

**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 17, 2018**

**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.)**

**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 7.01 Regulation FD Disclosure.**

On September 17, 2018, Travis C. Mickle, the president and chief executive officer of KemPharm, Inc., or the Company, will present at the Janney Montgomery Scott Healthcare Conference on, among other things, the Company's product pipeline, co-lead clinical product candidates KP415 and KP484, both based on a prodrug of methylphenidate, and U.S. Food and Drug Administration approved product, APADAZ<sup>®</sup>, an immediate-release combination product of benzhydrocodone, the Company's prodrug of hydrocodone, and acetaminophen, for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

A copy of the presentation 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 presentation 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, 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 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description   |
|-------------|---|
| 99.1        | <a href="#"><u>Presentation titled "Janney Healthcare Conference" dated September 17, 2018.</u></a> |

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**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 17, 2018

By: /s/ R. LaDuane Clifton

R. LaDuane Clifton, CPA

Chief Financial Officer, Secretary and Treasurer



**KemPharm**

**Janney Healthcare Conference**

**September 17, 2018**

## 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, 2018, 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 Product Pipeline

| Category | Product Candidate | Parent Drug          | Development Status | Next Milestone                    | Potential NDA Submission   |
|----------|-------------------|----------------------|--------------------|-----------------------------------|----------------------------|
| ADHD     | KP415             | Methylphenidate (ER) | Clinical           | NDA Submission                    | Q1 2019                    |
|          | KP484             | Methylphenidate (ER) | Clinical           | Initiation of Efficacy Trial      | 2019                       |
| PAIN     | Apadaz®           | Hydrocodone/ APAP    | FDA Approved       | Potential Commercial Partnerships | N/A                        |
|          | KP201/IR          | Hydrocodone          | Clinical           | IN HAP Data                       | 2019* with Priority Review |
|          | KP511/ER          | Hydromorphone        | Clinical           | POC in ER Formulation             | 2020* with Priority Review |
|          | KP511/IR          | Hydromorphone        | Clinical           | BE and HAP Data                   | 2019* with Priority Review |

\* NDA timing is contingent upon status of Apadaz commercialization efforts



## Prodrug New Product Development Partnering

- Strategy to potentially leverage KemPharm's proprietary LAT™ Platform Technology through partnering
- Partner benefits may include new or improved products based on potential:
  - Creation of new, long-lived IP protection
  - Modification of pharmacokinetic profile
  - Targeted tissue/organ delivery
  - Delivery of active metabolites
  - Modification of physicochemical or synthetic properties
  - Modifications in metabolism
  - Improved side effect profile
- Announced agreement with Genco Sciences to develop prodrug-based therapy for potential rare pediatric indications of Tourette's syndrome with ADHD on October 4, 2017



# Attention-Deficit/Hyperactivity Disorder:

**KP415 and KP484  
for the Treatment of ADHD**



## The ADHD and ER Methylphenidate Market

- ~\$13 billion ADHD market with TRx growth of ~4% per year on average
- The branded portion of the ADHD market was ~\$6.1B in 2017 and more than 95% of these branded prescriptions are for extended release
- Methylphenidate (MPH) accounted for approximately 19.6 million TRx's and \$4.0 billion in sales in 2017
- 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 also indicates that prescribers estimate that MPH is given as the preferred first line of therapy for children under the age of 13 approximately 60% of the time

Source: Symphony Health, PHAST 2016



## Selected ER Stimulant Products for ADHD

| Brand Name<br>Active Ingredient          | Sponsor  | Dosage<br>Form (1)    | Strengths<br>(1)                                | Features (1)   | Reduced<br>Drug<br>Liking (1) |
|--|----------|-----------------------|---|--|-------------------------------|
| Vyvanse®<br>(lisdexamfetamine)           | Shire    | Capsule &<br>Chewable | 10, 20, 30, 40,<br>50, 60 & 70<br>(cap only) mg | <ul style="list-style-type: none"> <li>• Prodrug of d-amphetamine</li> <li>• Ages: 6 years and older</li> <li>• Onset: 1.5 hours</li> <li>• Duration: 13 hours</li> <li>• Indicated for binge eating disorder</li> </ul> | Some<br>Difference            |
| Adderall XR®<br>(mixed salts of<br>AMPH) | Shire    | ER<br>Capsule         | 5, 10, 15, 20,<br>25 & 30 mg                    | <ul style="list-style-type: none"> <li>• Comprised of both L-AMPH &amp; D-AMPH</li> <li>• Ages: 6 years and older</li> <li>• Extended release profile</li> </ul>   | No                            |
| Focalin XR®<br>(dexmethylphenidate)      | Novartis | ER<br>Capsule         | 5, 10, 15, 20,<br>25, 30, 35<br>& 40 mg         | <ul style="list-style-type: none"> <li>• Ages: 6 years and older</li> <li>• Onset: 0.5 hours</li> <li>• Duration: 12 hours</li> </ul>  | No                            |
| Concerta®<br>(methylphenidate)           | Janssen  | ER<br>Tablet          | 18, 27, 36 &<br>54 mg                           | <ul style="list-style-type: none"> <li>• Ages: 6 years to 65 years</li> <li>• Onset: 2 hours</li> <li>• Duration: 12 hours</li> </ul>  | Small<br>Difference           |

