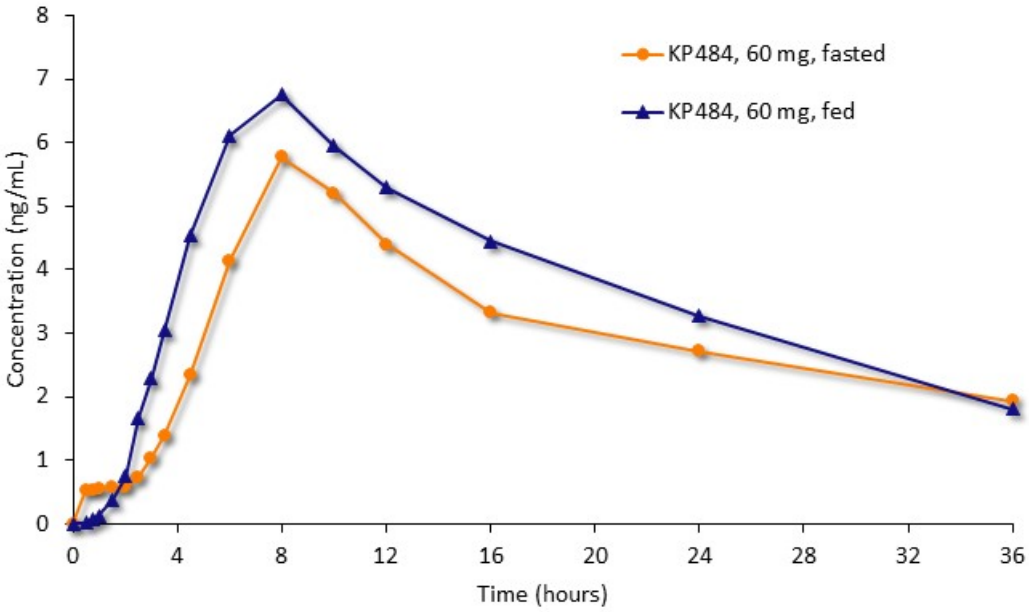
KP484 vs Mydayis – C_{max} Normalized



Disclaimer: Mydayis steady-state plasma concentrations were modeled based on Mydayis single-dose data[1] and were normalized so that the mean AUC_{0-24}/C_{max} for d-amphetamine released from Mydayis matches the mean AUC_{0-24}/C_{max} for d-methylphenidate released from KP484. The representation is not intended for predictions or direct comparison of efficacy between the two drugs. Methylphenidate and amphetamine are different stimulants with different potency and MOA.

(1) Spencer TJ, Adler LA, Weisler RH, Youcha SH. Triple-Bead Mixed Amphetamine Salts (SPD465), a Novel, Enhanced Extended-Release Amphetamine Formulation for the Treatment of Adults with ADHD: A Randomized, Double-Blind, Multicenter, Placebo-Controlled Study. *J Clin Psychiatry*. **2008**;69*(9)*:1437-48.

Data Indicates KP484 May Have No Food Effect



Note: Subjects in the fed treatment arm received a single dose of KP484, 60 mg within 20 minutes following a standardized breakfast.

KP415 Clinical Update and Development Timeline

- Completed End-of-Phase 1 Meeting on June 14, 2017
- FDA raised no objections to proposed KP415 clinical program
  - Single efficacy study
- Data from multiple PK studies support potential efficacy of the prodrug and KP415 in both single dose and multiple dose settings
- No food effect with a normal breakfast
- Intravenous (IV) Human Abuse Liability (HAL) data anticipated in early 2018, with oral and intranasal (IN) HAL data anticipated later in 2018
- KP415 pivotal efficacy study anticipated to commence in 2H 2017, with final data expected in 1H 2018
- KP415 NDA anticipated to be filed in late 2018

KP484 Clinical Update and Development Timeline

- KP484 IND filing announced on September 20, 2017, but clinical program already initiated under KP415's IND

- KP484 and KP415 are each expected to benefit from each other's development program, with KP484/KP415 clinical studies completed to date including:
  - Single and multiple dose study with KP415 at (12/56 mg)
  - Single dose oral bioavailability study (20, 40, and 60 mgs)
  - Single dose urinary excretion study (6 and 60 mgs)
  - Food effect study (60 mg)