(1) Package insert information



## Selected ER Stimulant Products for ADHD (Cont'd)

| Brand Name<br>Active Ingredient       | 2017<br>TRx's (1) | 2017<br>Sales (1) | 2017<br>WAC Unit<br>Price (2) | 2017<br>Plan<br>Approval<br>Rate (1) | 2017<br>Avg. Patient<br>Out-of-Pocket<br>Expense (1) |
|---------------------------------------|-------------------|-------------------|-------------------------------|--------------------------------------|--|
| Vyvanse®<br>(lisdexamfetamine)        | 11.6MM            | \$3.3B            | 40mg: \$9.02                  | 94%                                  | \$41.65  |
| Adderall XR®<br>(mixed salts of AMPH) | 3.6MM             | \$895MM           | 20mg: \$7.12                  | 95%                                  | \$24.04  |
| Focalin XR®<br>(dexmethylphenidate)   | 964K              | \$352MM           | 20mg: \$11.90                 | 94%                                  | \$26.93  |
| Concerta®<br>(methylphenidate)        | 761K              | \$285MM           | 36mg: \$10.57                 | 94%                                  | \$32.66  |
| Generic ER Mixed AMPH                 | 9.4MM             | \$1.6B            | 20mg: \$4.90                  | 94%                                  | \$22.06  |
| Generic ER D-MPH                      | 2.0MM             | \$448MM           | 20mg: \$7.80                  | 93%                                  | \$23.22  |
| Generic ER MPH HCL                    | 7.8MM             | \$2.0B            | 36mg: \$8.23                  | 94%                                  | \$22.56  |

(1) Symphony Health, PHAST 2011-2017

(2) Medi-Span Price Rx (Nov 2017)



## KP415 Product Overview

- Prodrug of d-MPH (serdexmethylphenidate) with extended release properties, co-formulated with immediate release d-MPH
- Potential KP415 features and benefits
  - Once-daily dosing
  - Earlier onset and longer duration of therapeutic effect
  - 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
- May be the first MPH product approved for pre-school patients (4-5 yrs old)
- No generic equivalent product
- Composition-based patent expires in 2032; pending applications, if granted, may potentially expire in 2037; potentially NCE eligible



## KP415.E01 Pivotal Efficacy Trial Overview

- First patient treatment on December 20, 2017
- Double-blind, placebo-controlled, randomized, parallel, analog classroom trial
- Children 6 to 12 years with ADHD (150 completers)
- 5 U.S. trial sites, 2-3 cohorts each; 5-18 subjects per cohort/per site
- 3-week open-label KP415 dose optimization period ending with 2-day drug washout period
- On Visit 5 (Day 21), baseline SKAMP-C scores were collected at pre-dose, patients were given their last open-label dose and then they were randomly assigned to either placebo or their optimized dose of KP415 once daily in the morning for 1 week
- On Visit 6 (Day 28), SKAMP-C scores were collected at pre-dose and post-dose efficacy assessments were taken at 0.5, 1, 2, 4, 8, 10, 12 and 13 hours



## KP415.E01 Pivotal Efficacy Trial Met Primary Endpoint

- KP415.E01 met the primary endpoint of mean difference in change from baseline (pre-dose Visit 5) across all post-dose time points for the SKAMP-C score ( $p < 0.001$ )

| Change in SKAMP-C from Pre-dose Visit 5                                  |                 |                |                            |                         |       |         |
|--|-----------------|----------------|----------------------------|-------------------------|-------|---------|
| Statistical Measure  | LS Mean (SE)    |                | Difference in LS mean (SE) | 95% Confidence Interval |       | p-Value |
|  | KP415           | Placebo        | KP415 – Placebo            | KP415 – Placebo         |       |         |
| Mean difference in change from baseline across all post-dose time-points | -4.87<br>(0.62) | 0.54<br>(0.70) | -5.41<br>(0.87)            | -7.10                   | -3.71 | <0.001  |



## KP415.E01 Pivotal Efficacy Trial: Differences in SKAMP-C Change Between KP415 and Placebo Are Statistically Significant

| Time               | SKAMP-C Change at Visit 6 from Baseline    |         |  |         |
|--------------------|--|---------|--|---------|
|                    | Baseline = predose Visit 5 (prespecified)* |         | Baseline = predose Visit 6 (post hoc)* |         |
|                    | Difference in LS mean (SE)                 |         | Difference in LS mean (SE)             |         |
|                    | KP415 – Placebo                            | p-Value | KP415 – Placebo                        | p-Value |
| Predose            | 2.37 (1.18)                                | 0.044   | 0.60 (1.14)                            | 0.600   |
| 0.5 hours postdose | -2.28 (1.18)                               | 0.053   | -4.19 (1.14)                           | <0.001  |
| 1 hours postdose   | -7.40 (1.18)                               | <0.001  | -9.22 (1.14)                           | <0.001  |
| 2 hours postdose   | -10.14 (1.18)                              | <0.001  | -12.25 (1.14)                          | <0.001  |
| 4 hours postdose   | -9.76 (1.18)                               | <0.001  | -11.88 (1.14)                          | <0.001  |
| 8 hours postdose   | -7.05 (1.18)                               | <0.001  | -9.37 (1.14)                           | <0.001  |
| 10 hours postdose  | -3.91 (1.18)                               | <0.001  | -6.20 (1.14)                           | <0.001  |
| 12 hours postdose  | -0.96 (1.18)                               | 0.412   | -3.07 (1.14)                           | 0.007   |
| 13 hours postdose  | -1.63 (1.18)                               | 0.167   | -3.71 (1.14)                           | 0.001   |

\* Statistical model includes pre-dose Visit 5 or Visit 6 as covariate, respectively.