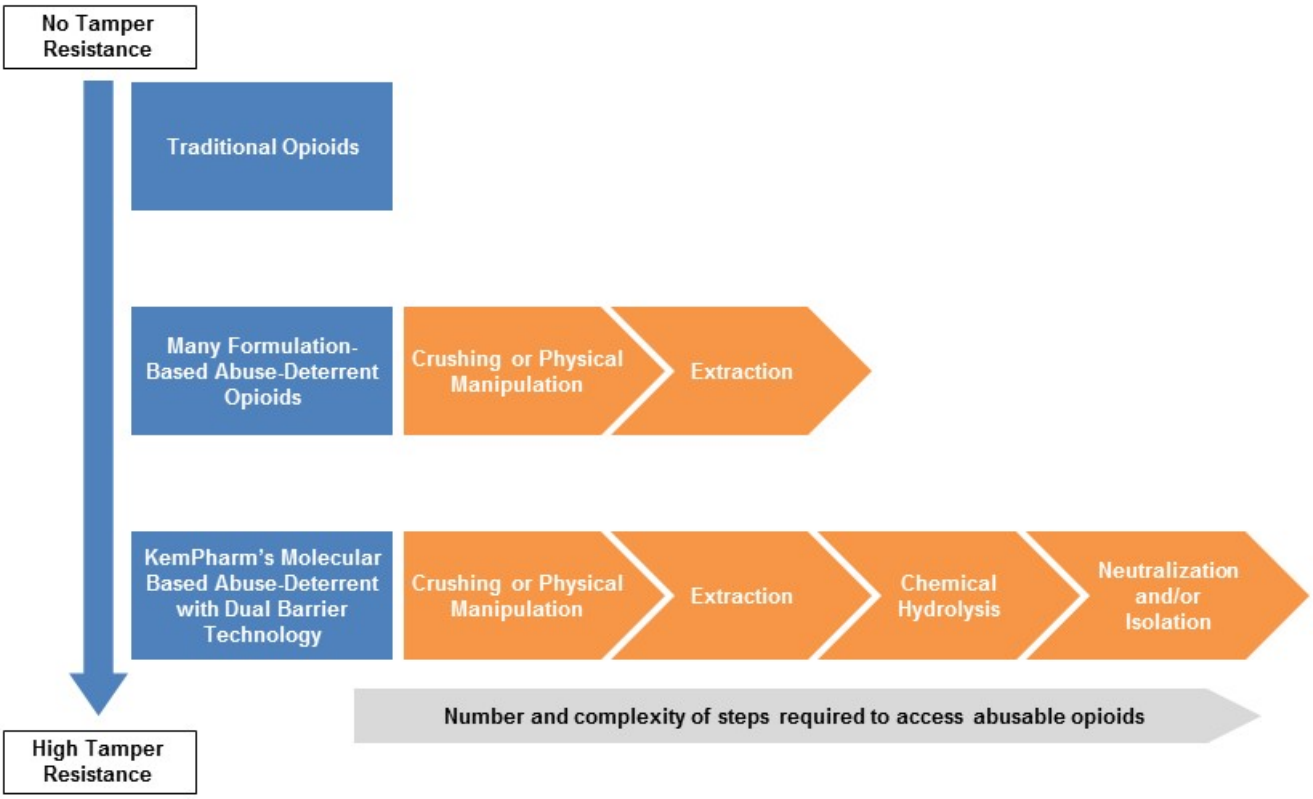
- Intravenous (IV) Human Abuse Liability (HAL) data anticipated in early 2018, with oral and intranasal (IN) HAL data anticipated later in 2018