## KP415.E01 Pivotal Efficacy Trial: Differences in PERMP-A Change Between KP415 and Placebo Are Statistically Significant

| Time               | PERMP-A Change at Visit 6 from Baseline    |         |  |         |
|--------------------|--|---------|--|---------|
|                    | Baseline = predose Visit 5 (prespecified)* |         | Baseline = predose Visit 6 (post hoc)* |         |
|                    | Difference in LS mean (SE)                 |         | Difference in LS mean (SE)             |         |
|                    | KP415 – Placebo                            | p-Value | KP415 – Placebo                        | p-Value |
| Predose            | -0.43 (5.18)                               | 0.933   | 0.26 (4.40)                            | 0.953   |
| 0.5 hours postdose | 20.12 (5.18)                               | <0.001  | 22.13 (4.40)                           | <0.001  |
| 1 hours postdose   | 27.91 (5.18)                               | <0.001  | 29.66 (4.40)                           | <0.001  |
| 2 hours postdose   | 39.35 (5.18)                               | <0.001  | 41.44 (4.40)                           | <0.001  |
| 4 hours postdose   | 32.62 (5.18)                               | <0.001  | 35.57 (4.40)                           | <0.001  |
| 8 hours postdose   | 23.03 (5.18)                               | <0.001  | 25.77 (4.40)                           | <0.001  |
| 10 hours postdose  | 17.36 (5.18)                               | <0.001  | 19.81 (4.41)                           | <0.001  |
| 12 hours postdose  | 12.08 (5.18)                               | 0.020   | 14.50 (4.40)                           | 0.001   |
| 13 hours postdose  | 16.57 (5.18)                               | 0.001   | 19.17 (4.40)                           | <0.001  |

\* Statistical model includes pre-dose Visit 5 or Visit 6 as covariate, respectively.

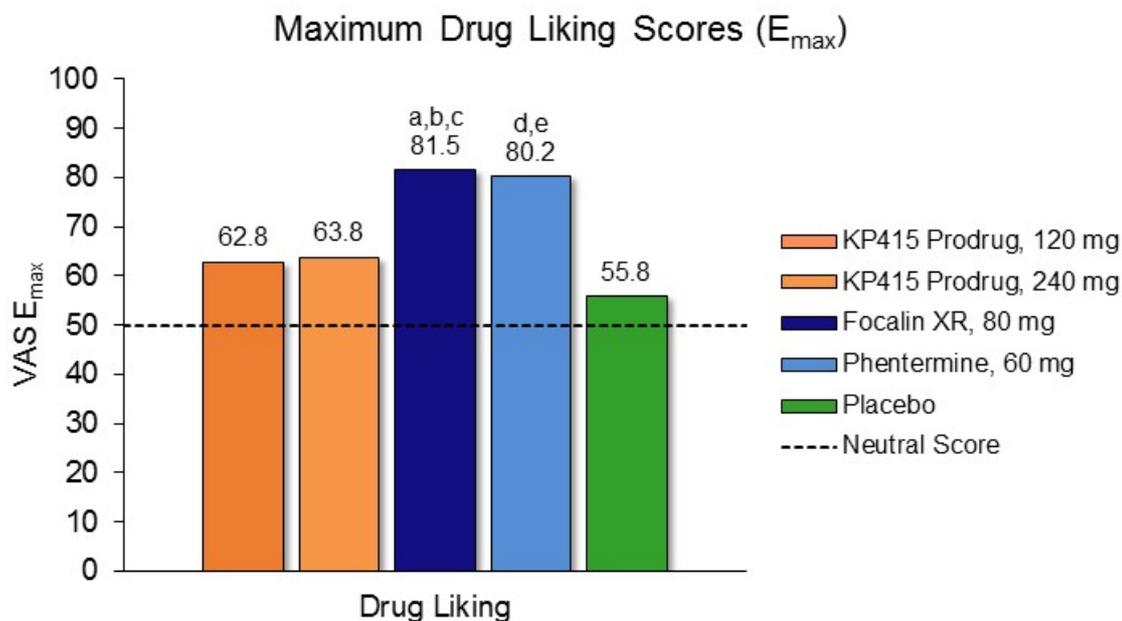


## KP415.E01 Pivotal Efficacy Trial Summary

- KP415.E01 efficacy trial met its primary endpoint
- SKAMP-C trial data using Visit 6 as the pre-dose baseline demonstrate a 30-minute onset of effect with duration up to 13 hours
- PERMP-A and PERMP-C trial data are also supportive of a 30-minute onset of effect with duration up to 13 hours
- Secondary endpoint of morning and evening behaviors as rated by parents are supportive of a 30-minute onset of effect with duration up to 13 hours
  - WREMB-R
- Additional secondary endpoints are also supportive of efficacy, including:
  - ADHD-RS-5
  - Conners 3-P
  - CGI-S, CGI-I
- Effect size calculations show similar clinical effect sizes as literature reported data for products like Vyvanse<sup>®</sup>, Concerta<sup>®</sup> and Focalin XR<sup>®</sup>



## KP415 Prodrug Drug Liking $E_{max}$ After Oral Administration was Significantly Lower vs. Focalin XR and Phentermine

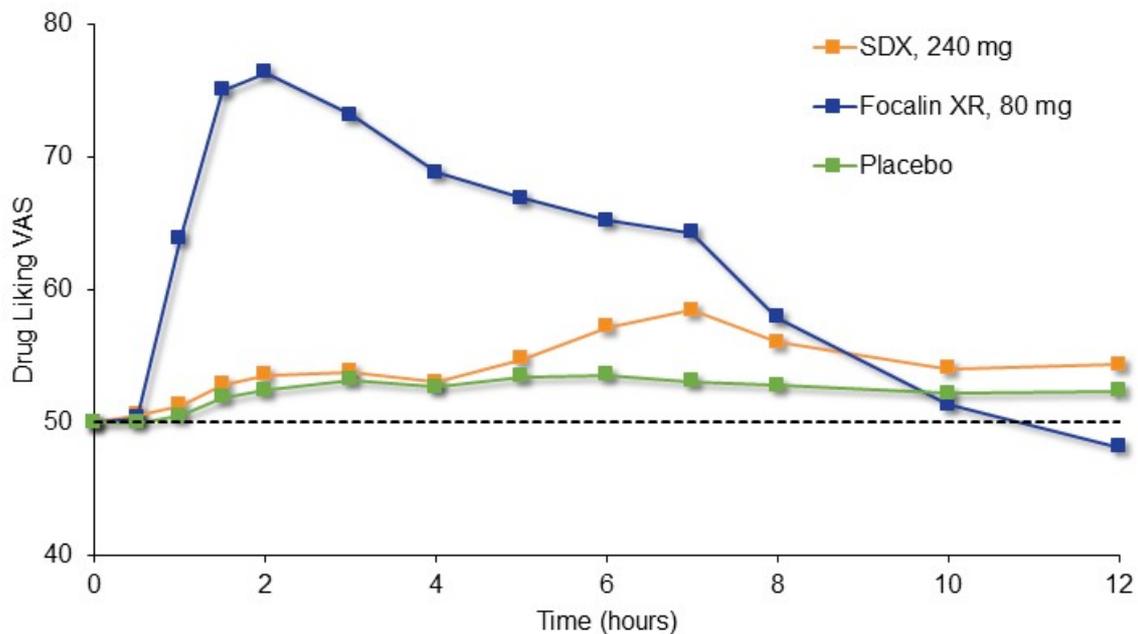


- <sup>a</sup> significantly higher vs KP415 Prodrug, 120 mg by at least a 10-point margin ( $p=0.001$ ),  
<sup>b</sup> significantly higher vs KP415 Prodrug, 240 mg by at least a 10-point margin ( $p=0.006$ ),  
<sup>c</sup> significantly higher vs Placebo by at least a 15-point margin ( $p<0.001$ ),  
<sup>d</sup> significantly higher vs KP415 Prodrug, 120 mg by at least a 10-point margin ( $p=0.020$ ),  
<sup>e</sup> significantly higher vs Placebo by at least a 10-point margin ( $p<0.001$ )



# KP415 Prodrug At-the-Moment Drug Liking After Oral Administration vs. Focalin XR

## At the Moment Drug Liking VAS

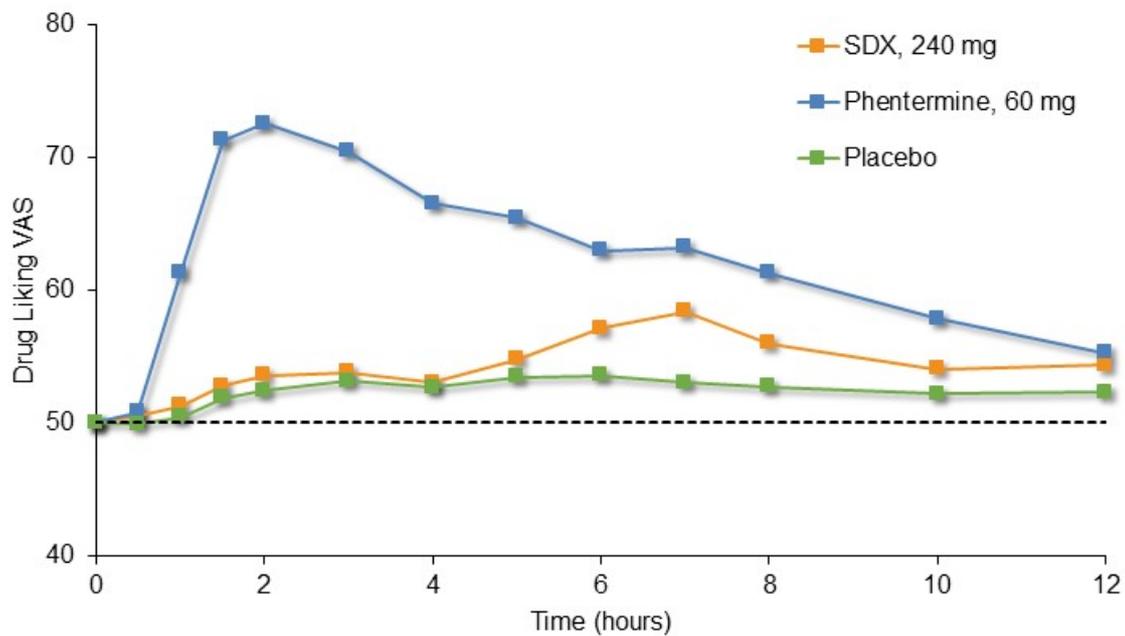


Note: SDX = serdexmethylphenidate = KP415 Prodrug  
Drug Liking was assessed on a bipolar scale  
(0 = Strong Disliking, 50 = Neutral, 100 = Strong Liking)