- KP484 NDA anticipated to be filed in late 2019

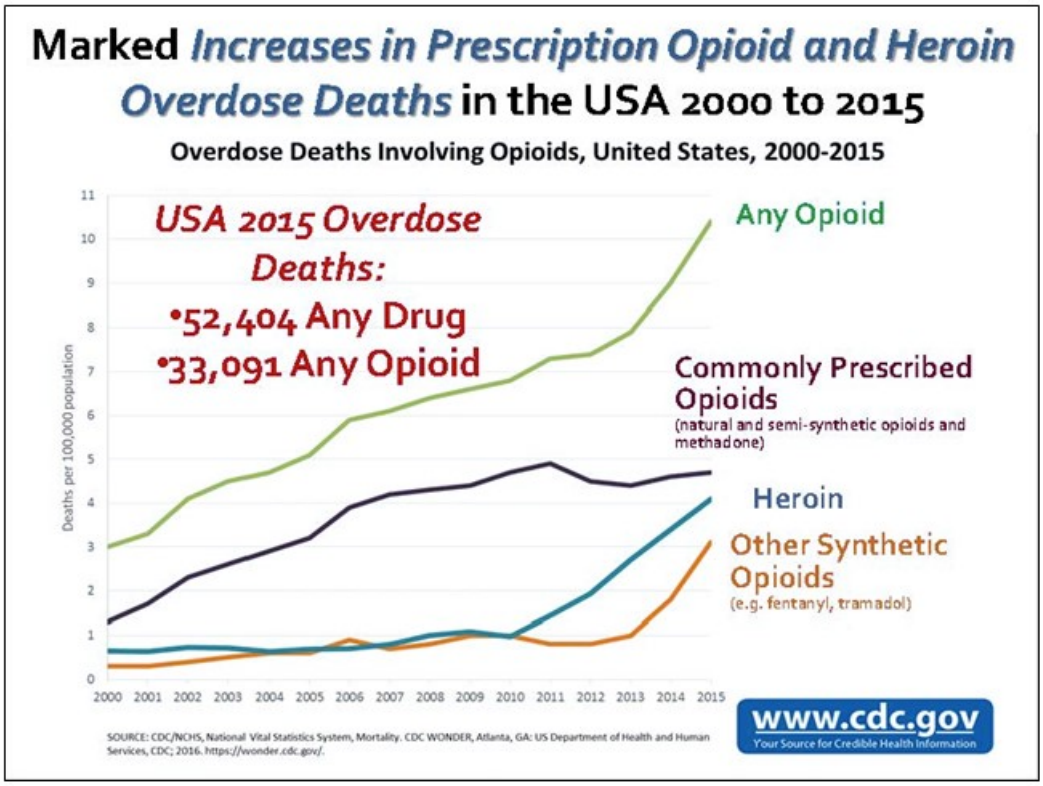
Abuse-Deterrent Opioid Prodrugs

For the Treatment of Pain

KemPharm's Abuse-Deterrent Opioid Prodrug Technology



U.S. Opioid Epidemic Remains Uncontrolled



Source: D. C. Throckmorton, MD, Deputy Director for Regulatory Programs, CDER, FDA, presentation at CBI Abuse Deterrent Formulations Summit, March 7-8, 2017

FDA Expanding Access to ADFs to Discourage Abuse

Development of New Pain Treatments

FDA

Abuse-deterrent Opioid formulations

Pro-drugs

Crush/extraction resistant formulation

Drug combinations with adverse effects if injected

Non-Opioid based analgesics
Cannabinoids;
Inflammatory mediators;
Ion channel blockers

Non-pharmacological treatments
Surgical interventions;
Neural stimulation;
Spinal cord stimulation

Transcranial Magnetic Stimulation

19

Source: D. C. Throckmorton, MD, Deputy Director for Regulatory Programs, CDER, FDA, presentation at CBI Abuse Deterrent Formulations Summit, March 7-8, 2017