# KP415 Prodrug At-the-Moment Drug Liking After Oral Administration vs. Phentermine

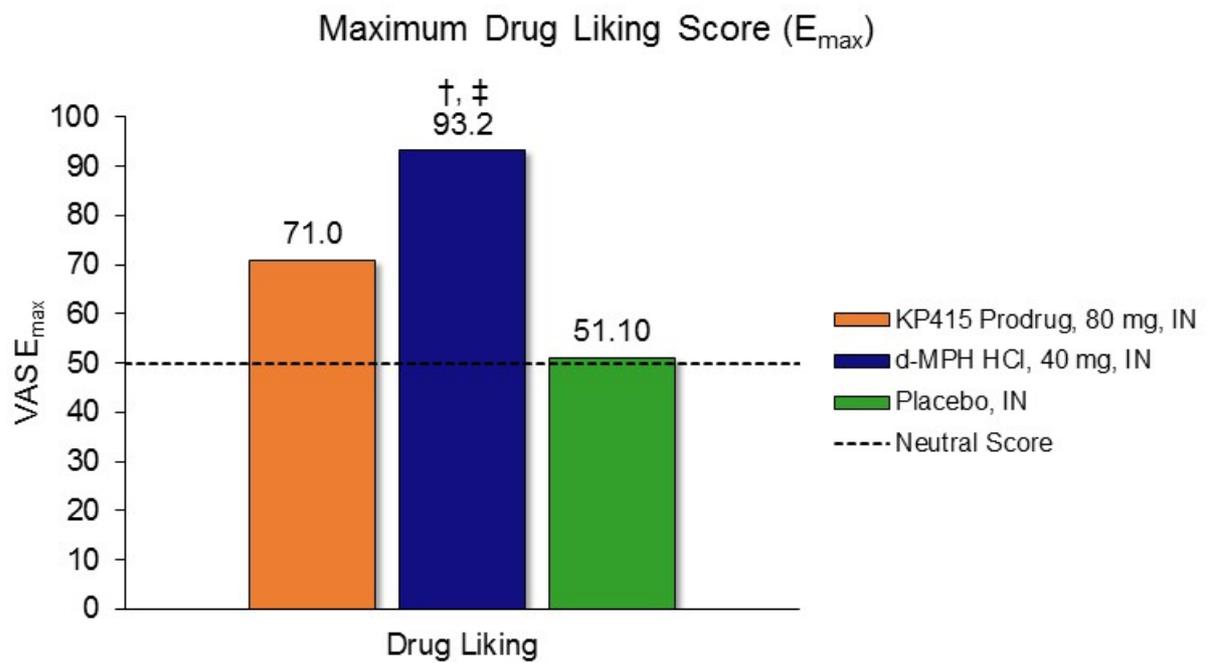
## At the Moment Drug Liking VAS



Note: SDX = serdexmethylphenidate = KP415 Prodrug  
Drug Liking was assessed on a bipolar scale  
(0 = Strong Disliking, 50 = Neutral, 100 = Strong Liking)



# KP415 Prodrug Drug Liking $E_{max}$ After Intranasal Administration was Significantly Lower vs. D-Methylphenidate

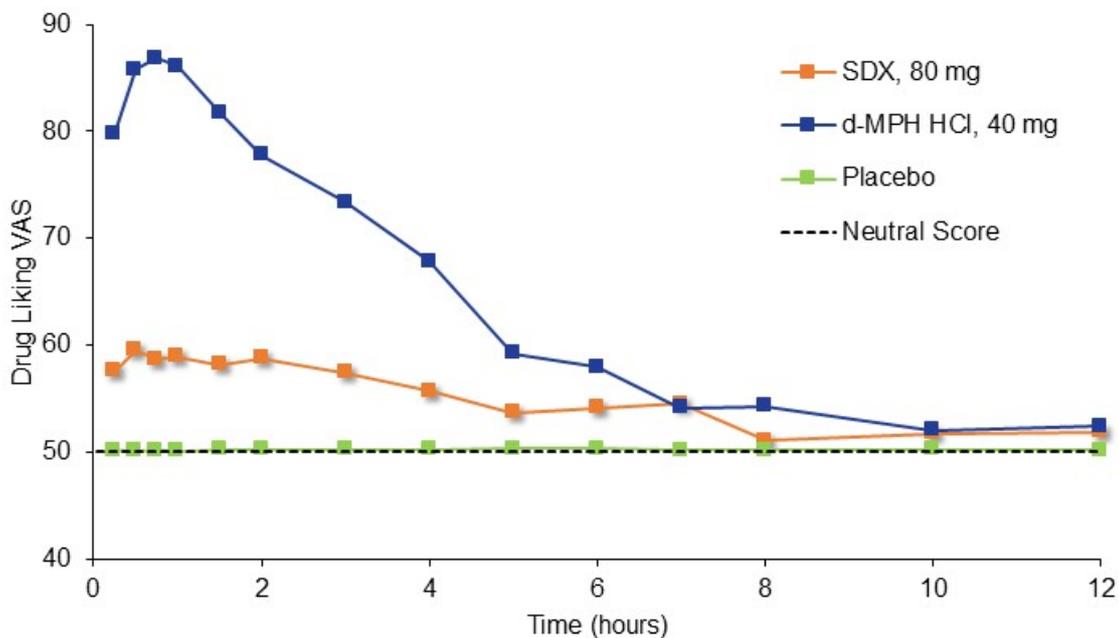


† significantly higher vs KP415 Prodrug by at least a 10-point margin ( $p=0.001$ ),  
‡ significantly higher vs placebo by at least a 15-point margin ( $p<0.001$ )



# KP415 Prodrug At-the-Moment Drug Liking After Intranasal Administration vs. D-Methylphenidate

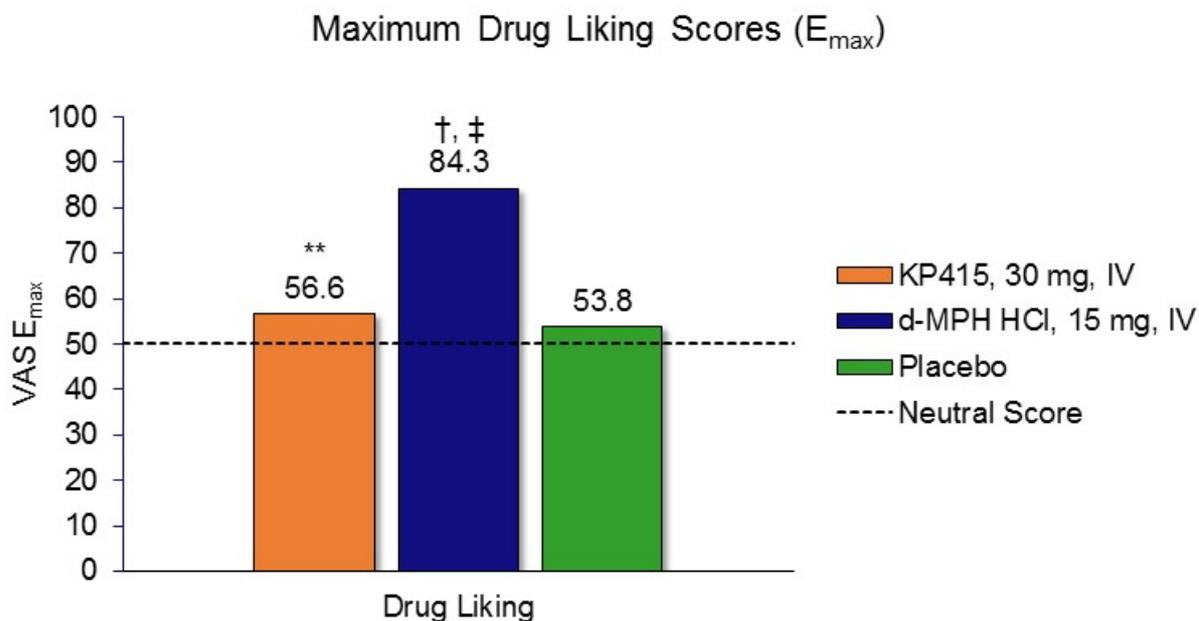
## At the Moment Drug Liking VAS



Note: SDX = serdexmethylphenidate = KP415 Prodrug  
Drug Liking was assessed on a bipolar scale  
(0 = Strong Disliking, 50 = Neutral, 100 = Strong Liking)