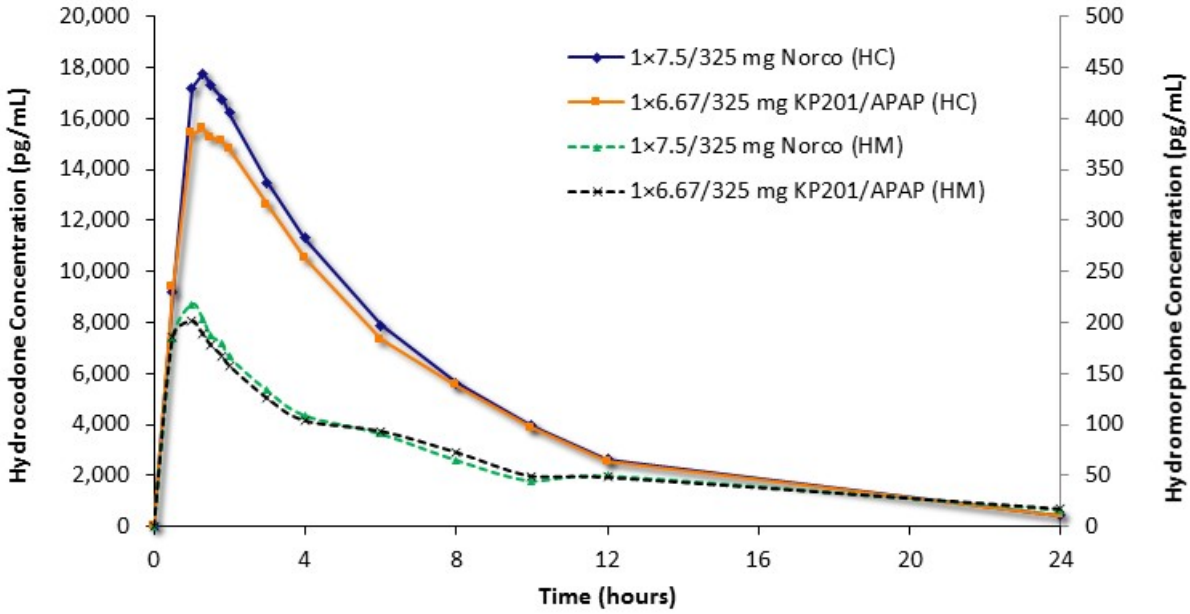
Apadaz

For Short-Term Treatment of Acute Pain

Apadaz Product Overview

- IR opioid fixed-dose combination product comprised of 6.67 mg benzhydrocodone HCl (a prodrug of hydrocodone equivalent to 7.5 mg hydrocodone bitartrate) and 325 mg APAP
- Prodrug consists of hydrocodone plus benzoic acid
- Molecular-Based Abuse-Deterrent Technology
- Potential valuable properties based on clinical development program include
  - Reduced hydrocodone C_{max}, reduced early systemic hydrocodone exposure and delayed hydrocodone T_{max} for IN Apadaz vs. IN Norco
  - Delayed Drug Liking for IN Apadaz vs. IN Norco
  - Highly tamper resistant vs. Norco
- Developed using a 505(b)(2) regulatory pathway
  - Bioequivalent, with no food effect
- Composition-based patent expires in 2031

Apadaz vs. Norco Bioequivalence (Study 102)



	C_{max}	AUC_{0-t}	AUC_{inf}	T_{max}
Hydrocodone	87%	94%	94%	102%
Hydromorphone	92%	100%	90%	120%

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

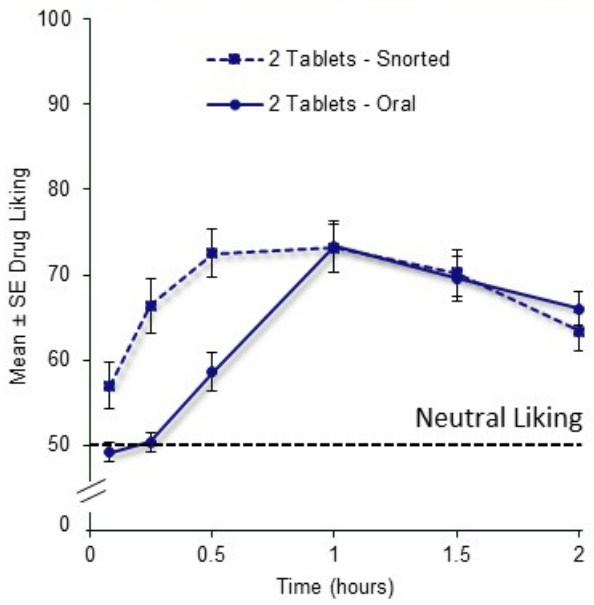
Differences Observed in Drug Liking, Feeling High and Take Drug Again of IN and Oral Apadaz vs. Norco (Study A02)

Parameter	LS Mean		IN vs. Oral P-value
	IN Norco	Oral Norco	
Drug Liking E_{max}	79.0	77.8	0.6881
Feeling High E_{max}	59.1	60.4	0.8049
Take Drug Again (12 hrs)	72.1	74.0	0.6835