## KP415 Prodrug Drug Liking $E_{max}$ After Intravenous Administration was Significantly Lower vs. D-Methylphenidate

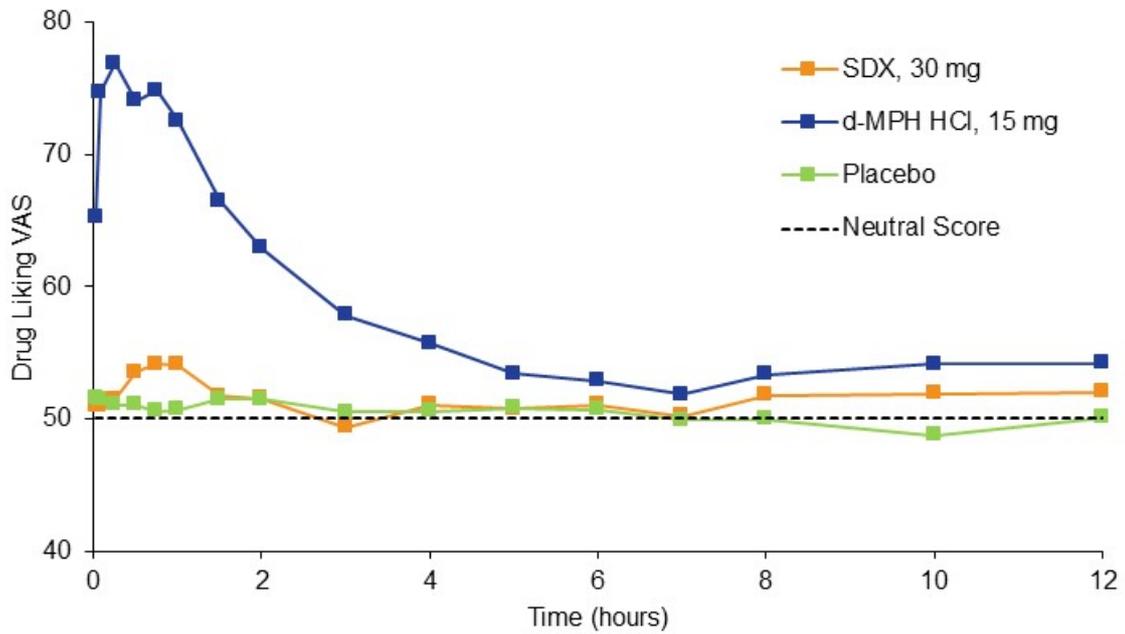


\*\* significantly non-inferior to placebo within at most an 11-point margin ( $p=0.001$ ),  
† significantly higher vs KP415 Prodrug by at least a 10-point margin ( $p=0.001$ ),  
‡ significantly higher vs placebo by at least a 15-point margin ( $p<0.001$ )



# KP415 Prodrug At-the-Moment Drug Liking After Intravenous Administration vs. D-Methylphenidate

## At the Moment Drug Liking VAS



Note: SDX = serdexmethylphenidate = KP415 Prodrug  
Drug Liking was assessed on a bipolar scale  
(0 = Strong Disliking, 50 = Neutral, 100 = Strong Liking)



## KP415 Prodrug Human Abuse Potential Trials Summary

- KP415 Prodrug HAP trials were required by FDA to help it determine a recommendation for controlled substance scheduling of the KP415 Prodrug
- Statistically significant differences in key HAP endpoints were observed between KP415 Prodrug and active comparators for the following routes of administration:
  - Oral
  - Intranasal
  - Intravenous
- Additional tampering and manipulation data will be included in the KP415 NDA as part of the human abuse potential assessment of the KP415 Prodrug



## The Adult ADHD Market

- Over 4% of U.S. adults, or approximately 10.5 million adults have ADHD and are now the largest part of the ADHD market, comprising 53% of total TRx<sup>1,2</sup>
- The adult ADHD market has grown at ~11% per year on average vs. 4% for the pediatric ADHD market for the last several years<sup>1</sup>
- Vyvanse<sup>®</sup>, the ADHD product known for its duration and abuse deterrent features has seen significant growth in the adult market averaging 22% year-over-year growth since 2009<sup>1</sup>
- Shire's Mydayis<sup>®</sup> was recently approved as a super long-acting product in the amphetamine category (2-16 hour duration)
- Other potential market opportunities exist within indications where efficacy has been demonstrated by other stimulants or which remain as currently unmet medical needs

1. Symphony Health, PHAST 2011-2017

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

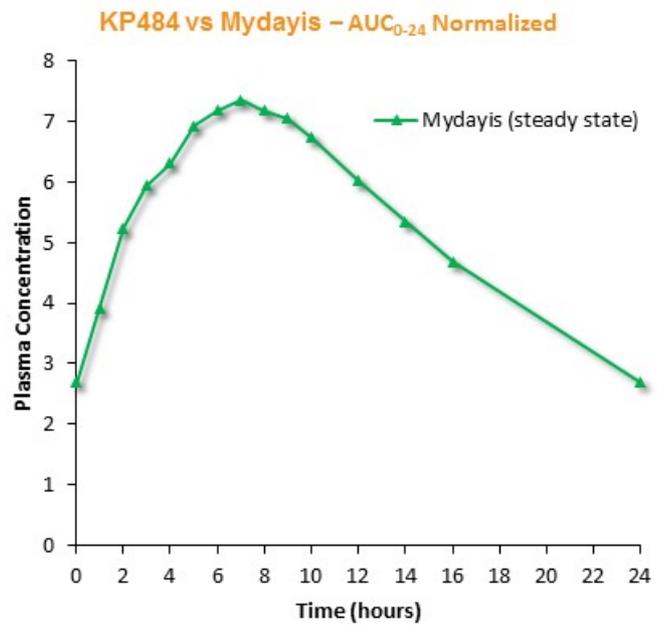
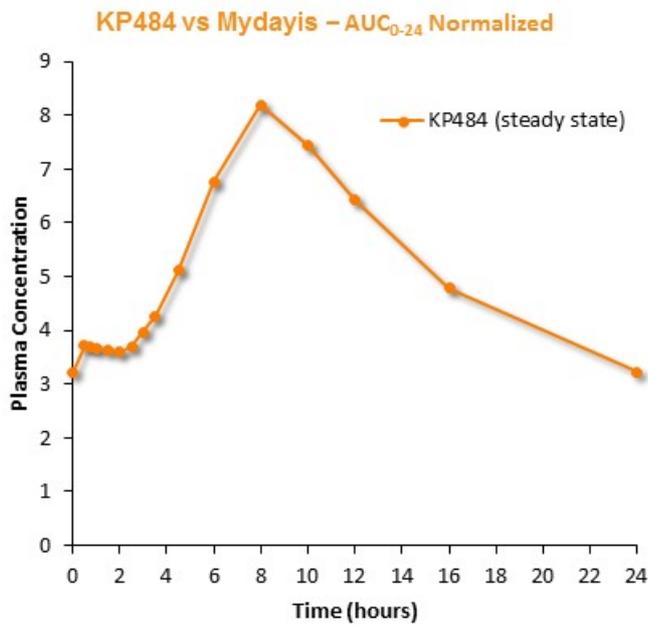


## KP484 Product Overview

- Prodrug of d-MPH (serdexmethylphenidate) with extended release properties
- Potential KP484 features and benefits
  - Once-daily dosing
  - Longer duration than other super-extended release ADHD products
  - Active metabolism may offer more predictable therapeutic effect
  - Lower abuse potential
  - Patient-friendly dosage form
    - Capsule 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; pending applications, if granted, may potentially expire in 2037; potentially NCE eligible



# KP484 Steady State PK vs. Mydayis®<sup>1</sup>



Disclaimer: Mydayis steady-state plasma concentrations were modeled based on Mydayis single-dose data<sup>1</sup> and were normalized so that the mean AUC<sub>0-24</sub>/C<sub>max</sub> for d-amphetamine released from Mydayis matches the mean AUC<sub>0-24</sub>/C<sub>max</sub> 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.



## Next Steps

- KP415 NDA remains on track for submission in Q1 2019
- KP484 NDA submission expected to follow later in 2019
- Strategic partnering discussions for KP415 and KP484 continue based on:
  - Significant, near-term ADHD prodrug commercial opportunities
  - Differentiated onset and duration efficacy profile for KP415
  - Differentiated oral, intranasal and intravenous HAP data for serdexmethylphenidate
  - Long patent life and potential NCE status



**Apadaz<sup>®</sup>**

**FDA Approved for the Short-Term Treatment of  
Acute Pain**



## Apadaz® Overview

- First prodrug of hydrocodone (benzhydrocodone) combined with acetaminophen to be approved by the FDA
- IR fixed-dose combination comprised of 6.67 mg benzhydrocodone HCl (equivalent to 7.5 mg hydrocodone bitartrate) and 325 mg APAP
- Apadaz DEA product scheduling and quota allocation is complete
- Absent of “abuse-deterrent” claims, differentiated properties include:
  - Reduced early systemic hydrocodone exposure and delayed hydrocodone  $T_{max}$  for Intranasal (IN) Apadaz vs. IN Norco
  - Lowered early Drug Liking for Intranasal (IN) Apadaz vs. IN Norco in first 2 hours post dose
  - Conversion (hydrolysis) of benzhydrocodone to hydrocodone in vitro is a difficult process
- Composition-based patent expires in 2031



## Apadaz® Commercialization Strategy

*KemPharm is pursuing two potential strategies for commercializing Apadaz. Neither strategy requires KemPharm to establish its own sales force.*

| Non-traditional PBM Partnerships   | Traditional Pharma Partnership  |
|--|---|
| <ul style="list-style-type: none"><li>• Collaborative partnerships with leading US PBMs and MCOs who would agree to Tier 1 or equivalent status for Apadaz (including most favorable co-pay) in return for price parity with available generic products</li><li>• PBMs and MCOs would work to educate prescribers/plan sponsors and actively manage Apadaz prescriptions</li></ul> | <ul style="list-style-type: none"><li>• Partnership with a US-based or global generic pharmaceutical manufacturer and distributor</li><li>• Takes advantage of generic pharma's economies of scale to optimize Apadaz COGS</li><li>• Generic pharma partner may also utilize non-traditional PBM/MCO partnership strategy</li></ul> |



## KemPharm Expected Milestones

| Product      | Event                               | Date     |   |
|--------------|-------------------------------------|----------|---|
| KP484        | IND Filing                          | 2017     | ✓ |
| KP415        | Initiate Pivotal Efficacy Study     | 2017     | ✓ |
| Apadaz®      | <b>FDA Approval</b>                 | 02/23/18 | ✓ |
| KP415/ KP484 | IV Human Abuse Potential (HAP) Data | Q2 2018  | ✓ |
| KP415        | Pivotal Efficacy Study Results      | Mid-2018 | ✓ |
| KP415/ KP484 | Oral HAP Data                       | 2H 2018  | ✓ |
| KP415/ KP484 | IN HAP Data                         | 2H 2018  | ✓ |
| KP484        | Initiate Pivotal Efficacy Study     | 2019     |   |
| KP415        | <b>NDA Submission</b>               | Q1 2019  |   |
| KP484        | Pivotal Efficacy Study Results      | 2019     |   |
| KP484        | <b>NDA Submission</b>               | 2019     |   |



## Q2 2018 Financial Results

- Q2 2018 net loss of \$10.0 million, or \$0.65 per basic share and \$0.91 per diluted share, vs. Q2 2017 net loss of \$6.5 million, or \$0.44 per basic and diluted share
  - Net loss for Q2 2018 was primarily due to loss from operations of \$13.9 million and net interest expense and other items of \$1.7 million, partially offset by non-cash fair value adjustment income of \$5.6 million
  - Loss from operations increased to \$13.9 million for Q2 2018 compared to \$8.2 million for Q2 2017, primarily due to an increase of \$5.8M in research and development expenses, partially offset by a decrease of \$0.1 million in general and administrative expenses
- As of June 30, 2018, total cash and security-related items<sup>1</sup> were \$29.3 million, which was a decrease of \$7.9 million compared to March 31, 2018
- Based on the Company's current forecast, existing resources are expected to fund operating expenses and capital expenditure requirements into, but not through, Q1 2019

1 - Includes cash, cash equivalents, restricted cash, marketable securities, and trade date receivables





**KemPharm**

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