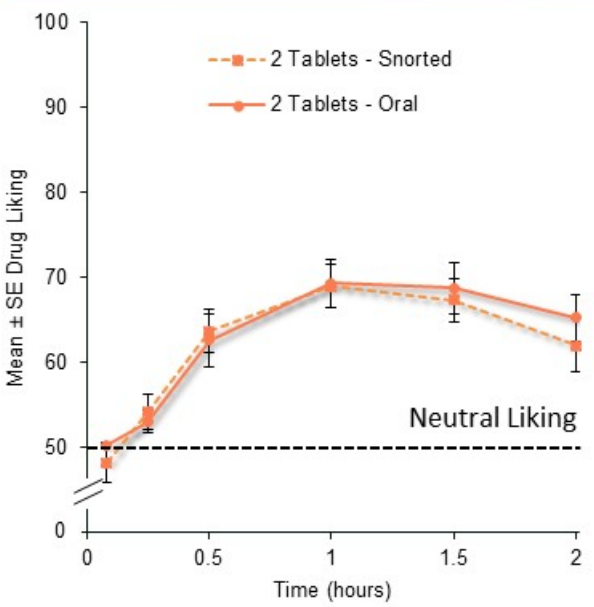
Parameter	LS Mean		IN vs. Oral P-value
	IN Apadaz	Oral Apadaz	
Drug Liking E_{max}	75.9	76.9	0.7319
Feeling High E_{max}	61.9	61.3	0.9064
Take Drug Again (12 hrs)	68.3	72.4	0.3664

Oral and IN Drug Liking of Apadaz vs. Norco (Study A02)

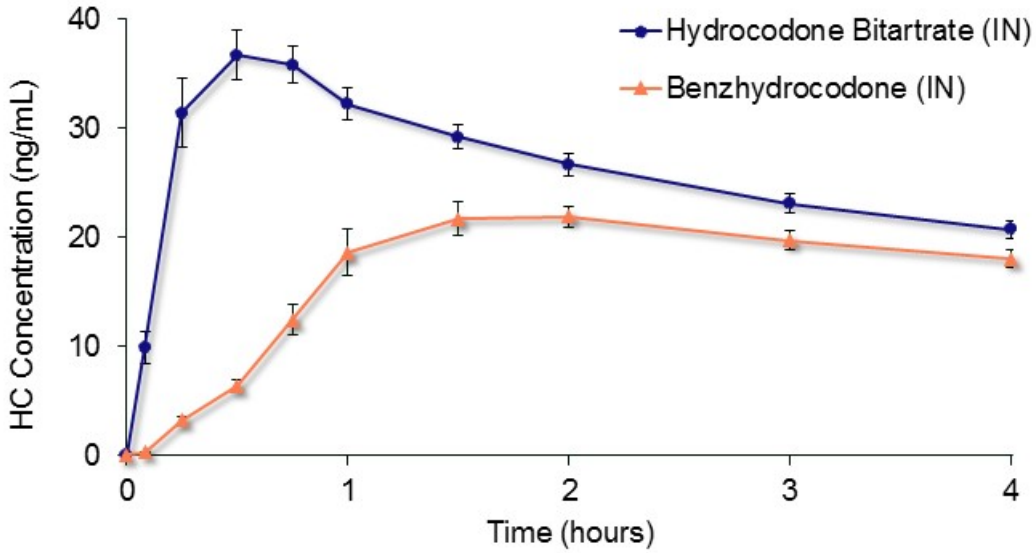
Norco Drug Liking: Oral vs Intranasal



Apadaz Drug Liking: Oral vs Intranasal



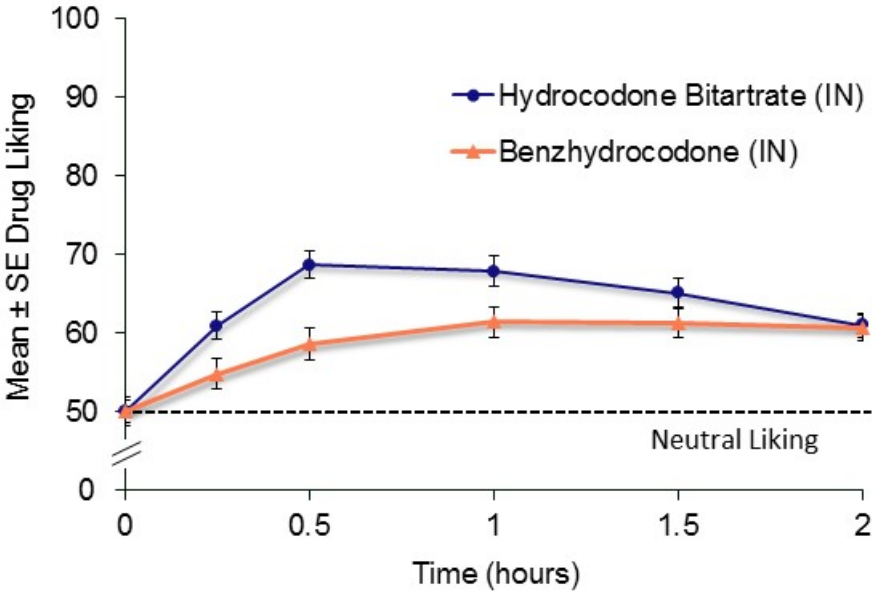
IN PK of Apadaz API[1] vs. Norco API[2] (Study A03)



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]	–	–

1. Benzhydrocodone
2. Hydrocodone Bitartrate (HB)

IN Drug Liking of Apadaz API[1] vs. Norco API[2] (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

1. Benzhydrocodone
2. Hydrocodone Bitartrate (HB)

Differences Observed in IN Drug Liking and Ease of Insufflation of Apadaz API vs. Norco API (Study A03)

Parameter	LS Mean		P-value
	Apadaz API[1]	Norco API[2]	
Drug Liking E_{max}	67.5	73.2	0.004
Ease of Insufflation[3]	78.5	65.8	0.0004

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

Apadaz NDA Resubmission Timeline

- FDA acknowledged receipt of Apadaz NDA resubmission on August 23, 2017
- Items included in NDA resubmission
  - Revised label
  - Updated tampering data
  - Updated abuse liability assessment
  - Updated CMC information to include blister packaging (18-tablet pack, comprising a 3-day prescription)
- Apadaz NDA resubmission deemed complete and considered a Class 2 response by FDA
- FDA has assigned Apadaz a PDUFA date of February 23, 2018

KemPharm Expected Milestones

Product	Event	Date	
Apadaz	FDRR Resolution and NDA Resubmission	2017	✓
KP484	IND Filing	2017	✓
KP415	Initiate Pivotal Efficacy Study	2017	
KP415 / KP484	IV Human Abuse Liability (HAL) Data	2018	
Apadaz	PDUFA Date	02/23/18	
KP415	Pivotal Efficacy Study Results	2018	
KP484	Initiate Pivotal Efficacy Study	2018	
KP415 / KP484	Oral and IN HAL Data	2018	
KP415	NDA Submission	2018	
KP484	Pivotal Efficacy Study Results	2019	
KP484	NDA Submission	2019	

Q2 2017 Financial Update

- Total cash[1] of $65.8 million as of June 30, 2017
  - Used $6.6 million of cash during Q2 2017
- Q2 2017 net loss of $6.5 million, or $(0.44) per basic and diluted share vs. Q2 2016 net income of $9.8 million, or $0.59 per basic share and net loss of $(0.58) per diluted share
  - Net loss for Q2 2017 was driven primarily by a loss from operations of $8.2 million, and net interest expense and other items of $1.8 million; these expenses were partially offset by a non-cash fair value adjustment income of $3.5 million
  - Loss from operations decreased to $8.2 million in Q2 2017, as compared to $9.3 million in Q2 2016, which was due primarily to a decrease in general and administrative costs related to overhead and personnel spending
- Based on the Company's current forecast, existing resources are expected to fund operating expenses and capital expenditure requirements through Q2 2019
- 14,657,430 common shares outstanding at June 30, 2017

1.Includes cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments

KemPharm

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Slides 8 and 13: KP415 and KP484 Market Data Sources

1. Symphony Health, PHAST 2011-2016
2. Ronald C. Kessler et al. (April 2006). The Prevalence and Correlates of Adult ADHD in the United States: Results From the National Comorbidity Survey Replication, American Journal of Psychiatry 163(5):71